

# Impact Of An Antimicrobial Drain Sponge Dressing Upon Specific Bacterial Isolates At Tracheostomy Sites

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## INTRODUCTION

Several publications have described the risk factors and infections associated with tracheostomies. One study reported the incidence of positive post-tracheostomy blood cultures as 10.4 %, citing bacteremia as a common complication caused by organisms from the subject's trachea or skin.<sup>1</sup> Results from this study also demonstrated that no significant differences were observed between subjects receiving prophylactic antibiotics as compared to those who did not.<sup>2</sup> Another study concluded that a tracheostomy post coronary artery bypass grafting is associated with increased incidence of mediastinitis and mortality.<sup>3</sup>

Because the subject with a tracheostomy is prone to infection, this clinical case series evaluated a new antimicrobial drain sponge dressing's clinical performance with this particular subject population. The purpose of this trial was to determine whether or not the application of an antimicrobial drain sponge dressing to tracheostomy sites would reduce 4 specifically targeted bacterial pathogens versus a regular, non-antimicrobial drain sponge dressing. Two additional microbes were selected in order to determine any effects upon resident normal skin flora. Final analysis semi-quantitatively compared the recovered bacteria from both the study group and the control group.

## METHODOLOGY

This was a prospective, randomized, controlled, open-label clinical case series comparing a nonwoven drain sponge dressing that contains an antimicrobial agent (*EXCILON AMD™ Drain Sponge Dressing, TYCO Healthcare Group LP, Mansfield, MA*) to the study control, a nonwoven drain sponge dressing without an antimicrobial component. This clinical case series tested the following alternative hypothesis: Use of an antimicrobial drain sponge dressing will significantly reduce 4 targeted bacterial pathogens as compared to the study control, a non-antimicrobial drain sponge dressing. Effects upon resident normal skin flora were also assessed by tracking 2 selected microbes.

The EXCILON AMD Drain Sponge Dressing is a 50/50 Rayon-Polyester blend dressing impregnated with the antimicrobial agent, Polyhexamethylene Biguanide (PHMB). Like the common topical antiseptic, Chlorhexidine Gluconate (CHG), PHMB is a biguanide; it is a broad-spectrum biocide that provides protection against gram negative, gram positive and fungi/yeast microorganisms.<sup>4</sup>

This compound is classified as a "membrane-active" antibacterial and is proven to resist bacterial colonization within the dressing and reduce bacterial penetration through the dressing. The lethal action of PHMB is an irreversible loss of essential cellular components as a direct consequence of cytoplasmic membrane damage.<sup>5</sup>

PHMB provides broad spectrum of activity against a wide range of microorganisms, regardless of the presence of organic matter, and is highly active against gram-negative bacteria.<sup>6</sup> Furthermore, PHMB has the following properties: Low mammalian toxicity, minimal to no odor, non-foaming, chemically stable, and non-volatile.<sup>7</sup> The FDA has reviewed PHMB as an antimicrobial component in drain sponge dressings and has cleared its use in like devices under the pre-market notification (510k) process.

Upon receiving approval from the site's institutional review board (IRB), 10 subjects were recruited from a specialized tracheostomy/ventilator-dependent care unit located within a post-acute care hospital. The Principal Investigator enrolled those individuals who granted written informed consent and met entry criteria. Study inclusion criteria were: 1) The application of a drain sponge dressing to the tracheostomy site was an appropriate intervention; 2) Subject's expected length of stay would allow the 5 study-related dressing changes; 3) Drainage at the tracheostomy site was light, moderate, or heavy and; 4) Subject had no known sensitivity to PHMB. Subjects were randomized according to a schedule created using the Microsoft™\* Excel™\* 2000 computer program and assigned to either a study group that received the antimicrobial drain sponge dressing (n=5) or a control group that received the drain sponge dressing without antimicrobial properties (n=5).

