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In Vivo Study of an Antimicrobial Surgical Drape System

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We performed a double-blind clinical study to determine the efficacy of nonwoven laparotomy drapes in which 3-(trimethoxysilyl)propyldimethyloctadecyl ammonium chloride, an antimicrobial agent, was chemically bonded to the absorbent reinforcement surrounding the fenestration. The reinforcement portion of the surgical drape that contained the fenestration was segmented into four identical-appearing sections, two on each side of the fenestration. One segment on each side was antimicrobial. The locations of the treated segments were randomly varied. At the end of each operation, test strips were removed. Bacteria were harvested from each segment by mechanical agitation. Bacterial CFU were counted. There were 110 surgical cases in the study, including clean, clean contaminated, and contaminated procedures. Data analysis divided the cases into two distinct groups. Group 1 was composed of 59 cases in which less than 30 total CFU was recovered from the four test samples. The average duration of surgery for this group was 1.8 h. Group 2 was composed of 51 cases in which bacterial recovery was in excess of 30 CFU per procedure (range, 30 to 25,000 bacterial CFU). The average duration of surgery was 3.3 h. Bacterial reduction in the treated strips was 84%. The most common organisms identified on the laparotomy drapes were *Staphylococcus epidermidis*, *S. hominis*, and *Micrococcus luteus*. This study demonstrated that the reinforcement of a laparotomy drape is a reservoir for potential pathogens. It demonstrated that an organosilicon quaternary ammonium antimicrobial agent covalently bonded to the reinforcement reduced the number of potential pathogens surrounding the surgical incision by 84%, independent of the size of the bacterial challenge.

It has been estimated that 30,000 to 60,000 organisms are deposited on a 3- to 4-m^2 sterile field during every hour of major operations. In a recent 2-year study of 15,207 patients admitted to a hospital, there were 1,851 nosocomial infections reported, for an infection rate of 12.8%. Postoperative wound infections were the most common nosocomial infections encountered in the surgical services during this study. They accounted for one-third to one-half of all of the infections in the patients studied by Egoz and Michaeli (4). It has been found that the surgical wound infection rate increases from 1% for operations lasting 30 min to 14% for operations lasting 3.5 h (8).

One of the primary sources of bacterial contamination of wounds during surgery has been operative personnel. Charnley and Eftekhar (2) have shown that bacteria from a surgeon's skin penetrate clean scrub suits and sterile gowns to reach the sterile field. However, difficulty has arisen in trying to document that the organisms generated by the personnel in the operating room are the primary cause of wound infections. In a computer analysis of factors influencing surgical wound infection, Davidson et al. (3) cited the degree of contamination of the wound with microorganisms to be the most important determinant in the development of perioperative infections.

The preferred use of nonwoven barriers for the surgical staff and patient has been well documented (1, 6, 7, 12, 13, 16). Now nonwoven drapes have been developed with a broad-spectrum organosilicon quaternary ammonium antimicrobial agent covalently bonded to the absorbent reinforcement that surrounds the fenestration. This bactericidal fabric should reduce the number of viable bacteria on the surface of the drape. In vitro data have demonstrated this antimicrobial agent to be effective against *Staphylococcus aureus*, *Enterococcus faecalis*, *Escherichia coli*, *Salmonella typhi*, *Mycobacterium tuberculosis*, *Pseudomonas aeruginosa*, *Enterobacter aerogenes*, *Candida albicans*, several *Asperigillus* species, *Trichophyton* species, and other potential pathogens (5, 10, 11). Furthermore, the antimicrobial fabric has been shown in the laboratory to be effective against the same series of potential pathogens. The antimicrobial fabric is capable of reducing the number of bacterial CFU recoverable from the fabric by 91% within 15 to 30 min when compared with a nonantimicrobial control fabric (5) (C. Herring, personal communication). The purpose of the present work was to establish the efficacy of the drapes by means of a clinical study and demonstrate that an antimicrobial draping system can reduce the number of potential pathogens surrounding a surgical incision.

