Unique Sprayable Burn Dressing Combines Lidocaine and Silver for Advanced Burn Management in Field Care through Fixed Care

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Introduction

- The current burn clinical practice guidance relies on separate dressings, antimicrobial agents and analgesics that require repeated application and frequent dressing changes.
- Current hydrogel and silver-based dressings may provide only one or two therapeutic function, while limiting wound visualization, conformability, or ease of use.
- Burn injuries carry a high risk of infection that can lead to significant delays in healing and complications, where approximately 38% of combat-related wounds are colonized with bacteria upon hospitalization, a problem likely to worsen with prolonged evacuation times.
- This highlights the need for field-deployable therapies that are multi-modal and provide robust burn care in a single, low burden dressing that can treat multiple wounds.
- This study evaluates a novel spray-on burn dressing containing antimicrobial silver hydrosol and anesthetic lidocaine (Field Shield Wound Dressing, FSWD), compared to the standard issue silver-based nylon dressing currently slotted in burn kits.
- The study assesses treatment of partial to deep partial thickness burns (≥100 cm² per site; 5–30% TBSA total).

Objectives

(1) Evaluate the effect of FSWD on burn wound healing
(2) Evaluate the effect of the FSWD on prevention of burn wound infection
(3) Evaluate the effect of the FSWD on pain management
(4) Evaluate the ability of the FSWD to mitigate burn progression by evaluating (a) the proportion of subjects requiring grafting, and (b) the proportion of subjects that experience a progression or deepening of their burn wound during the initial treatment period (approximately 2 weeks).

Methods

- A 40 patient clinical trial is currently underway evaluating the efficacy of FSWD as a treatment for 5-30% TBSA burns in a randomized crossover study vs a silver nylon dressing.
- Three study sites are enrolled in the trial: US Army Institute for Surgical Research, Valleywise Health Medical Center, and Medstar Washington Research Institute.
- Dressing applications and wound assessments were completed on Days 0, 3 (+/- 1 day), 7, 12, 19, 28 (+/- 2 days), and Day 35 (+/- 4 days).
- The first two subjects enrolled in a 40 patient multi-site clinical trial is presented here.
- Patient and Observer Scar Assessment Scale (POSAS), Burn Health Outcome Survey were administered at day 35.

Results

PATIENT 1

The patient presented with 6% TBSA of partial thickness burn wounds, where the upper and lower right forearm burn was enrolled in the study. The forearm was divided into two areas, one 117cm² (Site A) and one 112cm² (Site B). Site A received Field Shield (upper forearm), and Site B received Silverlon (lower forearm) as the initial primary dressings. Secondary dressing of Tegaderm was applied to both burn sites.

On Day 3, patient stated preference for the spray on dressing over the nylon dressing. However, the staff noted patient complained of irritation from the Tegaderm pulling on the remaining arm hair causing some discomfort. On Day 7, Site A and Site B reached 75-100% granulation and 75-100% epithelialization. The patient's pain was reduced from a 4 to a 1 by this day for both sites. The patient preferred the nylon dressing on this day,

As healing progressed, the patient preferred the spray dressing on Day 12. Burns were identified as fully healed by this day, although some edema remained, which was more prominent for Site B. Site B was changed to lotion on this day, with FSWD remaining for Site A as the primary treatment. By Day 28, both sites were considered superficial. The blinded physician assessor noted "Site A does not have small blisters expected from burn wound healing process." These blisters were evident on Site B treated with Silverlon.

Overall, the patient preferred FSWD for the majority of burn healing process, and was happy with the outcome of the treatments, scoring both equally. Cosmetically, there was a clear difference in the healing outcomes of the two treatments, where the FSWD treated burn had optimal healing and provided smoother, softer skin and minimal scarring, whereas Silverlon had visible areas of scarring and some areas of blistering remaining on Day 35.

Figure 1. Subject VHMC-01. Left images are of the burn on Day 0 (Middle image is Site A, Lower image is Site B). Right images are of the burn on Day 35 (Left image is of Site B-Silverlon, Right image is Site A-FSWD).

PATIENT 2

The patient presented with 15.5% TBSA of deep partial thickness burn wounds, where the two upper arm burns were enrolled in the study. The burns were circumferential, measuring 666cm² and 648cm², respectively, and one treatment was applied to one arm. Site A received Field Shield, and Site B received Silverlon as the initial primary dressings. Secondary dressings of Telfa, kerlix, and burn netting were applied to both burn sites.

