

A Comparison of an Antimicrobial Wound Cleanser to Normal Saline in Reduction of Bioburden and its Effect on Wound Healing

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A COMPARISON OF AN ANTIMICROBIAL WOUND CLEANSER TO NORMAL SALINE IN REDUCTION OF BIOBURDEN AND ITS EFFECT ON WOUND HEALING

– Julie Lindfors, RN, CWCCN

Microbial bioburden in both acute and chronic wounds is an important factor in wound healing. Consequently, the reduction of bioburden to host-manageable levels, as well as the elimination of certain virulent forms of wound pathogens (regardless of their number), has become a goal of the wound care professional. A prospective, controlled clinical study using accepted sampling methods was conducted to compare the use of an antimicrobial wound cleanser (0.057% sodium hypochlorite in an isotonic saline solution) to normal saline on the reduction of bioburden and wound size. During the 2-month study, 100% of the wounds cleansed with the antimicrobial wound cleanser (n = 9) demonstrated aerobic bioburden reduction from baseline in a range from 1 to 4 logs per wound, while 56% of the wounds cleansed with normal saline (n=9) showed an increase in aerobic bioburden levels. The proportion of wounds exhibiting a reduction in wound size was higher in the antimicrobial wound cleanser group than in the saline group. Further research to increase understanding of the relationship between wound bioburden, healing, and cleansing agents is needed.

KEYWORDS: wound cleanser, bioburden, antibacterial, infection control, wound healing

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Bacteria and other micro-organisms affect wound healing. Almost 40 years ago, Bendy et al¹ demonstrated a direct link between bacterial wound bioburden and subsequent healing. Further investigation by Robson et al² confirmed that a wound bioburden in excess of 1.0×10^5 colony forming units (CFUs) per gram of tissue was a factor in delayed wound healing and closure. Consequently, reduction of wound bioburden became a necessary goal in the wound-healing scheme. Nevertheless, many wounds have been reported to heal despite high bacterial bioburden, suggesting that wound bioburden may be only an interrelated aspect of wound infection.³ Betahemolytic Streptococci, even at 10^2 to 10^3 CFU/g of tissue, play a significant role in pathogenesis and can result in massive tissue injury.⁴ Bacterial virulence, rather than bioburden levels, represents the critical factor in infection and delayed wound healing. Other factors independent of bioburden levels, such as inadequate host resistance and systemic conditions including vascular disease and diabetes, contribute to wound infection risk.⁶

The bacterial populations of wounds that constitute bioburden are a complex amalgam of aerobic and anaerobic micro-organisms that exhibit many adaptive interactions, such as synergism.⁷

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Bacterial synergy has been recorded for a wide variety of micro-organisms, and investigators have noted that anaerobic bacteria such as *Bacteroides spp.*, like most other anaerobic commensals, can act as pathogenic opportunists in cases of decreased resistance and particularly in synergism with other micro-organisms, can produce genuine infections and necrosis.⁸ The pattern of bacterial synergy has been documented for numerous combinations of microbes, even where micro-organisms of low virulence (eg, *Enterococcus spp.*) may contribute to host injury when present with other pathogens.⁹

The topical treatment of wounds has a long and well-developed history. The horrific wounds encountered on the battlefields of World War I brought about the development of a wound antiseptic substance through the efforts of Dakin and Carrel.¹⁰ This antiseptic is still known as Dakin's solution. Generically, Dakin's solution is referred to as sodium hypochlorite. Sodium hypochlorite is also the active agent in the antimicrobial wound cleanser (AWC) tested, albeit in a less concentrated amount. The concentration of sodium hypochlorite in Dakin's solution is 0.5%; whereas, its concentration in the AWC is 0.057%. The AWC also differs from Dakin's solution in that it contains 0.85% sodium chloride that renders, by nominal concentration, the solution isotonic. Dakin's solution is only stable for 30 days¹¹; the AWC used in this study has a 2-year shelf life.

