First-in-Class Spray-On Antimicrobial Barrier Film Dressing

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Statement of Purpose:

The skin is the first line of defense against foreign and pathogenic substances. When the skin is wounded the normal flora comes into contact with the moist, warm and nutritive subcutaneous tissues. The immune response must be carefully regulated to destroy invasive organisms while avoiding excessive inflammatory response that harms the host. Therefore, it is essential to have a multifunctional biomaterial that can provide protection from microorganisms which can infiltrate damaged skin via bodily fluids, friction, and or adhesive trauma.

A novel, first-in-class, antimicrobial barrier film (ABF) spray has been engineered as the first tool after minor skin damage, especially in vulnerable areas like skin folds and skin that comes in contact with bodily fluids. The film helps prevent moisture from getting into the wound with the addition of an antimicrobial to exclude influences of bacteria that can cause infection and impede wound healing. This is vital to prevent wound infection and reduce chances of morbidity, mortality, and expenses.

The liquid barrier consists of a reverse microemulsion utilizing a siloxysiloxane polymer in non-stinging solvent as the continuous phase with a bisguinide polymer aqueous phase emulsified by a biocompatible surfactant. Upon evaporation of the solvent, this unique microemulsion provides a non-stinging antimicrobial barrier with extended shelf-life. The functionality of the ABF was thoroughly tested in its ability to provide protection and prevent microbial penetration into the subcutaneous tissues.

Methods:

Skin Trauma After Razor Shaving (STARS) bioassay was used to assess stinging of ABF after disrupting the integrity of the stratum corneum. After dry shaving the skin, self-assessments of stinging were recorded 2 minutes after treatment on a 0-10 scale (0 = no sensation, 10 = severe stinging/burning). In total, the data was pooled from two studies (33 subjects, 49 test sites).

The antimicrobial efficacy was assessed by inoculating ABF with a known quantity of bacteria and incubated for 24 hours. At the specified time point, an aliquot was removed and neutralized, diluted to establish log reduction, plated, cultured, and then analyzed.

The tackiness of ABF was determined by creating a thin film on the skin of 23 panelists. After application, the film was allowed to dry for 3 minutes. Using a gloved hand, an independent expert grader measured the tack of the films using a scale of 0 (no tack) to 5 (Scotch Tape).

Barrier functionality was tested by applying activated carbon dust to the skin of 23 panelists and then coated with ABF. As the barrier films wore off, the carbon black would also be removed giving an indication of the barrier properties.

Digital photographs were taken of each test site at time zero, 24, 48, and 72 hours. The photos were analyzed for remaining carbon content using Image Pro Premium software.

Following ISO 10993 guidelines, the biocompatibility of ABF was determined (cytotoxicity, irritation, and sensitization).
For all applicable tests, a commercially available control group was utilized, and statistical analysis was calculated by Repeated Measures ANOVA.

Results:

The STARS stinging bioassay showed highly significant differences between positive and negative controls ($p<0.001$), but there were no significant differences between the negative control, commercial control, and ABF. ABF and the commercial control were booth considered to be non-stinging.
AFB's antimicrobial properties produced complete kill (over 7 log) of all microorganisms (bacteria and fungi) tested at 24 hours indicating the presence of an effective antimicrobial preservative. Minimal tackiness was felt after application of ABF, while the control was significantly tackier ($p<0.01$). This demonstrates ABF would have a decreased adherence to bed clothes and sheets.

The barrier function of ABF was similar to the commercial control at all time points using Carbon Black Retention testing.

ABF was considered to be biocompatible according to ISO 10993 guidelines, passing all tests.

Conclusion:

In conclusion, ABF retains all the functionality of the commercially available control, reduced tack, and added benefit of antimicrobial activity.

It is expected that these properties will provide protection from microbes in vulnerable areas after minor skin damage. This biomaterial can provide the first line of defense after skin damage to protect from further contamination.

References:

1. Lisa Gould, MD, PhD. J Am Geriatr Soc 2015;63:427-438.