MATERIALS AND METHODS

All of the surgical procedures were performed by the same surgeon in the surgical suites normally used by his service. Clean, clean contaminated, and contaminated surgical procedures were included in the study. All of the procedures allowed appropriate usage of the modified laparotomy drape developed for the study. The surgical cases included in the study varied in length from 0.5 to 6 h. The surgical team wore nonwoven masks, hair covers, and shoe covers. All other wearing apparel and fabrics used on the patient or by the surgical team were closely woven, washed linen.

Preoperative patient preparation included washing the wound site with a standard iodophor scrub solution followed by a standard iodophor prep solution. After the iodophor solution had dried, the special laparotomy drapes were

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† Julius Conn died during the preparation of this report. We dedicate this small token of our combined efforts to his memory.

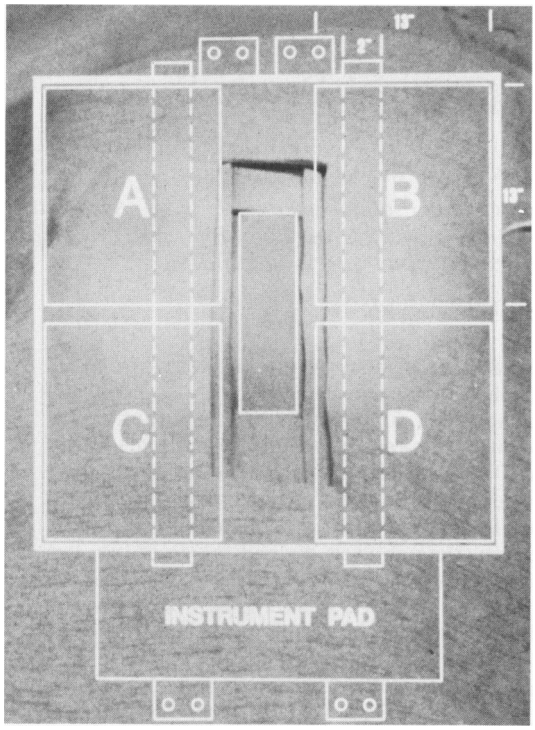

FIG. 1. A standard laparotomy drape reinforcement was modified to consist of four sections (A, B, C, and D), and only two were made of antimicrobial fabric. The locations of the antimicrobial sections were randomly varied. The standard test sections are shown by dotted lines.

placed in the usual manner. The special fenestrated laparotomy drape was the only variable from the routine prepping and draping of the surgical team. (The fenestration is the opening or hole in a surgical drape through which surgery is performed.)

To ensure unbiased sampling, special nonwoven, fenestrated drapes were manufactured for this study by using good manufacturing practices as required by the U.S. Food and Drug Administration. The experimental drapes were standard nonwoven, nonantimicrobial laparotomy drapes on which four 13- by 13-in. (1 in. = 2.54 cm) swatches (A, B, C, and D) of identical-appearing fabric had been attached on the reinforced area surrounding the fenestration (Fig. 1). Two of the swatches were treated with an antimicrobial agent, and two were untreated. Each drape was given a code number, and the locations of the antimicrobial swatches were recorded during the manufacturing process. The positions of the treated and untreated swatches were not known to anyone associated with the study. The positions of the swatches were randomized at the time of manufacturing. The study was conducted by a double-blind protocol. The antimicrobial agent covalently bonded to the treated swatches was 3-(trimethoxysily)propyldimethyloctadecyl ammonium chloride, as used in in vitro studies (5, 10, 11).

At the end of each surgical procedure, standardized 2- by 13-in. patches of swatches A, B, C, and D were aseptically removed from the drape with a clean scalpel and a sterile measuring template. These patches were placed in labeled, sterile, disposable petri dishes. The drape specimens were taken to the microbiology laboratory for immediate processing.