Topical wound care products in recent use include a variety of anti-infective agents such as antibiotic creams, antiseptics, and silver dressings. All are employed to help control bioburden and prevent wound infection. However, an ongoing controversy exists in the effective topical treatment of heavily colonized or contaminated wounds.¹² The use of antiseptics and antimicrobial wound cleansers has been discouraged because the *in vitro* studies conducted by Lineweaver (1985)¹³ and Kozol and colleagues (1988)¹⁴ indicated that sodium hypochlorite (Dakin's solution) exhibits cytotoxic properties. In response to the Kozol study, in 1989 Cuono published the following (excerpted) statements:

The apparently contradictory results obtained by Kozol et al may, in part, be explained by the wound module, which bears little similarity to the real wound milieu." And, "Hypochlorites have an excellent antimicrobial spectrum and act rapidly against Gram-positive and Gram-negative bacteria, viruses (including human immunodeficiency virus), fungi, and spores. Resistant organisms do not develop. No adverse effect has developed in the clinical wound and no systemic toxicity has been found no matter what the duration of use in recommended concentrations. Actual clinical use has proven to us that hypochlorites are effective tools in wound management."¹⁵

Hegggers et al¹⁶ also reported bactericidal and wound-healing properties of sodium hypochlorite solutions; however, other research has established that 0.1% to 0.5% sodium hypochlorite concentrations (Dakin's solution) are toxic to tissue.¹⁷

With the advent of antibiotics and controversy about their safety, the use of most topical treatments declined. However, the liberal use of antibiotics brought serious crises in the management of infectious disease in the form of antibiotic-resistant micro-organisms. The emergence of bacterial resistance to a battery of previously effective agents, coupled with an inadequate spectrum of action, exposed the Achilles' heel of antibiotics. It was later reported that systemic antibiotics are of little use in trying to

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KEY POINTS

- During the past 20 years, the use of antimicrobial cleansing agents has declined as a result of reported in-vivo toxicity and increased availability of anti-infective agents such as topical antibiotics.
- In this pilot study, the author compared the effects of a wound cleansing agent containing 0.057% sodium hypochlorite to normal saline on wound bioburden and healing.
- The results suggest that this low concentration sodium hypochlorite product may be a safe and effective method to reduce wound bioburden. Larger, well-controlled clinical studies are needed to confirm these preliminary findings.

re-establish the bacterial balance of a heavily contaminated or infected wound.¹⁸ Subsequently, topical antimicrobials once again emerged as a potentially powerful tool in infection control and wound care. Prevention of clinical infection of the wound and its detrimental effect on the patient is, perhaps, the most important goal in treating patients with chronic wounds. In light of emerging antibiotic-resistance and more recent research related to toxicity levels of sodium hypochlorite solutions, a study was conducted to compare the reduction of bioburden and its effect on wound size in chronic wounds using an AWC (0.057% sodium hypochlorite in an isotonic saline solution) (Anasept[®] Skin and Wound Antiseptic, Anacapa[®] Technologies, Inc., San Dimas, Calif.) and normal saline as a control for wound cleansing.

Materials and Methods

Methods and design. Patients included in the study were divided into two groups of equal number without regard to type of wound or condition of the patient; participation in a group was based exclusively on location within the facility. The long-term care facility was divided in half geographically. Patient wounds in the east half of the facility were cleansed with the AWC at each dressing change and patient wounds in the west half of the facility were cleansed with normal saline. Bioburden was determined for all wounds using standard and well-accepted laboratory methodology.

Each of the study groups represented comparative wounds, ages, and physical condition. All wounds in persons with multiple wounds were cleansed with the product assigned to that study group. A final assessment of all wounds was conducted after 2 months. All wounds in both groups under study were assessed by same personnel of the Wound Team. The team consisted of the Certified Wound and Continence Care Nurse (CWCCN, Coordinator of Enterostomal Therapy Services); a physical therapist; a licensed vocational nurse (LVN) treatment nurse; and a registered dietician. All team participants had some additional training in wound treatment and assessment (a minimum of four contact hours).