All study dressings were changed by the Principal Investigator at least once every 24 hours during the 5 consecutive study days. The documented time points were: *Baseline* (Screening & Enrollment, baseline wound swab culture, and first application of the randomized dressing), *Day 1, Day 2, Day 3, and Day 4*. During each study-related dressing change, the Principal Investigator photographed the tracheostomy and surrounding skin area. Institutional policy and the presence of copious drainage at the stoma site also dictated the frequency of dressing changes; additional dressing changes were conducted in compliance with the randomization scheme.

Per institutional policy, all study-related dressing changes were initiated by cleansing the peri-stomal area with a solution of half normal saline/half hydrogen peroxide followed by a normal saline rinse; if necessary, the inner cannula was also cleaned at this time. Dressings were then applied via clean technique. During the study-related dressing change, clinical assessment parameters were documented on the case report form. These included the following: Pain at the stoma site, condition of the surrounding skin, color and odor of the drainage, and any other pertinent clinical observations. The Principal Investigator concluded the EXCILON AMD group's assessments by completing 2 additional case report forms on *Day 4*. These 2 forms evaluated the performance of the antimicrobial drain sponge dressing and prompted the clinician to rank its product characteristics. These qualitative characteristics included patient comfort, ability to control odor, and ability to absorb drainage.

Semi-quantitative wound swab cultures were used in this trial to identify the presence of 4 selected pathogenic bacteria. These 4 bacterial pathogens were specifically targeted due to their known prevalence within the tracheostomy patient population. The targeted pathogens were the following:

- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- *Pseudomonas aeruginosa* (PA)
- *Enterobacter cloacae* (EC)
- *Staphylococcus aureus* (SA)

Two additional microbes, members of resident normal skin flora, were also tracked:

- *Alpha-hemolytic streptococci* (AHS)
- *Staphylococcus epidermidis* (SE).<sup>8</sup>

Wound swab cultures were collected per aseptic technique at Baseline (*prior* to initial application of either the study or control drain sponge dressing during the *Baseline* visit) and once during each study-related dressing change for a sum total of 5 wound swab cultures per subject. All cultures were collected in the following manner: 1) The peristomal area was cleansed with a solution of half normal saline/half hydrogen peroxide followed by a normal saline rinse; 2) If necessary, the inner cannula was also cleaned; 3) A rayon-tipped swab applicator was rotated over the peristomal area in a zigzag pattern; 4) The tip of the swab was then inserted into a sterile round bottom polypropylene tube containing a non-nutritive, highly conductive transport medium (*Starswab II Bacteriology Culture Collection and Transport System*). All culture samples were then immediately sent to a CLIA-certified laboratory for susceptibility testing and analysis.

In the laboratory, the semi-quantitative wound culture swabs were inoculated on standard media and streaked in 4 quadrants. Results ranged from “no growth” to “1 - 4+ growth” of the microorganism, depending upon the number of streaked quadrants that supported bacterial growth.

## PROFILE OF ENROLLED STUDY SUBJECTS

Ten subjects with mature tracheostomy stomas were randomized to either the antimicrobial drain sponge dressing (EXCILON AMD) or the control (non-antimicrobial drain sponge dressing). The 2 groups contained an equal distribution of 5 participants. The study duration was a total of 25 days.

One subject used the ventilator intermittently; 4 subjects were dependent upon the ventilator for “nights only,” while 2 subjects did not require the ventilator. Five subjects had diabetes whose status was currently “controlled.” The Principal Investigator assessed for the presence of pain at the stomal site using a “0-10 Verbal Descriptor Scale” (0 = “no pain;” 10 = “the most severe pain”). For 9 of the 10 subjects, stomal pain was rated a zero; pain could not be assessed on the remaining subject.