Within 30 min after the operation was completed, each patch was placed into a 250-ml sterile disposable flask containing 75 ml of letheen broth (Difco Laboratories, Detroit, Mich.) adjusted to pH 9.5 with NaOH. Control studies with letheen broth adjusted to pH 7.2 determined that the higher-pH broth did not affect the bacterial survival rate when exposure time was limited as described above. This broth is an accepted neutralizer of the bactericidal activity of quaternary ammonium compounds. The flask was placed on a wrist action shaker and agitated at the highest setting for 15 min. After agitation, the letheen broth was decanted from the flask and filtered through a sterile 0.22-μm (pore size) microporous filter. The filter was then removed and placed on a nutrient pad (Sartorius) in a 50-mm (diameter) petri dish. In some instances, when it was apparent that the letheen broth was highly contaminated, samples of the broth were filtered and counted. This was done to prevent clogging of the filter. The nutrient pad was rehydrated with sterile deionized water containing 1.0% yeast extract. The microbiological specimens were then placed in a humidified incubator at 36°C. The bacterial CFU on the microporous filters were counted and photographed after 72 h of incubation.

Identification of the bacterial isolates was done by standard clinical microbiological techniques. Minitek Enterobacteriaceae II (BBL Microbiology Systems, Cockeysville, Md.), the Staph-Ident system (Analytab Products, Plainview, N.Y.), Sero-STAT Stap (Scott Laboratories, Inc., Fiskeville, R.I.), and the Minitek aerobic gram-positive cocci test (BBL) were used as directed by the manufacturers.

RESULTS

Scanning electron micrographs. To test the antimicrobial characteristics of the treated and untreated fabrics used in this study, we obtained electron micrographs of the fabrics incubated with *E. coli*. These scanning electron micrographs showed that the morphology of bacteria was greatly altered after 15 min of contact with the antimicrobial-agent-treated fabric (Fig. 2B). The same organisms in contact with untreated fabric remained unchanged for at least 2 h (Fig. 2A). The obvious change in bacterial morphology attributed to the antimicrobial fabric is evidence that the bacterial cell wall membrane complex has been disrupted as postulated by Hugo (9) as the mode of action for this class of antimicrobials agent and agrees with the work of Malek and Speier (J. Coated Fabrics **12**:38-45, 1982) and Richards and Cavill (14).

Surgical procedures. The experimental drape used in this study was a modified, fenestrated, nonwoven laparotomy drape. Therefore, the majority of the procedures involved abdominal incisions. The surgical procedures by general type were as follows: vascular, 35%; liver and biliary tract, 12%; gastrointestinal (including resections, ostomy, etc.), 10%; hernia repair, 9%; miscellaneous (debridement, biopsies, abscess drainage, mastectomies), 34%.

Bacterial isolation. One hundred and ten surgical procedures were analyzed during this study. Analysis showed that the bacterial CFU recovered from the drapes divided the surgical procedures into two distinct groups. The groups were determined by the total number of CFU isolated from a single set of drape samples.

In group 1, the bacterial CFU recovered from each case totaled less than 30. Analysis of this group indicated that a comparison of the number of organisms recovered from the antimicrobial portion of the drape versus the CFU recovered from the nonantimicrobial drapes was not statistically relevant. This group was composed of 59 drapes in which the

