

A Multidisciplinary Approach to Establishing the Safety and Performance Characteristics of a New Calcium Alginate Wound Dressing

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OVERVIEW

New wound care products must be evaluated carefully before commercialization. Successful product testing requires a corporate team approach as well as formation of a partnership with experienced wound care clinicians. In this three step product evaluation, professionals from various disciplines worked together to establish the safety and performance characteristics of Restore CalciCare Wound Care Dressing, a new calcium alginate dressing (Hollister Incorporated, Libertyville, IL).

STAGE 1 TESTING LABORATORY EVALUATION

In the initial stage of testing, Restore CalciCare and commercially available alginate dressings (Kaltostat and Sorbsan) were compared in a laboratory evaluation.

Overall Objective of Laboratory Testing:
 To compare the functional characteristics of Restore CalciCare to other commercially available alginates.

Performance Parameters Tested:
 Test methods simulating the end use of the dressings such as wet strength, absorption and lateral wicking were chosen.

As presented at the
 11th Annual Clinical Symposium
 on Wound Management
 Reno, Nevada
 September 9-11, 1996



Figure 1: Restore CalciCare versus Sorbsan

Wet Strength: Wet strength, an important attribute for alginate dressings, allows the dressing to be removed from the wound bed in one piece. The ability to remove the dressing in one piece reduces the need for irrigation that may damage fragile new tissue. The developed wet strength test method used concepts from ASTM D5034. Samples of alginates were soaked for 0.5 hours in 37°C solution of sodium chloride and calcium chloride described in the British Pharmacopoeia. The samples were carefully removed from the solution, blotted dry and mounted in a tensile testing machine. The samples were pulled at a crosshead speed of 12 inches per minute until they broke. The maximum load per inch of sample width was recorded. For sponges, the test results indicated that Restore CalciCare is similar to Kaltostat but stronger than Sorbsan in wet strength (Figure 1). For ropes, Restore CalciCare was 70% stronger than Kaltostat.

Photographic Documentation: In addition to a rating scale used on the *Product Performance Questionnaire*, wound photography was used to illustrate key performance parameters.



Figure 4: Stage III pressure ulcer of the coccyx.

Case Study - Subject ID# 206: This 82 year old patient had developed a Stage III pressure ulcer of the coccyx (Figure 4) with a wound depth of 2cm and undermining of greater than 4cm. The wound was packed with Restore CalciCare rope dressing (Figure 5 and 6). Photographs demonstrate positive performance in regard to *ease of application, conformability, absorption and wet integrity* (Figure 7).



Figure 5: Packing with Restore CalciCare rope dressing.

Clinical Evaluation Conclusion: Results indicated that Restore CalciCare Wound Care Dressings exhibited positive performance characteristics when used to treat exuding wounds.



Figure 6: Packing with Restore CalciCare rope dressing.



Figure 7: Dressing after removal.

SUMMARY

A multidisciplinary approach to the testing of Restore CalciCare enabled the project team to thoroughly document the performance of a new product. The resulting database can be used by clinicians seeking information about calcium alginate wound dressings.

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Absorption: Absorption was tested per the British Pharmacopoeia method by placing the alginate dressings in Petri dishes containing a 37 degree C solution of sodium and calcium chloride. This solution mimics the sodium and calcium content of blood plasma. At 0.5 hours, the dressings were removed and weighed. The test results indicate that Restore CalciCare is 55% more absorbent than Kaltostat and 96% more absorbent than Sorbsan (Figure 2).

Lateral Wicking: Lateral wicking, or the transport of fluid from one fiber to another, is not desired in a wound care alginate dressing. Contact of wound exudate may macerate periwound skin. Lateral wicking was tested in the laboratory by placing an alginate dressing over a 1.5 inch diameter and 0.125 inch deep well into which a 37 degree C solution of sodium and calcium chloride was pumped for 24 hours. The maximum distance of fluid travel from the center of the dressing was recorded. The test results indicate that Restore CalciCare, Kaltostat and Sorbsan wick similarly. The test method does have an unacceptably high coefficient of variation indicating that the lateral wicking test method needs improvement or that lateral wicking may be best judged in a clinical setting.