Setting. Study participants were drawn from a large hospital-based skilled nursing unit in southern California. The hospital Medical Director, the Director of the Skilled Nursing Facility, and the Assistant Chief Nursing Officer decided that because the product is manufactured under the guidelines of an over-the-counter (OTC) drug monograph, Institutional Review Board (IRB) review was not required. Patient privacy and rights were considered and followed at every stage in accordance with hospital policy. The hospital Product Evaluation Committee approved the use of the AWC as a new product evaluation.

Study population. Twenty-three (23) patients with a total of 34 wounds were enrolled in the study. [Ed. note: Patients described in this article have been consecutively numbered in their respective groups for editorial purposes only.]

Antimicrobial wound cleanser treatment group.

Patient 1, a 32-year-old Hispanic man with history including oxacillin-resistant *S. aureus* (ORSA) of soft tissue, osteomyelitis, anemia, recreational drug use, paraplegia secondary to a gunshot wound, and non-compliance with offloading, had three open wounds (sacrocoxygeal, left buttock, and right hip) evaluated. The wound bases of each wound initially appeared pink at the edges and pale gray at the center. Wound edges were rolled; this did not change throughout the study. Samples were evaluated for both aerobic and anaerobic bioburden. Wounds were cleansed with AWC and dressed with calcium alginate and absorbent foam dressing QOD. The patient's wounds did not increase or decrease in size (≥ 0.5 cm) by any measurement during the study.

Patient 2 was an 84-year-old Asian woman with a history including renal failure, dehydration, G tube feeding, atherosclerotic heart disease (ASHD), and diabetes. She had one open wound (sacrocoxygeal) evaluated. The wound base appeared beefy red and wound edges were rolled; this did not change throughout the study. The wound was evaluated for both aerobic and anaerobic bioburden. After each treatment, the wound was cleansed with AWC with pulsatile lavage and dressed with absorbent foam dressing QOD. The wound decreased in size by at least 0.5 cm in length, width, or depth during the study period.

Patient 3, a 73-year-old African American woman with a history of diabetes, non-compliance with offloading, hemiparesis secondary to a cerebral-vascular accident (CVA), osteomyelitis of her right heel, and obesity, had her right heel wound evaluated. The wound base appeared pink and wound edges had thick callous with maceration, which did not change throughout the study. The wound was evaluated for aerobic bioburden only. The wound was treated with sharp excision of the callous, cleansed with AWC, and covered with absorbent dressing daily. The patient's wound did not increase or decrease in size (≥ 0.5 cm) by any measurement during the study.

Patient 4 was a 73-year-old Caucasian woman with a history that included diabetes, pneumonia, dehydration, hemiparesis, and osteomyelitis. She had three open wounds (sacrocoxygeal and right and left heels) evaluated. All three of the wound bases appeared beefy red and were evaluated for both aerobic and anaerobic bioburden. The wounds were cleansed with AWC and covered with an absorbent dressing QOD. Her wounds did not increase or decrease in size (≥ 0.5 cm) by any measurement during the study.

Patient 5 was a 51-year-old Caucasian man with a history that included venous stasis disease, lymphedema, congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), osteoarthritis, and morbid obesity. His only open wound (lateral right lower extremity) was evaluated. The wound base appeared beefy red with mild fibrin coating and was evaluated for aerobic bioburden only. The wound was cleansed with AWC and covered with foam and compression dressing QOD. His wound decreased in size by resolving into five smaller wounds of < 1 cm each.

Control group. Patient 1 was a 71-year-old Hispanic woman who presented with a history that included chronic respiratory failure, ventilator dependent tracheostomy, diabetes, G-tube feeding anemia, CHF, and contractures. Both of her open wounds (sacrocoxygeal and left ankle) were evaluated. Both wound bases appeared beefy red; this did not change throughout the study. The sacrocoxygeal wound was evaluated for both aerobic and anaerobic bioburden and the left ankle wound was evaluated only for aerobic bioburden. Wounds were cleansed with normal saline, treated with silver sulfadiazine, and dressed with absorbent foam dressing daily. The patient's wounds increased in size by at least 0.5 cm in length, width, or depth during the study period.