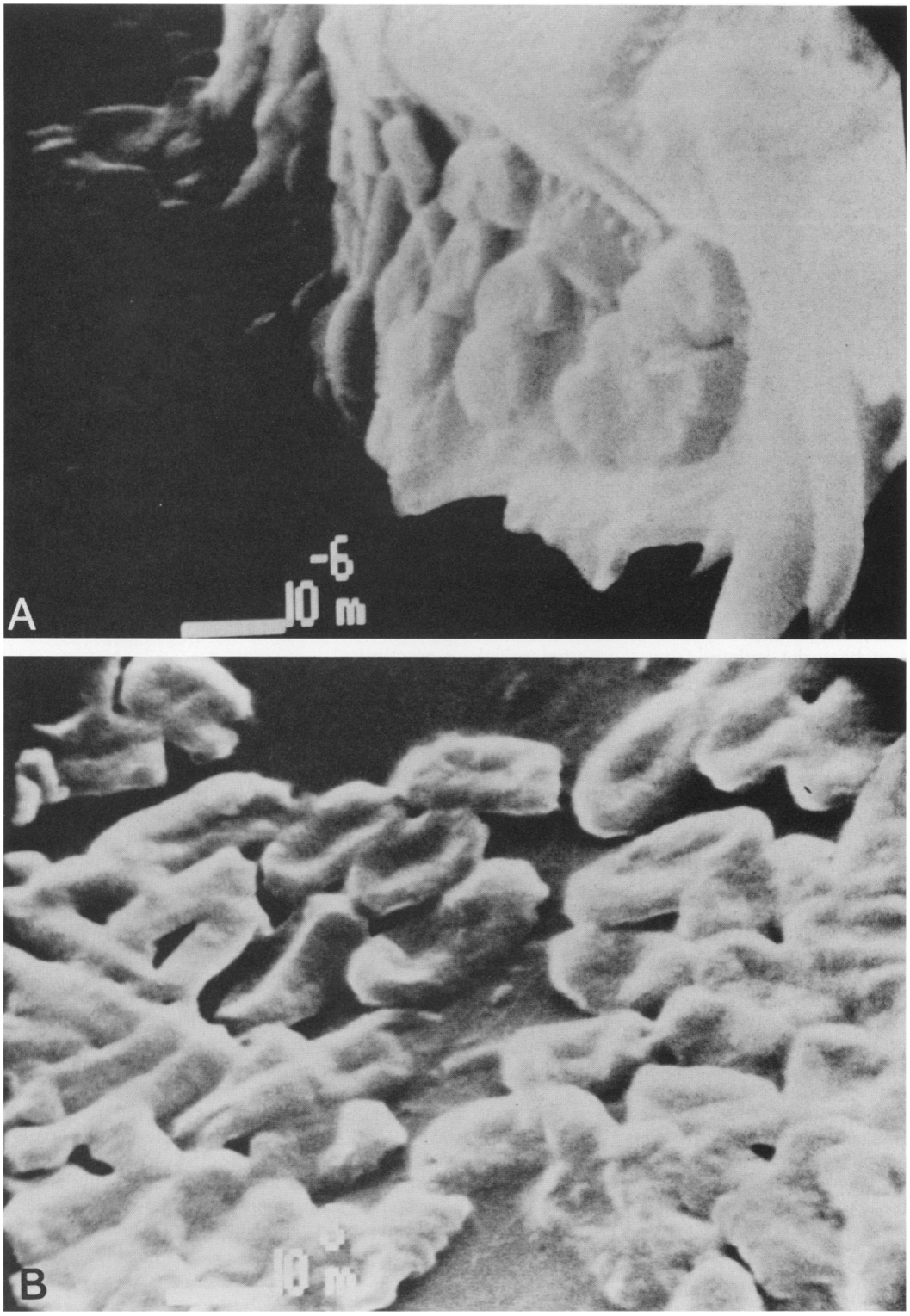

FIG. 2. Scanning electron micrographs of *E. coli* exposed to untreated and antimicrobial-agent-treated fabric (magnification, ×12,000). *E. coli* was suspended in phosphate-buffered water, and portions were placed on appropriate fiber samples. The specimens were incubated at 20°C for 120 min for the control (A) and for 15 min for the antimicrobial sample (B) in a humidified chamber. After incubation, the samples were rapidly vacuum dried and coated with gold. The samples were then examined and photographed with a Cambridge SEM-Stereoscan Mark II. Note the depressed centers of the bacteria on the treated fabric (B) compared with the bacteria on the untreated fabric.