Starting on Day 7, patient stated they preferred the spray on dressing over the silver nylon dressing. Prior to this, patient was sedated and unable to provide this information due to the more severe burns incurred. Patient had two surgical excision procedures by Day 12 for both study sites, as well as excision of other deep partial and full thickness burns incurred.

On Day 12, after both study sites were surgically excised, the Sub-I completing the surgery applied Recell to the patient's entire right arm, including the upper right study wound (Site B). The arm was then covered in clear telfa and secured with staples. Dry xeroform was placed over the clear telfa and then dressed in kerlix and burn netting.

Site A, treated with the spray on dressing, did not require Recell or additional grafting or surgical intervention. Wound healing for Site A had progressed to 75-100% epithelialization by this day, whereas Site B remained at 25-50% and had additional mild erythema progress.

Patient continued to state preference for Site A (FSWD) on the progressing assessment days. We anticipate the Site B may have faster healing overall due to the surgical intervention and cellular grafting it received. Day 35 the patient stated their preference was for the Recell treated burn as the Site A still had small open blisters that required continued dressing application.

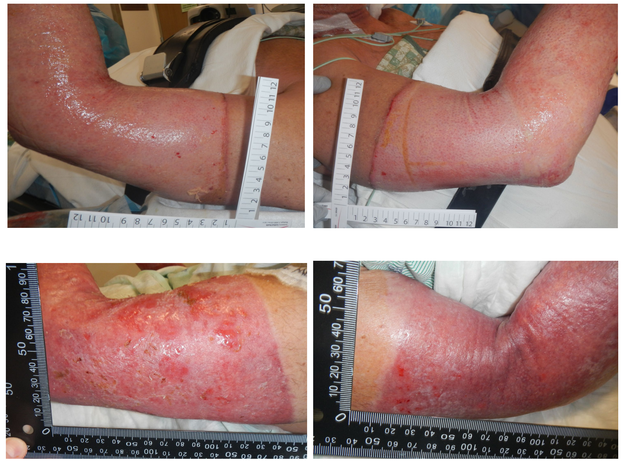

Figure 2. Subject VHMC-02. Left – Site A. Right – Site B. Top images: Day 3 burns. Bottom images: Day 28 burns (right image 2 weeks post-Recell treatment).

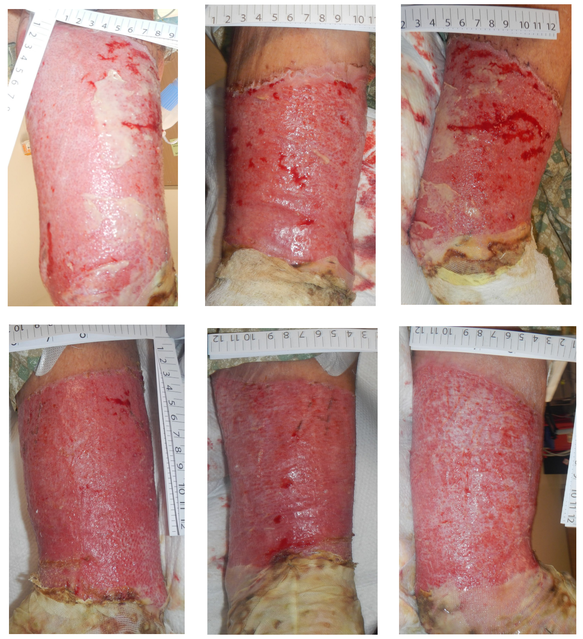

Figure 3. Subject VHMC-02, Day 12. Top images: Site B burns prior to Recell treatment. Bottom images: Site A burns treated with FSWD.

Conclusions

- This is an ongoing study, with the preliminary results from the first two subjects reviewed here.
- While early, the initial healing outcomes are promising, and patient preference has been strongly in favor of the spray on wound dressing.
- Patient 1 progressed to lotion by Day 12 from the silver nylon treatment for Site B, whereas Site A maintained the FSWD treatment as part of the protocol for post-treatment cosmetic healing support and itch/pain relief.
- Patient 2 experienced deep partial thickness burns that required surgical intervention for Site B by Day 12. Site A, treated with FSWD, was progressing well and did not require surgical intervention during the study protocol period.
- Both sites underwent surgical excision on Day 12, where Site B was then treated with Recell and covered with antimicrobial secondary dressing.
- Overall, the initial results show that the FSWD is a promising new treatment for deep partial thickness burns, and has the potential to reduce the number of surgical interventions required for healing.

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