## RESULTS

### QUANTITATIVE RESULTS

Overall, culture results displayed an absence of bacterial growth in the EXCILON AMD group for a total of 11 days versus 6 days for the control group (Refer to **Graph 1: No Growth of Bacterial Isolates**). Significant clinical findings include the number of subjects who tested positive for MRSA, as well as the number of days that **both** MRSA and *Pseudomonas aeruginosa* were present. MRSA was recovered from 2 tracheostomy sites of the control group at Baseline. An additional 2 tracheostomy sites (for a total of 4 out of 5 sites) in the control group became positive for MRSA during the study. At least one subject in the control group tested positive for MRSA every day a culture was taken. In contrast, only 1 subject randomized to the EXCILON AMD Drain Sponge dressing cultured positive for MRSA, yet concluded the study with no bacterial growth at all.

*Pseudomonas aeruginosa* was present for a total of 10 days in the control group, versus only 3 days in the EXCILON AMD group. This data trend continued, as the remaining other pathogens, *Enterobacter cloacae* and *Staphylococcus aureus*, were also present for a greater number of days in the control group as compared to the EXCILON AMD group.

**Graph 3** displays the semi-quantitative wound swab culture results for the normal skin flora localized at the enrolled tracheostomy sites, specifically *Alpha-hemolytic streptococci* (AHS) and *Staphylococcus epidermidis* (SE). These microorganisms were present in both groups. However, the number of days these isolates were present in the control group was much less than for the EXCILON AMD group: 2 days versus 11 days, respectively. This disparity could be attributed to microbial competitive inhibition, a phenomenon that can occur when the presence of one organism limits the growth of another due to competition for the shared nutrient base. As the dominant organism continues to thrive, it may begin to inhibit the propagation of the other microbe. One possible study example of this can be detected

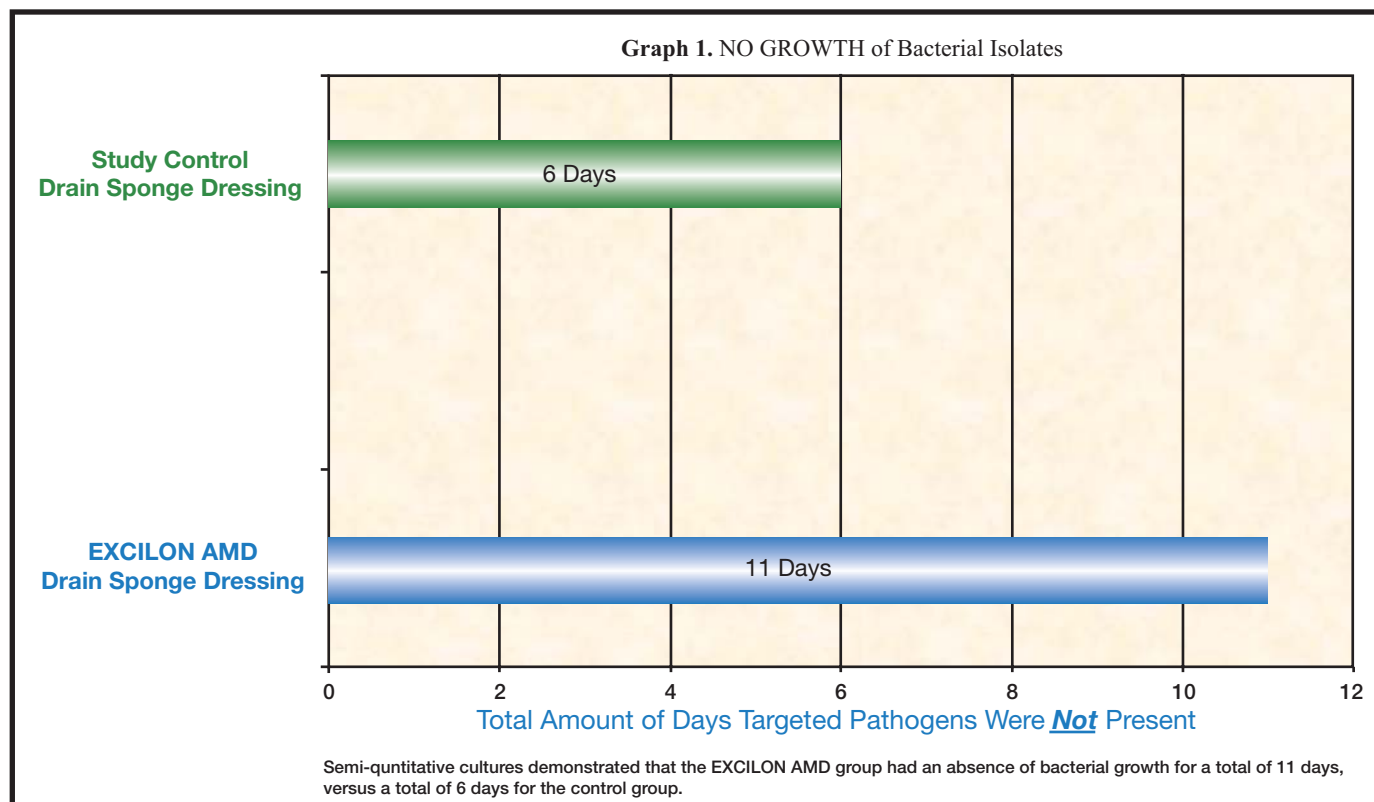
in the control group's laboratory results: The lack of presence of the slow growing normal skin flora, *Alpha-hemolytic streptococci*, may be due to it being suppressed by the MRSA and *Pseudomonas aeruginosa* that were both prominent in the control group.

