Efficacy of BIOGUARD™ Dressings Utilizing Advanced NIMBUS® Technology

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Summary

The efficacy of BIOGUARD™ dressings treated with the patented NIMBUS® technology was demonstrated against a broad range of wound pathogens. In addition to the efficacy testing, Scanning Electron Microscopy (SEM) was used to generate images of *E. coli* on NIMBUS treated and untreated surfaces. The images confirm the mechanism by which BIOGUARD dressings provide broad antimicrobial efficacy, including against resistant species.

Mechanism of Antimicrobial Activity

The BIOGUARD antimicrobial barrier dressing is based on NIMBUS® technology (Quick-Med Technologies, Inc.) which utilizes poly(diallyldimethylammonium chloride) (polyDADMAC) as the active antimicrobial agent. The active antimicrobial agent is permanently bound to the dressing surface, and acts on the wound pathogen by physically disrupting the bacterial cell wall. Electron micrographs show *E. coli* cells on a control surface compared to a NIMBUS treated surface. Figure 1a shows healthy intact cells on the control surface. Figure 1b shows disrupted and lysed cells on the polyDADMAC treated surface resembling deflated membrane sacs with their intracellular contents released. This mechanism provides the broad range of antimicrobial efficacy documented in Table 1 below for various wound pathogens in addition to the imaged *E. coli*.

Methods

The control untreated gauze and BIOGUARD gauze substrates were evaluated for antimicrobial efficacy using AATCC method 100: Antimicrobial Finishes on Textile Materials: Assessment of. 10% fetal bovine serum (FBS) was used to simulate wound exudate, and % kill was evaluated against overnight controls (Table 1).

For the SEM experiment, 200µl aliquots containing 10^5 cells/mL of the microorganisms (*E. coli* ATCC 15597) were pipetted directly onto the substrates and cultured overnight for approximately 12hours. The samples were processed for SEM by a combination of fixation and dehydration techniques designed to preserve delicate organic structures.

Imaging of *E. coli* on Treated Surface

The SEM micrographs of the substrates carrying bacterial loads are representative of the surfaces investigated.

E. coli are clearly recognizable on the surface of the control substrate (Figures 1a and 2a), showing aggregates as well as active cell growth and division. The *E. coli* bacteria on the control surface, shown in the high resolution image (2a), display intact membranes and normal rod shape appearance. Isolated single *E. coli* cells can be identified on the polyDADMAC treated surface (Figures 1b and 2b), with no evidence of cell growth or division. The higher magnification image (2b) depicts visible changes in membrane appearance and general morphology. The cells appear to have indentations and/or small holes, indicating significant damage to the cellular envelope. These observed morphological features lead to conclusion that bacterial cells visible on the treated surface are 1) not viable and 2) represent the residual remains of dead bacteria deposited during the inoculation.

Table 1- Antimicrobial efficacy of BIOGUARD dressings		
Wound pathogen	**ATCC #**	**Average % kill**
Escherichia coli	ATCC 15597	>99.9999%
Staphylococcus aureus	ATCC 6538	>99.9999%
MRSA (Methicillin resistant *S. aureus*)	ATCC BAA-44	>99.9999%
Staphylococcus epidermis	ATCC 12228	>99.9999%
Pseudomonas aeruginosa	ATCC 15442	>99.9999%
Enterococcus faecium	ATCC 19434	>99.9999%
Acinetobacter baumannii	ATCC 19606	>99.9999%
VRE (Vancomycin resistant *Enterococcus faecium*)	ATCC 51299	>99.9999%