Patient 2 was a 74-year-old Caucasian man whose history included chronic respiratory failure, ventilator dependent tracheostomy, diabetes, G tube feeding anemia, and contractures. Both of his open wounds

(left and right buttocks) were evaluated. Both wound bases appeared beefy red with mild fibrin coating and wound edges were rolled; this did not change throughout the study. Both wounds were evaluated for aerobic and anaerobic bioburden. The wounds were cleansed with normal saline and dressed with calcium alginate packing daily. Cadexomer iodine was added 1 month into the study to manage drainage. The patient's wounds increased in size by at least 0.5 cm in length, width, or depth during the study period.

Patient 3 was a 64-year-old African American woman with history including acute respiratory failure, tracheostomy, diabetes, G tube feeding anemia, and COPD. Her only open wound (sacrocoxygeal) was evaluated. The wound base appeared beefy red and wound edges were rolled; this did not change throughout the study. The wound was evaluated for both aerobic and anaerobic bioburden. It was cleansed with normal saline and initially treated with an enzymatic debriding agent and packed with calcium alginate daily. The wound packing was later changed to absorbent foam dressing to manage drainage. The wound did not increase or decrease in size (≥ 0.5 cm) by any measurement during the study.

Patient 4 was a 67-year-old African American woman with a history of respiratory failure, tracheostomy, type 2 diabetes, G tube feeding, and organic brain syndrome. Her only open wound (sacrocoxygeal) was evaluated. The wound base appeared beefy red and wound edges were rolled; this did not change throughout the study. The wound was evaluated for both aerobic and anaerobic bioburden. It was cleansed with normal saline, packed with calcium alginate, and covered with absorbent foam dressing QOD. The wound did not increase or decrease in size (≥ 0.5 cm) by any measurement during the study.

Patient 5, a 75-year-old Hispanic man with a history including chronic respiratory failure, ventilator dependent tracheostomy, diabetes, dehydration, septic shock, pneumonia, G tube feeding anemia, and contractures, had two open wounds (left hip and right heel) evaluated. The hip wound base appeared pale pink with mild fibrin coating and wound edges

were rolled. The heel wound was 90% covered in black eschar. This did not change throughout the study. The hip wound was evaluated for both aerobic and anaerobic bioburden and the heel wound was evaluated only for aerobic bioburden. Wounds were cleansed with normal saline and dressed with an enzymatic debriding agent daily. The wounds did not increase or decrease in size (≥ 0.5 cm) by any measurement during the study.

Patient 6 was a 47-year-old African American man whose history included peripheral vascular disease (PVD) resulting in bilateral below-the-knee amputation, respiratory failure, tracheostomy, and G tube feeding. His only open wound (sacrocoxygeal) was evaluated. The wound base appeared beefy red and shallow and was evaluated for aerobic bioburden only. The wound was cleansed with AWC, treated with electrical stimulation, and dressed with petrolatum- and bismuth -impregnated dressing QOD. The patient's wound decreased in size by at least 0.5 cm in length, width, or depth during the study period.

Patients excluded. Among treatment group patients excluded was a 76-year-old homeless, transient Caucasian man with history including malnutrition, maggot infestation, and depression with psychotic features. His only open wound (of the left foot) was evaluated. The wound presented as a fulminating mass that enveloped the second and third toes; this did not change throughout the study. He was excluded because the affected foot was amputated below the knee for both basal and squamous cell carcinoma before the end of the study.

A second patient excluded from the treatment group was an 89-year-old African American woman with history including respiratory failure, ventilator dependent tracheostomy, G tube feeding, hypertension, CVA, and morbid obesity. Her only open wound (sacrocoxygeal) was evaluated. The wound base appeared beefy red and wound edges were rolled; this did not change throughout the study. She was excluded because she was placed on negative pressure therapy, which was considered not compatible with allowing the product to remain in place (the suction device removed the product as soon as it was placed on the wound).

