Bactericidal Efficacy of Kerlix™ AMD Antimicrobial Gauze Dressing vs Bioguard™* Gauze Dressing

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SUMMARY
In this study, bactericidal performance of Kerlix AMD antimicrobial gauze dressing and Bioguard gauze dressing was assessed over the period of 72 hours using four clinically relevant bacteria. This study was performed at an independent contract laboratory (NAMSA). The results indicate that Kerlix AMD antimicrobial gauze dressing demonstrated uniform bactericidal efficacy against all bacteria at all time points whereas Bioguard gauze dressing exhibited inconsistent antimicrobial performance.

INTRODUCTION
Kerlix AMD antimicrobial gauze dressings contain 0.2% Polyhexamethylene Biguanide (PHMB) HCl as a broad-spectrum antimicrobial agent that reduces bacterial colonization within the dressing and bacterial penetration through the dressing. Effectiveness of Kerlix AMD antimicrobial gauze dressing as a barrier to bacterial penetration has been demonstrated in an animal model as well as in a human clinical case series. It has been also demonstrated that packing wounds with Kerlix AMD antimicrobial gauze dressings may be beneficial in reducing the bacterial bioburden in terms of both the total amount of microorganisms and the number of species.

Broad-spectrum activity of Kendall AMD antimicrobial dressings against gram positive and gram negative bacteria as well as fungi has also been demonstrated in several in vitro studies. In one study, Kerlix AMD antimicrobial gauze dressings visually exhibited a very high degree of antimicrobial efficacy and reduced growth of MRSA and VRE at 24 and 48 hours following direct inoculation on the dressing at 105 CFU / mL challenge level. In another study, Kerlix AMD antimicrobial gauze dressings exhibited high antimicrobial activity by 3-6 log reduction of MRSA challenge and 4-5 log reduction of VRE challenge at 30 minutes and 2 hours post inoculation of the dressing. Clinically, the Kerlix AMD family of gauze dressings has been associated with statistically significant Surgical Site Infection (SSI) reductions. Recent studies have shown reductions in the overall SSI rate by utilizing the AMD product family along with the current infection control program. These reductions ranged from 24.1% to 81.3% and produced cost avoidances of more than $500,000 in each study. The other 30+ clinical studies represent reductions that fall between these percentages. The evidence indicates that there is a clinical benefit from the conversion to the impregnated products.

We performed a comparative in vitro study assessing efficacy of both Kerlix AMD antimicrobial gauze dressings and Bioguard™* barrier dressings. The study protocol involved direct inoculation of dressings with test organisms (S. aureus, P. aeruginosa, C. albicans, and S. epidermidis) and quantification of bacterial counts at selected times. The test model concept is similar to that used in other studies. The test conditions may be different.

MATERIALS AND METHODS

Test Dressings

<table>
<thead>
<tr>
<th>Dressing</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kerlix AMD™ antimicrobial gauze dressing</td>
<td>Large Roll, Product Code 3331, 6 Ply – 4.5 in x 4.1 yd (11.4 cm x 3.7 m). Lot # 90562603</td>
</tr>
<tr>
<td>Bioguard™* barrier dressing</td>
<td>Large Roll, Product Code 97322, 6 Ply – 4.5 in x 4.1 yd (11.4 cm X 3.7 m) Stretched. Lot # G09003</td>
</tr>
<tr>
<td>Kerlix™ Gauze Dressing</td>
<td>Large Roll, Product Code 6715, 6 Ply – 4.5 in x 4.1 yd (11.4 cm x 3.7 m) Stretched. Lot # 93492601</td>
</tr>
</tbody>
</table>

Test Organisms

- Staphylococcus aureus ATCC 6538
- Pseudomonas aeruginosa ATCC 9027
- Candida albicans ATCC 10231
- Staphylococcus epidermidis ATCC 12228

Test organism preparation

Test organisms were prepared using standard microbiology procedures and per test method AATCC 100, 2004.
Test procedure

A modified AATCC100, 2004 test method was used in the study. This study in its entirety was performed at NAMSA. Briefly, samples approximately 2 inches in diameter were inoculated with 1 ml inoculum of concentration of bacterial colony forming units (CFU/mL) listed in table below. Each sample was composed of twenty-four layers of the dressing.

<table>
<thead>
<tr>
<th>Organism</th>
<th>Initial Inoculum Concentration (log CFU/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus</td>
<td>5.12</td>
</tr>
<tr>
<td>P. aeruginosa</td>
<td>5.14</td>
</tr>
<tr>
<td>C. albicans</td>
<td>5.19</td>
</tr>
<tr>
<td>S. epidermidis</td>
<td>5.03</td>
</tr>
</tbody>
</table>

Quantitative assessment of the bacterial population on each sample was performed at zero time. For the quantitative assessment for longer contact periods, i.e 24 hours, 48 hours, & 72 hours, inoculated samples were incubated at 37 ± 2 °C. For contact periods, 24 hours, 48 hours, and 72 hours, the samples were not repeatedly challenged with fresh inoculums.

After each contact period, the solution was neutralized using D/E broth, serially diluted with water, and plated on nutrient agar and enumerated after 24 hours incubation at 37 ± 2 °C.

Zero counts were reported as “less than 100” or “less than 2 logs”.

Results and Discussion

Number of organisms, expressed as log counts, recovered from the specimen immediately after inoculation (at zero time) are shown in the table below. A higher difference between the initial inoculum level (~5.00 logs) and the number of bacteria recovered at zero-time was observed for Kerlix AMD antimicrobial gauze dressing with all organisms and for Bioguard gauze dressing only with S. epidermidis. This indicates that a portion of the bacteria was killed instantly by the dressing after inoculation.

The bacteria (log counts) recovered from each dressing after 24, 48, and 72 hours of contact period are plotted in Figures 1, 2, and 3 below. Lower number indicates that more bacteria were killed by the dressing.

For all three contact time intervals tested, no significant difference in the bactericidal efficacy was observed between Kerlix™ AMD antimicrobial gauze dressing and Bioguard™* gauze dressing dressings against S. aureus. However, against C. albicans and P. aeruginosa, Kerlix AMD antimicrobial gauze dressing demonstrated significantly higher growth inhibiting activity in comparison with Bioguard gauze dressing at all three contact time intervals (see Figures 1, 2, & 3).

Kerlix™ dressing was used as control. This dressing, having no antimicrobial treatment, supported growth of S. aureus and P. aeruginosa over all three contact time intervals. This is indicated by higher than initial log counts recovered from the dressing. However, this dressing exhibited lower than initial log counts at 24 and 48 hours with organisms C. albicans and S. epidermidis, which indicated that a small portion of the bacterial population was killed while in contact with the non antimicrobial dressing. For 72 hour contact time, very low amount of S. epidermidis was recovered from Kerlix dressing which suggests that perhaps the bacterial died on its own. Therefore, the comparison of the bactericidal efficacy between Kerlix AMD antimicrobial gauze dressing and Bioguard gauze dressing cannot be made for this time interval for S. epidermidis.
CONCLUSION

This study performed at an independent contract laboratory showed that PHMB treated Kerlix AMD™ antimicrobial gauze dressing demonstrated uniform antimicrobial performance against all organisms for various contact time intervals used in this study. Bioguard™* gauze dressing, on the other hand, exhibited inferior bactericidal activity against C. albicans and P. aeruginosa for these time intervals. More comparative studies between Kerlix AMD antimicrobial gauze dressing and Bioguard gauze dressing using various test organisms are warranted.

REFERENCES

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