### QUALITATIVE RESULTS

The Principal Investigator assessed each participant's tracheostomy site for drainage, erythema, and maceration. The study findings are as follows:

#### A) Study Control Drain Sponge Dressing Group (Non-antimicrobial Drain Sponge Dressing):

- One subject had no drainage present upon enrollment, yet developed green, thick drainage by Day 3.
- Another subject started the trial with serous drainage that later changed to copious, yellow exudate after 2 days.
- One subject presented with mild erythema localized at the peri-stomal area, which progressed over the course of the study.



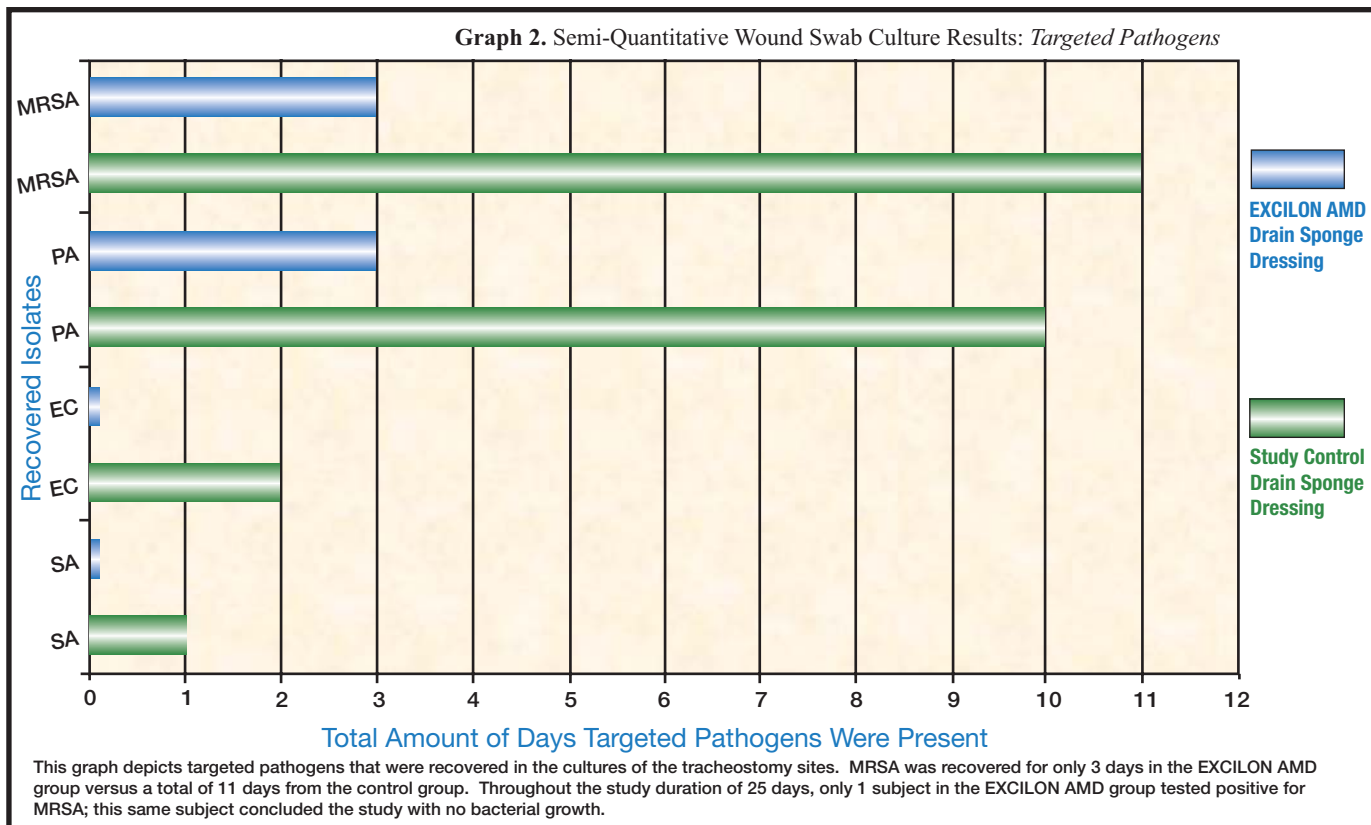
When accounting for the total amount of days each targeted pathogen was present per study group, the semi-quantitative laboratory results were as follows:

Targeted Pathogens	Study Control	EXCILON AMD
Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA)	11 days	3 days
<i>Pseudomonas aeruginosa</i> (PA)	10 days	3 days
<i>Enterobacter cloacae</i> (EC)	2 days	0 days
<i>Staphylococcus aureus</i> (SA)	1 day	0 days

Results of the recovered normal skin flora are as follows:

Normal Skin Flora	Study Control	EXCILON AMD
<i>Alpha-hemolytic streptococci</i> (AHS)	0 days	4 days
<i>Staphylococcus epidermidis</i> (SE)	2 days	7 days

**Graph 2** depicts the results of the semi-quantitative wound swab culture for the targeted pathogens, including Methicillin-resistant *Staphylococcus aureus* (MRSA), *Pseudomonas aeruginosa* (PA), *Enterobacter cloacae* (EC) and *Staphylococcus aureus* (SA). Each of these pathogens was present for a greater number of days in the control group than in the EXCILON AMD group.



**B) EXCILON AMD Drain Sponge Dressing Group (Antimicrobial Drain Sponge Dressing):**

- One subject had erythema present at the stoma site upon enrollment; within 2 days the stoma site was nonerythematous.
- Two subjects began with serousanguinous drainage, one with copious secretions. After Day 2, there was a significant decrease of drainage in the former while the latter had none at all.
- All subjects in the treatment group presented with intact, nonerythematous skin at study conclusion.

Additional qualitative data were collected during the study-related dressing changes, ranking clinical performance characteristics of the EXCILON AMD Drain Sponge dressing on a scale of “poor to excellent.” The clinicians rated EXCILON AMD Drain Sponge dressing as “excellent” or “good” for all 7-performance characteristics. The following dressing characteristics were consistently recorded as “excellent”: General appearance before application, conformability to tracheostomy site, ability to protect periwound skin, and ability to absorb exudate. For all subjects but one, EXCILON AMD Drain Sponge dressing was rated as “excellent” for its