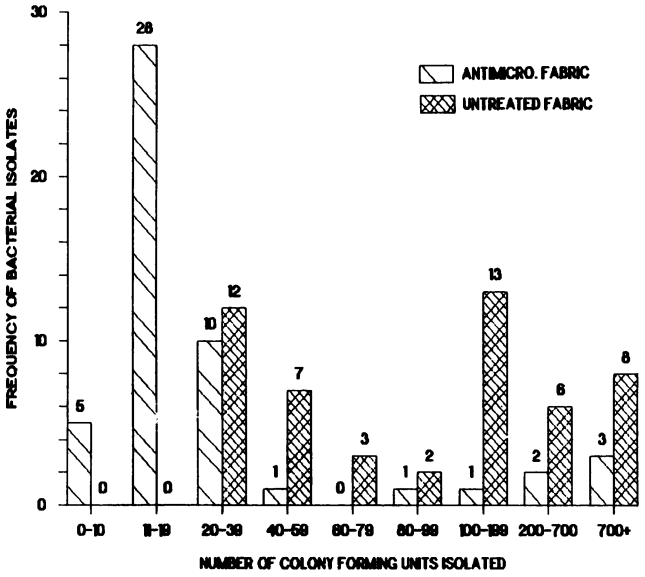

FIG. 3. Distribution frequency of the bacterial isolates recovered from the antimicrobial fabric and untreated fabric swatches from group 2. The actual number of surgical cases in which the indicated number of bacterial isolates recovered from the antimicrobial or untreated swatches is given at the top of each column.

mean number of bacterial isolates from the antimicrobial swatches was 4.5 CFU with a median of 1.9. The nonantimicrobial swatches had a mean bacterial recovery of 7 CFU with a median of 3.1. The range in total CFU was 1 to 29, and the mean length of surgery was 1.8 h with a median of 1.5 h.

Group 2 consists of 51 cases in which more than 30 CFU was isolated. The mean CFU for the antimicrobial swatches was 184 versus 1,172 CFU for the nonantimicrobial swatches. The mean duration of surgery was 3.3 h with a median of 2.9 h. Figure 3 demonstrates the frequency distribution of the bacterial isolates from the antimicrobial and nonantimicrobial swatches. Table 1 lists the numbers of CFU recovered from various locations on the surgical drapes included in group 2.

When each surgical procedure was individually analyzed for bacterial reduction, the bacterial reduction ranged between 15 and 99.9%. The average bacterial reduction percentage was 84.4%. Figure 4 graphically illustrates the bacterial reduction percentage frequency of the surgical procedures in group 2.

Analysis of the actual bacterial recoveries given in Table 1 showed that the data had positive skewness. The skewness is attributable to the clean contaminated and contaminated cases in which exceptionally large numbers of bacteria were isolated (greater than 1,000 CFU).

The surgical procedures from which the greatest number of isolates were recovered all demonstrated high bacterial reduction rates attributable to the antimicrobial fabric. In actuality, the average bacterial reduction percentage for this subgroup of cases was 83%, and the bacterial reduction percentage for the subgroup in which the bacterial isolates were less than 1,000 was 88%.

Bacterial identification was performed on the isolates from 64 cases. Since the organisms killed by the antimicrobial fabric could not be determined, analysis of the percentage of cases from which a particular organism was isolated was performed. Table 2 lists the organisms isolated and identified and the percentage of cases in which that particular bacterium was identified. *S. epidermidis*, *S. hominis*, and *Micrococcus luteus* were the most commonly isolated organisms.

DISCUSSION

The standard laparotomy drape used in this study had a reinforcement area of 676 in^2 surrounding the fenestration. In our study, we sampled four 2- by 13-in. areas (104 in^2) located 1.5 in. from the edge of the fenestration for bacterial content after each procedure. Therefore, our sample size was 15.4% of the total area immediately contiguous to the surgical incision site (approximately 2/13 of the reinforcement area). The size of the area analyzed was limited by the method of bacterial isolation used and was as large as practical.

We found that in any fabric some bacteria become trapped in the interstices of the fabric. These bacteria cannot be removed by mechanical agitation. When a known number of bacteria are placed on a fabric, the percentage of bacterial entrapment varies, depending on the fabric. The nonantimicrobial control fabric used in this study normally retains 12 ± 4% of the input bacterial population when the bacterial isolation technique used in this study is used; *i.e.*, approximately 7/8 of the input bacterial challenge was recovered in control studies. Therefore, when the unsampled drape area and expected bacterial entrapment are taken into consideration, it is apparent that the number of bacterial isolates recovered in the study represents only a small portion of the potential pathogens that might be present in the area surrounding the surgical incision. The theoretical total number of bacteria that actually were present in the surgical field at the end of each procedure can be derived from the following formulas: (i) (CFU isolated per procedure/7) 8 = total theoretical bacterial count on the sampled area of the reinforcement corrected for bacterial entrapment; (ii) (CFU [corrected for bacterial entrapment] per procedure/2) 13 = total theoretical bacterial count present on the surgical field at the end of the procedure after corrections for bacterial entrapment and inclusion of the CFU on the unsampled area of the reinforcement.