An 80-year-old African American man with history including PVD resulting in bilateral above-the-knee

amputation, late effects of CVA, and a failed myocutaneous rotational flap was excluded from the treatment group. His only open wound (sacrocoxygeal) was evaluated. The wound base appeared beefy red and wound edges were rolled; this did not change throughout the study. He was excluded because he was placed on negative pressure therapy.

An 82-year-old Caucasian woman with history including bilateral lower extremity venous and arterial insufficiency, seizure disorder, and anemia was excluded from the treatment group. All of her open wounds (right and left lower extremities) were evaluated. Her wounds presented as circumferential, knee to ankle with beefy red wound bases on thin, spindly shaped lower extremities. Her wounds were treated with trypsin/balsam of Peru/castor oil ointment (Xenaderm, Healthpoint, Fort Worth, Tex.) and decreased in size (≥ 0.5 cm) by all measurement during the study, completely resurfacing with skin before the conclusion of the study. However, this patient was excluded from the study due to inability to collect bioburden data after wound closure.

An 88-year-old Caucasian woman with history including colon cancer with metastasis, status post colectomy, renal insufficiency, malnutrition, and COPD also was excluded from the treatment group. Her only open wound (sacrocoxygeal) was evaluated. The wound base appeared pink initially but later became covered with eschar. She was excluded because she died before the end of the study.

Also excluded from the treatment group was a 54 year-old Hispanic man with history including end-stage renal disease (ESRD, severe anemia, hypotension, paralysis, below-the-knee amputation, and non-compliance with care. His only open wound (left buttock) was evaluated. The wound base appeared beefy red with mild fibrin coating and wound edges were rolled. He was excluded because he was discharged before the end of the study.

Patients excluded from the control group included a 69-year-old Caucasian man with history including chronic respiratory failure, pneumonia, ventilator dependent tracheostomy, diabetes, G tube feeding anemia, malnutrition, and coma. His only open wound (sacrocoxygeal) was evaluated. The wound base appeared beefy red with mild fibrin coating and wound edges were rolled; this did not change throughout the study.

The wound was treated with papain-urea debriding ointment and dressed with moist gauze packing. His wound increased in size by at least 0.5 cm in length, width, and depth during the study period. He was excluded from study because he was hospitalized in acute care on days of collection of bioburden data.

Another control group patient, an 88-year-old African American man with history including chronic respiratory failure, pneumonia, ventilator-dependent tracheostomy, G tube feeding, CHF, COPD, and chronic vegetative state, had all of his open wounds (sacrocoxygeal, left hip, and mid-back) evaluated. The wound bases initially appeared pink and were dressed with calcium alginate and foam. This patient was excluded because he died before the end of the study.

A third control group patient was an 81-year-old Asian man with history including chronic respiratory failure, pneumonia, ventilator dependent tracheostomy, diabetes, anemia, and renal dysfunction. His only open wound (mid-chest) as evaluated. The wound base appeared pink with 20% dead skin on the surface and was dressed with petrolatum gauze dressing (Xeroform, Tyco Health Care/Kendall, Mansfield, Mass.). He was excluded because he died before the end of the study.

A fourth excluded control group patient was a 77-year-old Asian woman with history including diabetes, G tube feeding, CHF, COPD, and chronic vegetative state. Her only open wound (sacrocoxygeal) was evaluated. The wound base appeared pink with 10% mild fibrin coating and wound edges were rolled; this did not change throughout the study. The wound was treated with trypsin/balsam of Peru/castor oil ointment. She was excluded because she was discharged before the end of the study.

A 56-year-old Hispanic woman with history including hepatocellular cancer, peritoneal carcinoma with metastasis to the bone, respiratory failure ascites, and muscle wasting was a fifth patient excluded from the control group. Her only open wound (sacrocoxygeal) was evaluated. The wound base appeared pink and wound edges were rolled. She was excluded because she died before the end of the study.

Eleven patients with 18 wounds were evaluated at the end of the study.