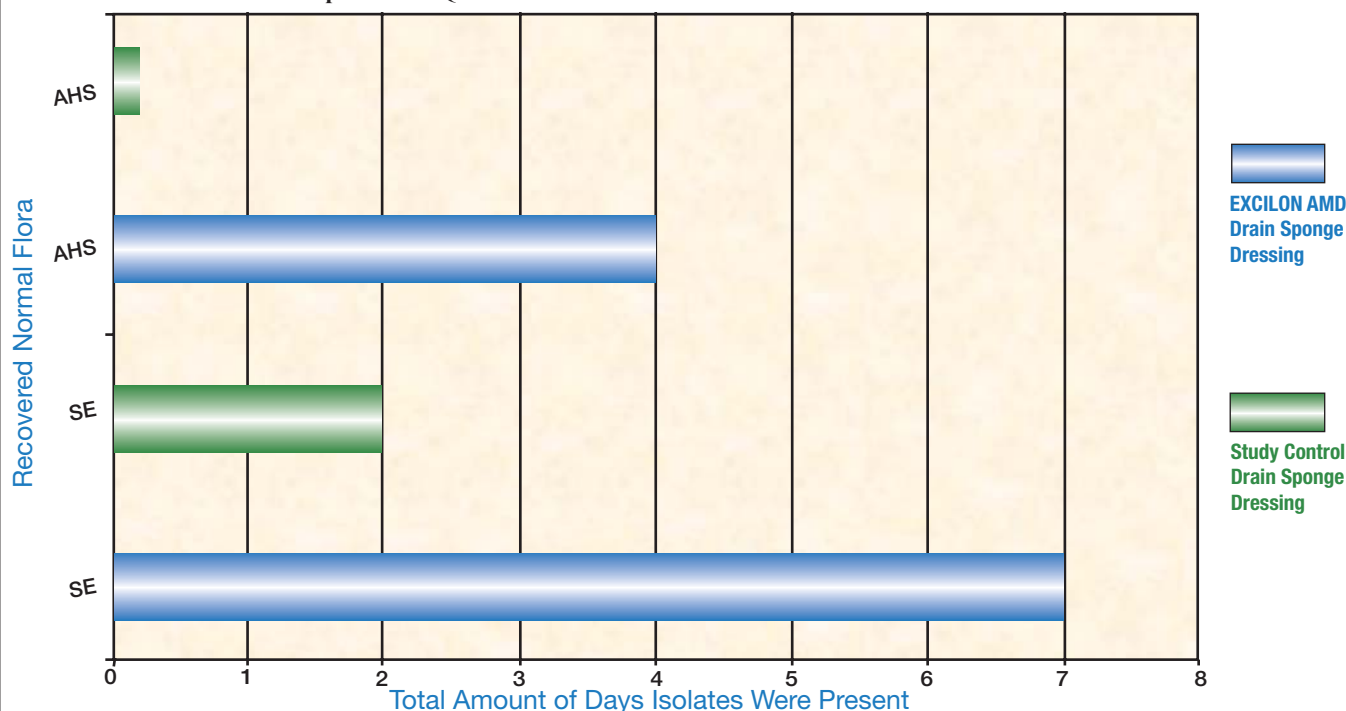
general appearance after application and for general patient comfort. For 3 subjects, clinicians rated the dressing’s ability to control odor as “excellent,” while for 2 subjects they rated this same characteristic as “good.”

The clinicians were also asked which features would influence their continued use of the EXCILON AMD Drain Sponge dressing with tracheostomy sites. An “Importance Ranking Scale” was used to measure their responses. Clinicians unanimously reported that the EXCILON AMD Drain Sponge dressing successfully met the following criteria: 1) Absorb exudate; 2) Conform to the tracheostomy site; 3) Provide patient comfort; 4) Ease of dressing application and removal; 5) Maintain the tracheostomy site clean and free of necrotic tissue or slough and; 6) Protect the peristomal skin area. The above criteria were deemed “extremely important” by the clinicians.