TABLE 1. CFU recoveries from surgical drapes

Side of patient	Bacterial recovery (CFU) from:								% Bacterial reduction attributable to antimicrobial fabric[a]
	Antimicrobial swatches				Nonantimicrobial swatches				
	No.	Mean	Range	Median	No.	Mean	Range	Median	
Both	8,025	184	0–5,000	12.5	51,586	1,172	21–20,000	105	84.4
Left	3,382	78	0–2,500	3	26,240	596	0–10,000	52	87.1
Right	4,643	105	0–2,500	8	25,349	576	0–10,000	25	81.7

[a] Percent reduction = (CFU recovery from nonantimicrobial fabric − CFU recovery from antimicrobial fabric)/CFU recovery from nonantimicrobial fabric.

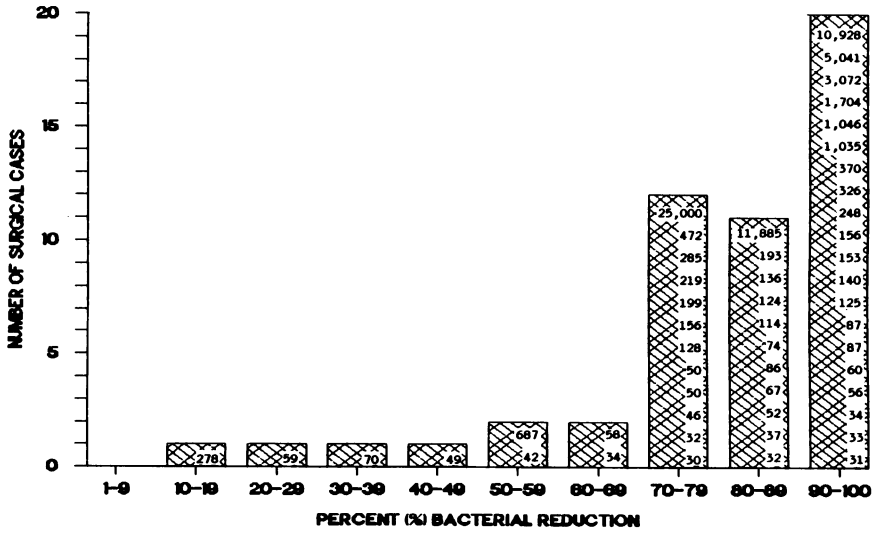

FIG. 4. Bacterial reduction percentage frequency. The individual numbers within each bar of the histogram refer to the actual number of total CFU isolated in the individual procedures analyzed. Each number refers to a single case demonstrating the indicated percentage of bacterial reduction.

These simple mathematical formulations supply a number that reflects the actual potential pathogen population present on the reinforced portion of the drape at the completion of a surgical procedure. The numbers of bacteria in the sterile field derived by using these procedures compared favorably with the bacterial counts found by Sampolinsky in his study on bacterial contamination in a sterile field (15).

Hooten et al. (8) reported that the length of a surgical procedure influences the postoperative infection rate. The differences in the duration of surgery as reflected in group 1 versus group 2 correlated well with their observations. The clinical data demonstrated that, as the time for a surgical procedure increased, the number of bacteria on the surgical field increased.

This double blind in vivo study demonstrated the effectiveness and established the efficacy of an antimicrobial fabric in which a broad-spectrum antimicrobial agent was bonded to the fibers. The antimicrobial fabric reduced the number of potential pathogens surrounding the incision by a substantial margin, independent of the bacterial challenge.