Wound care. Wound sites were catalogued as follows: ankle, buttocks, heel, hip, mid-back, and sacrum/coccyx. At the outset of the study, patient's wounds were initially sharp-instrument debrided, if appropriate. All personnel in the wound team were provided training on the technique for cleansing with AWC and normal saline. All wounds were cleansed¹⁹ at dressing change with approximately 5 cc to 15 cc of either the AWC or normal saline over a period of 2 months. Nine wounds were cleansed with AWC and nine wounds were cleansed with normal saline. Wound dressings varied from wound to wound and included absorbent foam dressing, hydrogel, debriding agents, and alginates. Because the purpose of the study was to assess a wound cleansing product that could be used with almost any dressing, no further consideration was given to dressing selection, other than clinical appropriateness. Samples for bioburden evaluations were taken initially and weekly thereafter for 2 weeks. These samples were collected before cleansing the wounds. After 2 weeks of bioburden study, a decision was made by the Wound Evaluation Team to continue the use of the product as described in the study and, subsequently, to assess wound healing on a monthly basis for 2 months.

Specimen collection and handling. Specimens were collected for recovery and isolation of aerobic and anaerobic micro-organisms before cleansing the wounds. Sampling for anaerobic micro-organisms was conducted only when presumptive evidence²⁰ indicated their presence. Out of nine wounds cleansed with the AWC, seven were sampled for both aerobic and anaerobic micro-organisms and two were sampled for aerobic micro-organisms only. Out of nine wounds cleansed with normal saline, six were sampled for both aerobic and anaerobic micro-organisms and three were sampled only for aerobic micro-organisms.

Aerobic bioburden. Aerobes were collected from all wounds using a modified quantitative swab technique following the guidelines described by Levine²¹ for determining bacterial bioburden. Aerobic specimens were collected in a BBL-Culture Swab Collection and Transport System (BBL Microbiology Systems Cockeysville, Md.) and transferred to the microbiology laboratory at Anacapa Technologies, Inc., San Dimas, Calif., where they were maintained

TABLE 1
AEROBIC BIOBURDEN AFTER 14 DAYS

Number of wounds	Bioburden decreased		Bioburden increased		Bioburden remained same	
	Number of wounds	Percentage	Number of wounds	Percentage	Number of wounds	Percentage
Wounds cleansed with AWC (9)	9	100%	0	0%	0	0%
Wounds cleansed with normal saline (9)	3	33%	5	56%	1	11%

under refrigeration until the following morning when each specimen was serially diluted and cultured onto Trypticase Soy Agar (TSA) Pour Plates according to standard practice.²²

The plates were incubated for 48 hours at 30° C to 35° C. Colony counts were performed from these plates to determine the total number of viable organisms from that wound sample. Isolated colonies were selected for identification by standard microbiological methods²³ that included morphological and cultural characteristics on TSA Plates, subculturing onto selective media such as Mannitol salt Agar, MacConkey Agar II, Cetrimide Agar USP, blood agar, and Gram stain. The genus and species of bacterial isolates were resolved with a battery of specific tests including hemolysis on blood plates, coagulase tests, and carbohydrate fermentation tests based on the commercial bacterial identification systems: BBL Crystal™ Gram Positive ID System and BBL Crystal™ E/NF Enteric Nonfermenter Systems (BBL also known as Becton Dickinson and Company, Sparks, Md.).

Anaerobic bioburden. A semi-quantitative specimen culture collection method was employed to assess the bioburden levels of anaerobic bacteria. This sampling method consists of rolling a sterile, polyester swab across a prepared wound bed and inoculating the specimen onto specialized anaerobic growth media and streaking the sample into four separate quadrants. In this study, anaerobic specimens were obtained by means of a sterile, polyester-tipped swab and immediately inoculated onto pre-marked four quadrants of prepared BBL™, CDC Anaerobic Blood Agar culture plates. Shortly thereafter, the inoculated plates were placed into a BBL™ Gas Pak System™ that was activated to create an anaerobic environment.

All anaerobic specimens were then transferred to the microbiology laboratory at Anacapa Technologies, Inc., where they were incubated at 30° C to 35° C for 48 hours. Bioburden levels were ascertained from the growth, by quadrant, on the CDC Anaerobic Blood Agar Plates. Identification was limited to a Gram stain differentiation and reported by microscopic morphology.