**DISCUSSION**

The objective of this clinical case series was to evaluate whether or not the application of an antimicrobial drain sponge dressing would significantly reduce 4 targeted pathogens commonly found at tracheostomy sites [*Methicillin-resistant Staphylococcus aureus* (MRSA),

**Graph 3. Semi-Quantitative Wound Swab Culture Results: Normal Skin Flora**



This graph depicts the recovered isolates that are found in the skin's normal flora, which is critical to control bacterial balance and maintain the skin's function as a barrier. The EXCILON AMD group exhibited a notable reduction in the pathogenic bioburden, thus allowing the normal skin flora to thrive (as shown here). Conversely, the control group had a preponderance of MRSA and other pathogens, resulting in a limited capacity for normal skin flora to flourish.

*Pseudomonas aeruginosa* (PA), *Enterobacter cloacae* (EC) and *Staphylococcus aureus* (SA)]. Effects upon resident normal skin flora were tracked via 2 microorganisms typical of normal skin flora [*Alpha-hemolytic streptococci* (AHS) and *Staphylococcus epidermidis* (SE)]. Semi-quantitative wound swabs were used to recover and identify those isolates present marginal to the subject's stoma. This technique is advocated in the literature, as it is a noninvasive, reliable methodology that causes little or no patient discomfort.<sup>9,10,11,12</sup>

Although “the semi-quantitative swab technique has been correlated with the gold standard quantitative tissue biopsy, and reported to be a valid method for determining bacterial growth in the superficial layers of the wound bed,” there is not yet any published literature proving this laboratory technique to be both reliable and reproducible for repeated assessments of bioburden levels within chronic wounds.<sup>13,14</sup> Furthermore, semi-quantitative microbiology alone cannot predict the risk of sepsis; quantifying wound organisms does not address the question of bacteremia, nor take into account the cause and extent of the wound in relationship to the patient and underlying co-morbidities. Additional variables may also be considered when analyzing culture results, including the presence and/or stage of wound infection or the lingering presence of secretions at the tracheostomy site. During this case series, these variables were controlled to the extent possible, but nonetheless can be viewed as a potential study limitation.

As previously stated, this study targeted 4 pathogens known to be prevalent in the tracheostomy patient population. Compared to the control group, the group receiving the EXCILON AMD Drain Sponge dressing had fewer number of days where these pathogens were recovered. Most notably, only 1 subject in the EXCILON AMD group tested positive for MRSA and yet concluded the study with an absence of bacterial growth. However, a total of 4 of the 5 subjects in the control group tested positive for MRSA; in fact, MRSA was recovered from the control group every day throughout the study. In addition, cultures from the control group also had a greater number of days with *Pseudomonas aeruginosa* present as compared to the EXCILON AMD group. Clearly, the clinical implications of these findings are significant for controlling the presence of these pathologic microorganisms in the institutional setting.

EXCILON AMD Drain Sponge dressing does not inhibit growth of normal flora.<sup>15</sup> The presence of these microorganisms is critical to control bacterial balance and maintain the skin's barrier function. Decreasing the bioburden of pathogenic organisms facilitates the growth of resident normal skin flora. Conversely, having a preponderance of pathogens competing for a nutrient base limits the capacity of normal skin flora to proliferate and thus flourish. Perhaps as the EXCILON AMD Drain Sponge dressing reduced the pathogenic bioburden, it simultaneously created an environment that allowed normal skin flora to thrive.

## CONCLUSION

One of the multiple factors associated with the increased risk of acquiring antibiotic-resistant bacterial infection is the presence of any indwelling, invasive devices, such as a tracheostomy cannula. Existing literature have described the polymicrobial aerobic-anaerobic flora associated with wound infections at stomal sites.<sup>16,17</sup> Therefore, the results of this clinical case series are noteworthy; study findings suggest that an antimicrobial drain sponge dressing, specifically the EXCILON AMD Drain Sponge Dressing, could be an important adjunct in the control of antibiotic-resistant bacterial infection as well as other infections frequently found in patients with tracheostomies.