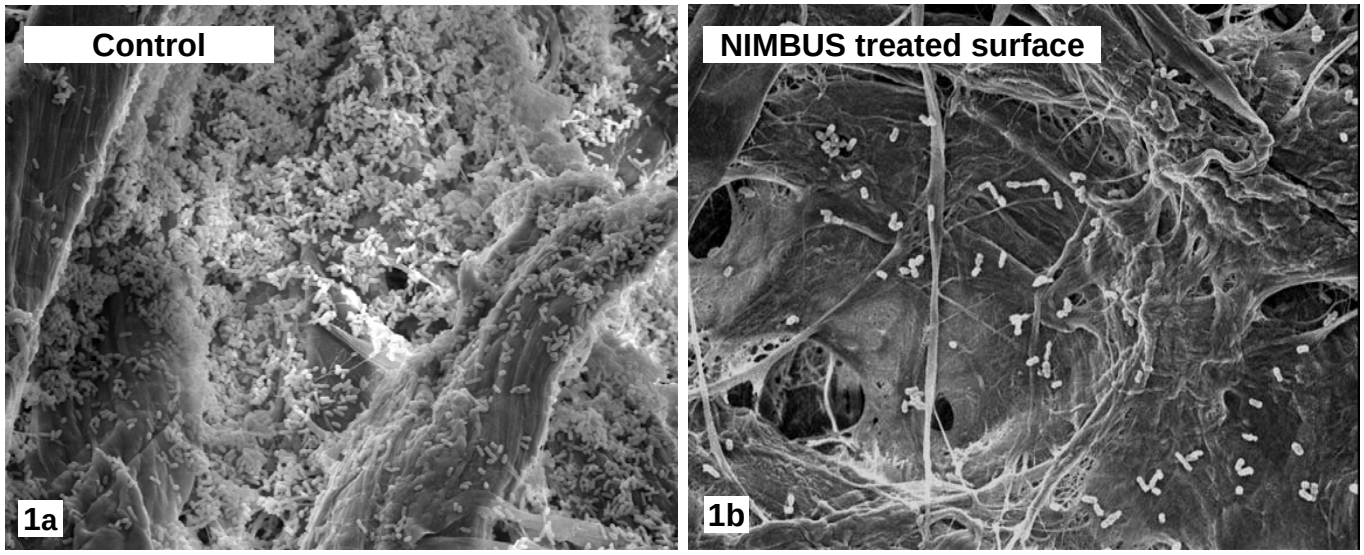

Figure 1 ***E. coli*-inoculated substrates after overnight incubation – 1,500 x magnification**

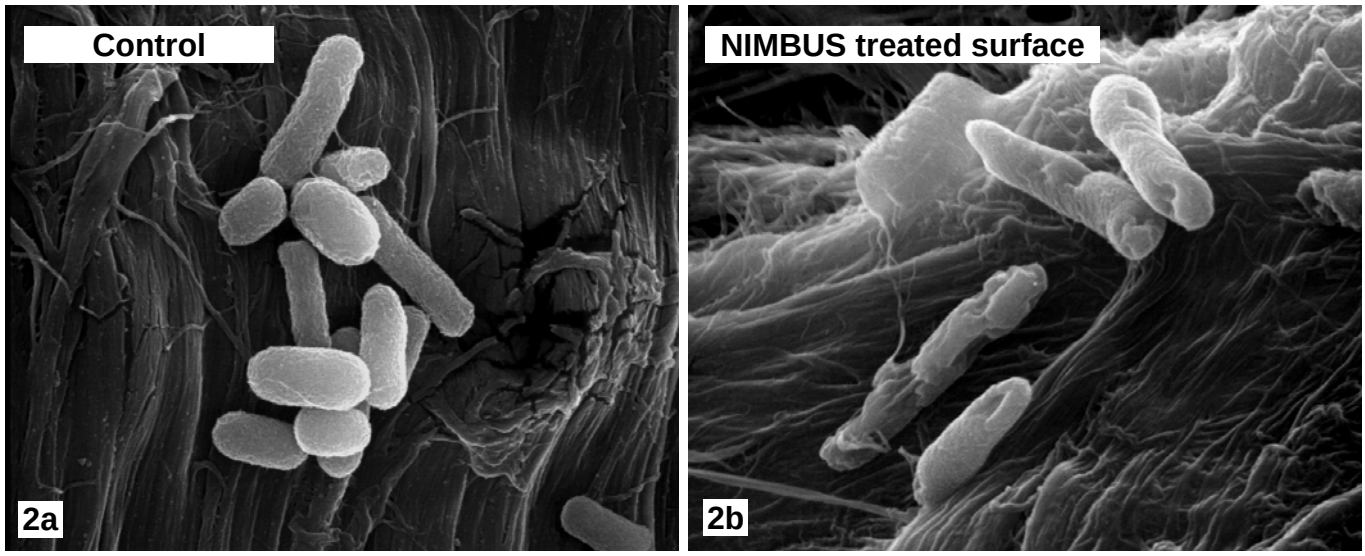

Figure 2 ***E. coli*-inoculated substrates after overnight incubation – 18,000 x magnification**

Conclusions

The bactericidal efficacy of the polycationic polymer utilized in BIOGUARD dressings was demonstrated by standard antimicrobial testing. A high resolution SEM study confirmed the changes in cell appearance as consistent with the mode of antimicrobial activity understood to be common to large polymeric cationic biocides: disruption of the bacterial membrane resulting in cell lysis and death. Both of these explorations demonstrate the advantages of the NIMBUS technology utilized in the BIOGUARD antimicrobial barrier dressing.

References

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