Wound measurement. Wounds were measured in linear fashion.²⁴ Wounds were considered decreased in size if one or more measurements of length, width, depth, or undermining had decreased by at least 0.5 cm. Likewise, increase in wound size was measured by an increase of at least 0.5 cm in measurement of length, width, depth, or undermining. Other wound characteristics were not consistently noted; thus, they are not included in the study.

Results

Bioburden. After 2 weeks of treatment, the aerobic bioburden was reduced in 100% of the wounds cleansed with AWC; however, it was reduced only in 33% of the wounds cleansed with normal saline (see Table 1). It is also important to note that the aerobic bioburden increased in 56% of the wounds cleansed with normal saline but no increase in the bioburden occurred in the wounds cleansed with the AWC. Bioburden was reduced by 1 to 4 logs in all wounds treated with AWC (see Figure 1); in wounds cleansed with normal saline, bioburden increased in many cases (see Figure 2). Also, anaerobic bioburden was reduced in 86% of the wounds cleansed with AWC (see Table 2), but no reduction in anaerobic bioburden occurred in wounds cleansed with normal saline (see Figure 3).

Figure 1: Aerobic bioburden levels for wounds cleansed with antimicrobial wound cleanser.

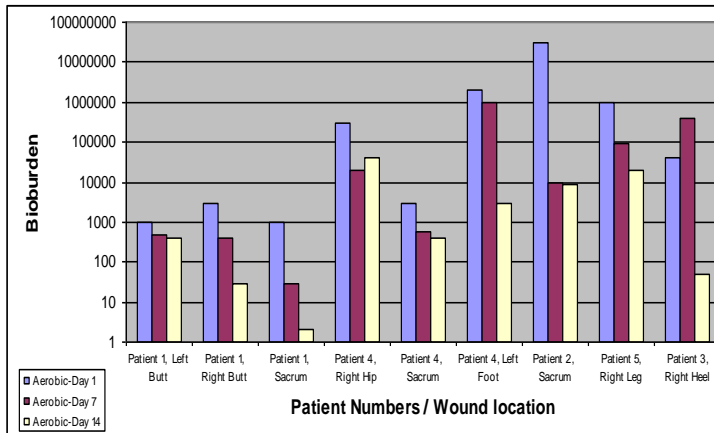
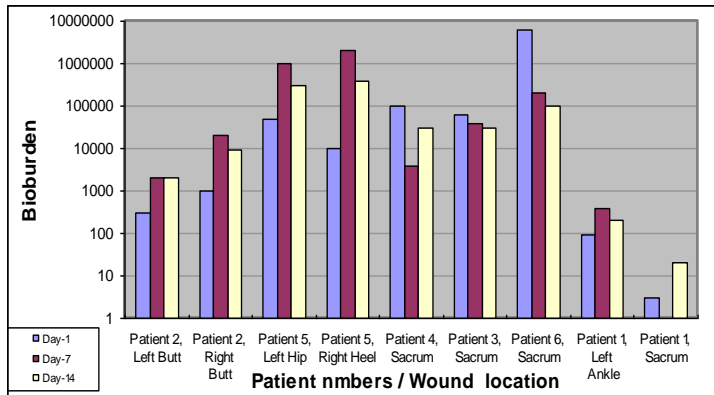


Figure 2: Aerobic bioburden levels for wounds cleansed with normal saline.



Wound healing. Of the wounds cleansed with AWC, 22% decreased in size, while only 11% of the wounds cleansed with normal saline decreased in size.

In addition, none of the wounds cleansed with AWC increased in size; however, 56% of the wounds cleansed with normal saline increased in size (see Table 3). The remaining wounds did not display greater than 0.5 cm of change in any measurement. The wounds cleansed with the AWC developed granulation tissue and were reduced in size at a faster rate than wounds cleansed with normal saline. No signs of any toxic effects or tissue damage were noted with the use of the AWC, and no relationship between wound healing and wound location was observed (see Table 4).