These results suggest that using an antimicrobial drain sponge dressing can help to control both MRSA and *Pseudomonas aeruginosa* in an institutional setting. MRSA is not an organism that occurs naturally; it is facility-acquired. *Pseudomonas aeruginosa* is neither a component of normal skin flora nor a species found routinely in healthy humans. The presence of either of these pathogens in a long-term care facility has probable serious consequences. A simple substitution from a regular drain sponge to one impregnated with PHMB fits into existing clinical protocols, while offers concurrently significant potential to improve infection control outcomes.

### **Study was presented as a poster at the following professional national conferences:**

- Wound Ostomy Continence Nursing (WOCN), Orlando, FL, June 2002
- Clinical Symposium on Skin and Advanced Wound Care, Dallas, TX, September 2002
- The Society for Healthcare Epidemiology of America (SHEA), Arlington, VA, April 2003
- Symposium on Advanced Wound Care (SAWC), Las Vegas, NV, April 2003
- Association of Professionals in Infection Control (APIC), San Antonio, TX, June 2003

## REFERENCES

- 1.,2. Teo N, Parr MJ, Finer SR. "Bacteraemia following percutaneous dilatational tracheostomy." *Anaesthesia and Intensive Care*, 1997; 25: 354-7.
3. Curtis JJ, Clark NC, McKenney CA, Walls JT, Schmalz RA, Demmy TL, Jones JW, Wilson WR, Wagner-Mann CC. "Tracheostomy: a risk factor for mediastinitis after cardiac operation." *Ann Thorac Surg* 2001; 72: 731-4.
4. PHMB is available under the trademark COSMOCIL™ CQ, manufactured by ZENECA Biocides.
5. Zeneca Biocides. Polyhexamethylene Biguanide (PHMB): A review of the mechanism of antimicrobial action. July 1994.
6. Ibid.
7. COSMOCIL® CQ Antimicrobial Agent - Technical Product Bulletin.
8. Brook, I. "Microbiological studies of tracheostomy site wounds." *Eur J Respir Dis* 1987; 71, 380-383.
9. Levin NS, Lindberg RB, Mason AD, Pruitt BA. "The quantitative swab culture and smear: a quick, simple method for determining the number of viable aerobic bacteria on open wounds." *J of Trauma* 1976; 16: 89-94.
10. Bill TH, Ratliff CR, Donovan AM, Knox LK, Morgan RF, Rodeheaver GT. "Quantitative swab culture versus tissue biopsy: a comparison in chronic wounds." *Ostomy Wound Management* 2001; 47 (1): 34-7.
11. Stotts NA. "Determination of bacterial burden in wounds." *Advances in Wound Care* 1995; 8: 46-52.
12. Stotts NA, Hunt TK. "Managing bacterial colonization and infection." *Clinics in Geriatric Medicine* 1997; 13: 565-573.
13. Thomson P, Taddonio T, Tait M. "Correlation between swab and biopsy for the quantification of burn wound microflora." *Proceedings of International Congress of Burn Injury*. 1990;8: 381.
14. Herruzo-Cabrera R, Vizcaino-Alcaide MJ, Pinedo-Castillo C. "Diagnosis of local infection of a burn by semi-quantitative culture of the eschar surface." *Journal of Burn Care and Rehabilitation*. 1992; 13: 639-41
15. Mertz et al. "The Effect of an Antimicrobial Gauze Dressing Impregnated With 0.2% Polyhexamethylene Biguanide (PHMB) as a Barrier to Prevent *Pseudomonas aeruginosa* Wound Invasion." Tyco Healthcare Group LP. May 2000; p. 1-6.
16. Brook, I. "Microbiological studies of tracheostomy site wounds." *Eur J Respir Dis* 1987; 71, 380-383.
17. Brook, I. "Bacterial colonization, tracheobronchitis, and pneumonia following tracheostomy and long term intubation in pediatric subjects." *Chest* 1979; 76, 420-424.

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