51 Wireless Electroceutical Dressing for the Treatment of Biofilm Infected Burn Wounds

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Introduction: Burn injuries are common to all military conflicts. In combat, eradication and prevention of burn wound infection is complicated by high rates of soft tissue contamination and prolonged delays to definitive stateside care. Furthermore, in the battlefield setting the salvage rate for infected burned extremities is low. Therefore, a simple, easy, non-invasive and rapid method to protect the wound, while also inhibiting infection, would represent a significant advance in the treatment of combat burn wounds. The purpose of this clinical trial was to investigate the efficacy of an FDA approved disposable and easily portable, wireless electroceutical dressing (WED) in the treatment of burn wounds. The hypothesis was that a low electric field generated by the moisture-activated WED will reduce infection load, improve graft survival and take, enhance wound healing and restore skin barrier function of biofilm infected wounds.

Methods: A phase I, prospective, randomized, controlled clinical trial was performed to evaluate the efficacy of the WED dressing as compared to the standard of care (SoC) dressing to prevent and disrupt biofilms. Subjects were screened from inpatient admissions for traumatic burns >300cm^2 in size. In total 38 subjects were enrolled to the study. Subject burn wounds were divided into two parts and randomized to receive either the SoC dressing or the WED dressing. Dressings were changed on day 4, removed on day 7 and the burns were followed for 30 days. Small biopsies were collected on days 4 and 7 for histology, SEM examination of biofilm and for quantitative bacteriological analysis. In addition, non-invasive wound imaging techniques were utilized to study wound healing. Furthermore, Vancouver scar scale and patient observer scar assessment were used to evaluate quality of healing.

Results: The results showed that at the time of dressing removal, non-grafted burns that were treated with the WED dressing presented statistically significantly less biofilm in comparison to the SoC treated burns ($p < 0.05$). The results also demonstrated that the WED dressing was more efficient at eradicating biofilm than the SoC dressing. At the time of the dressing removal, biofilm score [0-3] had decreased in 48% of the WED dressing treated burns in comparison to 28% in the SoC treated burns. In terms of wound healing and quality of healing no significant differences were observed between the WED and the SoC dressings.

Conclusions: This trial demonstrated that the WED dressing was more efficient against biofilm infection than the SoC dressing. In addition, the study concluded that the WED dressing performed equally well as the SoC in terms of burn wound healing.

52 Refinement of a Histologic Algorithm for Burn Depth Categorization Using 1142 Consecutive Burn Wound Biopsies

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Introduction: Our group previously reported a theoretical burn biopsy algorithm (BBA-V1) for the categorization of burn wound depth based on histologic analysis, and informed it with the largest series of burn wound biopsies in the literature. That iteration of the BBA resulted in clinical misclassification rates consistent with past literature. Since our last report of that process, we have refined the algorithm with new criteria and a larger repository of burn wound biopsies. Here, we sought to promulgate this newer, simpler version of the BBA (BBA-V2).

Methods: This was an IRB-approved, prospective, multicenter study. Patients with burn wounds assessed by burn experts as requiring excision and autograft underwent 4mm biopsies procured every 25cm^2. Serial still photos were obtained at enrollment and at excision intraoperatively.

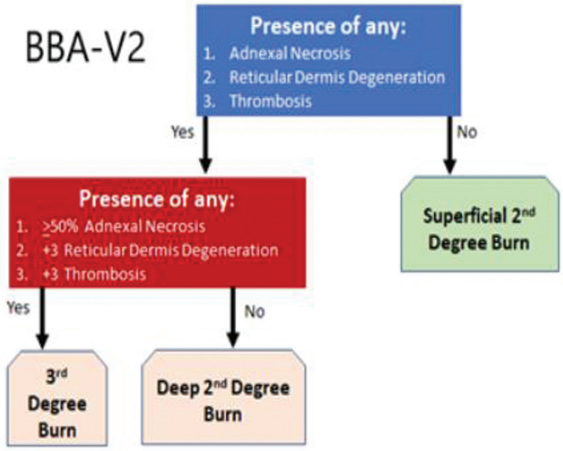
Using H&E with whole slide scanning, a board-certified dermatopathologist assessed each burn biopsy. The criteria used for categorization of burn wound depth in BBA-V1 were: 1) proportion of necrotic adnexal structures, and 2) presence/absence of each of epidermis, papillary dermis, and reticular dermis. The criteria used for BBA-V2 were: 1) magnitude of reticular dermal degeneration, 2) proportion of necrotic adnexal structures, and 3) magnitude of vessel thrombosis.

Biopsy pathology results were correlated with still photos by 3 burn experts for consensus of final burn depth diagnosis. Superficial partial thickness (SPT) wounds were considered to be burn wounds likely to have healed without surgery, while deep partial thickness (DPT) and full thickness (FT) were considered unlikely to heal by 21 days.

Results: The development of BBA V-1 was previously informed by 66 subjects with 117 wounds and 816 biopsies, and resulted in wound categorizations as follows: SPT (20%), DPT (43%), and FT (37%). Therefore, according to BBA-V1, 20% of burn wounds were incorrectly judged as needing excision and grafting by the clinical team. The overall cohort was enlarged to 162 subjects with 294 wounds and 1142 biopsies. The most recent 838 burn wound biopsies were then re-reviewed and re-categorized according to the new BBA-V2 criteria and algorithm. Under BBA-V2, 3% of all burn wound biopsies were categorized as superficial partial thickness, 69% were categorized as deep partial thickness, and 29% were categorized as full thickness.

Conclusions: Our study demonstrates that by adding dermal degeneration severity and vessel thrombosis to our previous criterion of adnexal structure necrosis, BBA-V2 had

a much higher rate of concordance with visual clinical assessment for burn wounds clinically judged as needing surgical excision. This study serves as the largest analysis of burn biopsies by modern day burn experts.



53 Use of Polylactic-acid-membrane in Split-thickness Skin Graft Donor Sites: A Prospective, Comparative, Randomized Study

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Introduction: Polyurethane film (PU) dressings are commonly applied for coverage of split-thickness skin graft (SSG) donor sites, while previous studies have suggested reduced morbidity using a polylactic acid membrane (PLM). To further investigate the optimal treatment approach, the presented study compared outcome of donor sites in patients receiving either PLM or PU.

Methods: This randomized clinical trial allocated patients requiring SSG to receive either PLM or PU at the donor-site. Primary endpoint was difference in donor site scar appearance between groups 3 months postoperatively (Vancouver Scar Scale – VSS). Secondary endpoints included pain, the number of and time required for wound dressing changes, and costs related to the wound dressing.

Results: 30 patients were allocated to each group. The median VSS scored lower for patients receiving PLM (PU: 3 (Q1: 2; Q3: 4) vs. PLM: 2 (Q1: 1; Q3: 3); p=0.049). Pain during change of wound dressing (PU: 2.0 ± 0.2 vs. PLM: 0.5 ± 0.2; p< 0.001) and mobilization (PU: 0.8 ± 0.2 vs. PLM: 0.3 ± 0.1; p=0.032) was reduced in the PLM group. Patients with PLM required less dressing changes per day of hospital stay (PU: 0.44 ± 0.06 vs. PLM: 0.28 ± 0.02; p=0.015). Mean time for wound dressing changes per patient was higher in the PU group (PU: 74.50 ± 5.72 vs. PLM: 21.43 ± 2.61 min; p< 0.001). Costs were higher in the PLM group (PU: 67.83 ± 5.56 vs. PLM: 162.79 ± 21.76 €; p< 0.001).

Conclusions: PLM improves outcome of SSG donor sites, however, higher treatment costs must be taken into consideration.