Discussion

The results of this study demonstrated that normal saline was not effective in reducing wound bioburden, an acknowledged influencing factor in the delay of wound healing. Comparatively, a broad spectrum antimicrobial^{25,26} proved effective in reducing bioburden and appeared to stimulate wound healing. The proportion of wounds exhibiting a reduction in wound size was higher in the AWC than in the saline treated group. The number of subjects evaluated in the study limited a thorough statistical review. Wound dressings used on some patients were not completely controlled and may have influenced some outcomes. Wound dressings varied from wound to wound and included absorbent foam dressing, hydrogel, debriding agents, and alginates. Because the purpose of the study was to assess a wound-cleansing product that could be used with almost any dressing, no further consideration was given to dressing selection, other than clinical appropriateness.

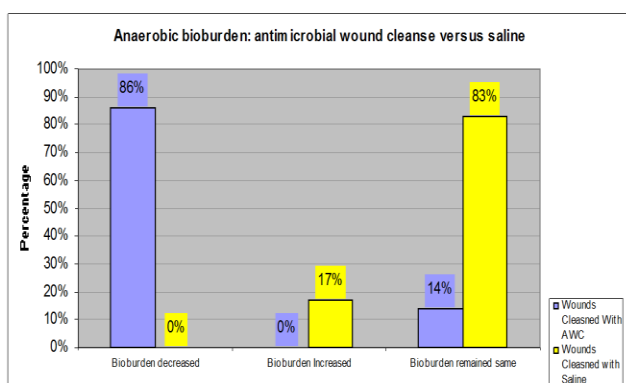
TABLE 2
AEROBIC BIOBURDEN AFTER 14 DAYS

Number of wounds	Bioburden decreased		Bioburden Increased		Bioburden remained same	
	Number of wounds	Percentage	Number of wounds	Percentage	Number of wounds	Percentage
Wounds cleansed with AWC (7)	6	86%	0	0%	1	14%
Wounds cleansed with normal saline (6)	0	0%	1	17%	5	83%

TABLE 3
WOUND SIZE / PERCENT AFTER 2 MONTHS

Number of Wounds	Wound size increased		Wound size decreased		No change	
	Number	Percentage	Number	Percentage	Number	Percentage
Wounds cleansed with AWC (9)	0	0%	2	22%	7	78%
Wounds cleansed with normal saline (9)	5	56%	1	11%	3	33%

Figure 3: Anaerobic bioburden: antimicrobial wound cleanser versus saline.



Conclusion

Although the limited size and scope of the study does not fully consider the underlying morbidity of each subject with regard to wound healing, the bioburden wound healing findings followed similar trends.

These preliminary findings should encourage other investigators to evaluate safe and effective broad-spectrum topical antimicrobial agents in order to establish a relationship between bioburden levels and wound healing.

Future controlled clinical studies also should include examination of the correlation between bioburden and the rate of wound infection,²⁷ the relationship of bioburden levels to the species of the micro-organisms, the rate of infection and/or wound healing, and the statistical confidence level of bioburden reduction with use of AWC or any other broad-spectrum antimicrobial agent. -OWM

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TABLE 4
WOUND HEALING BY LOCATION OF THE WOUND

Wound location/Total wounds	Increased by ≥ 0.5 cm		Decreased by ≥ 0.5 cm		No change of at least 0.5cm	
	Number of wounds	Percentage	Number of wounds	Percentage	Number of wounds	Percentage
Sacrum: AWC (3)	0	0%	1	33%	2	67%
Leg/hell/ankle: AWC (3)	0	0%	0	0%	3	100%
Buttocks/hip: AWC (3)	0	0%	0	0%	3	100%
Sacrum: normal saline (4)	2	50%	1	25%	1	25%
Leg/hell/ankle: normal saline (2)	1	50%	0	0%	1	50%
Buttocks/hip: normal saline (3)	2	67%	0	0%	1	33%

AWC= antimicrobial wound cleanser

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