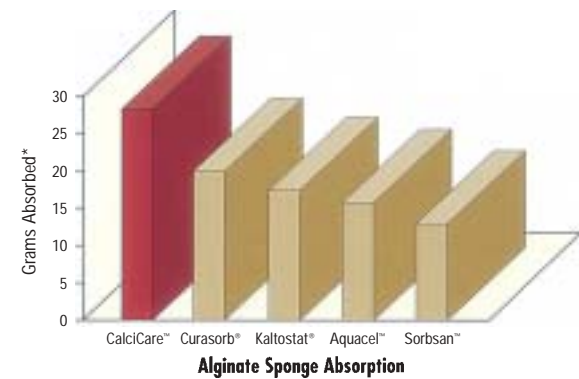


Figure 2: Using the test method of the British Pharmacopoeia, dressings were soaked for 30 minutes and then removed.

Summary of Laboratory Testing:

Wet strength: Restore CalciCare is similar to Kaltostat but stronger than Sorbsan.

Absorption: Restore CalciCare is 55% more absorbent than Kaltostat and 96% more absorbent than Sorbsan.

Lateral Wicking: Restore CalciCare is similar to Kaltostat and Sorbsan.

**STAGE 2 TESTING
BIOCOMPATIBILITY AND
SAFETY ASSESSMENT**

After laboratory evaluation, the biocompatibility of Restore CalciCare was assessed using guidelines established by:

- ISO 10993-1
- G95-1, General Program Memorandum, United States FDA Office of Device Evaluation

Restore CalciCare was found to meet these guidelines. This can be illustrated through the results of *in vitro* and *in vivo* tests.

Testing: Initial biocompatibility was established by performing the following tests:

- Cytotoxicity, MEM-Elution
- Acute Systemic Toxicity, Saline Extract
- Skin Sensitization, Maximization Technique

Results of these tests indicated that Restore CalciCare was acceptable for continued testing.

Prior to use on humans, final biocompatibility testing was performed to establish safety and efficacy. A synopsis of the final biocompatibility studies is presented below.

Seven Day Muscle Implant Study in Rabbits: Conclusions

- No remarkable clinical signs were observed.
- Under the test conditions, Restore CalciCare evoked a slight irritative response when compared to USP negative control.
- Kaltostat evoked an increased degree of irritative response when compared to Restore CalciCare.

Twenty-eight Day Muscle Implant Study in Rabbits: Conclusions

No remarkable clinical signs were observed.

- Under the test conditions, Restore CalciCare and Kaltostat elicited equivalent irritative response when compared to USP negative control.
- Wound healing was similar for both Restore CalciCare, USP negative control and Kaltostat.

Fourteen Day Wound Healing Study in Pigs (Figure 3), Rope form of dressing: Conclusions

- No remarkable clinical signs were observed.
- No appreciable differences in wound healing between Restore CalciCare and Kaltostat.



Figure 3: Wound healing study in pigs.

- Restore CalciCare was easier to remove than Kaltostat.
- Restore CalciCare caused less eschar formation than Kaltostat.

**STAGE 3 TESTING
CLINICAL EVALUATION**

The final stage of the testing was the implementation of a clinical evaluation. Twenty subjects were enrolled and treated with Restore CalciCare for 14 days or until an absorptive dressing was no longer needed.

Study Objective: To document the performance characteristics of Restore CalciCare when used on exuding wounds.

Study Design: The study design was a prospective product evaluation conducted at two wound care centers. Twenty subjects with wounds of various etiologies were enrolled from clinic, home care or long term care settings. Since the emphasis of the study was to evaluate performance characteristics rather than wound healing, a two week patient follow-up was selected.

The calcium alginate product was available in two forms - a 4" X 4" pad and a 12" rope configuration. The clinician chose to use the pad or rope according to the size and shape of the individual wound.

The calcium alginate treatment was continued until one of more of the following endpoints was reached: (1) 14 days of treatment had been completed, (2) the patient was discharged from the care facility and follow up was impossible, (3) the wound exudate had diminished and a highly absorptive dressing was no longer indicated, (4) the wound had healed and there was no longer a need for the treatment, (5) the patient elected to withdraw from the study population, or (6) an adverse event necessitated discontinuation of the dressing.

The condition of the wound was formally evaluated weekly and the performance characteristics of the wound dressing were evaluated at each dressing change.