TABLE 2. Percentage of surgical procedures in which specific organisms were identified

Organism(s)	% of cases in which organism(s) was isolated
S. epidermidis	60
S. hominis	53.9
S. capitis	26
S. haemolyticus	26.9
S. warneri	11.1
S. cohnii	4.7
S. aureus	3.2
Staphylococcus sp.	7
M. luteus	39.6
Miscellaneous gram-positive bacilli	15.8
Pseudomonas sp.	6.2
E. coli	4.7
Miscellaneous gram-negative bacilli	3.1

The antimicrobial fabric was efficacious in clean, clean contaminated, and contaminated cases regardless of the bacterial challenge. No wound infections or adverse healing problems developed in any of the patients. Also, no allergic reactions were seen.

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LITERATURE CITED

1. **Alford, D. J., M. A. Ritter, M. L. French, and J. B. Hart.** 1973. The operating room gown barrier to bacterial shedding. Am. J. Surg. **125**:589–591.
2. **Charnley, J., and N. Eftekhar.** 1979. Penetration of gown material by organisms from the surgeon's body. Lancet (i):172–173.
3. **Davidson, A. E., C. Clark, and G. Smith.** 1971. Post-operative wound infection; a computer analysis. Br. J. Surg. **58**:333–337.
4. **Egoz, N., and D. Michaeli.** 1981. A program for surveillance of hospital-acquired infections in a general hospital: a two-year experience. Rev. Infect. Dis. **3**:649–657.
5. **Farber, W. U., B. Wille, and S. Wirth.** 1981. Untersuchungen zur Keimkinetik bei künsticher Kontamination verschiedener OP-Abdeckmaterialien. Krankenhaus-Hy. Infektionsverhütung **4**:115–126.
6. **Ha'eri, G. B., and A. M. Wiley.** 1979. Wound contamination through drapes and gowns. Clin. Orthop. Relat. Res. **139**: 150–152.
7. **Hamilton, H. W., A. D. Booth, F. J. Lone, and N. Clark.** 1979. Penetration of gown material by organisms from the surgical team. Clin. Orthop. Relat. Res. **141**:237–246.
8. **Hooten, T. M., R. W. Haley, and D. H. Culver.** 1980. A method for classifying patients according to the nosocomial infection risks associated with diagnoses and surgical procedures. Am. J. Epidemiol. **111**:556–573.
9. **Hugo, W. B.** 1965. Some aspects of the action of cationic surpra-active agents on microbial cells with special reference to their action on enzymes. S. C. I. monograph no. 19, surface-active agents in microbiology. Soc. Chem. Ind. (London), Monogr. **1965**:67–82.
10. **Isquith, A. J., E. A. Abbott, and P. A. Walters.** 1972. Surface-bonded antimicrobial activity of an organosilicon quaternary

ammonium chloride. Appl. Microbiol. **24**:859–863.
11. **Isquith, A. J., and C. J. McCollum,** 1978. Surface kinetic test method for determining rate of kill by an antimicrobial solid. Appl. Environ. Microbiol. **36**:700–704.
12. **Moylan, J. A., E. Balish, and J. Chan.** 1975. Intraoperative bacterial transmission. Surg. Gynecol. Obstet. **141**:731–733.
13. **Moylan, J. A., and B. V. Kennedy.** 1980. The importance of gown and drape barriers in the prevention of wound infection. Surg. Gynecol. Obstet. **151**:465–470.
14. **Richards, R. M. E., and R. H. Cavill.** 1980. Electron microscope study of the effect of benzalkonium, chlorohexidine and polymyxin on *Pseudomonas cepacia*. Microbios **29**:23–31.
15. **Sampolinsky, D., F. Hermann, P. Oeding, and J. E. Rippon.** 1957. A series of post-operative infections. J. Infect. Dis. **100**:1–11.
16. **Whyte, W., R. Hodgson, P. V. Bailey, and J. Graham.** 1978. The reduction of bacteria in the operating room through the use of non-woven clothing. Br. J. Surg. **65**:469–474.