Failure is Not an Option: Bioelectric wound care as a means to successful skin regeneration in hard to heal wounds

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BACKGROUND

Large soft tissue defects pose a significant challenge, by impacting form as well as function and typically require complex surgical reconstruction to achieve closure. Unfortunately, the creation of skin and muscle flaps carries significant risks and may result in failure or complications (1-3). The costs involved and/or morbidity of reconstructive surgery may be prohibitive to uninsured or high risk individuals. Current alternatives to surgical reconstruction include the use of bioengineered tissue substitutes either alone or in combination with split thickness skin grafting. While these may favor those patients who are at too high of a risk for extensive surgical reconstruction, it remains cost prohibitive for many (4). For the remainder of the patients who are physically or financially ineligible for or fail reconstruction procedures, the only remaining option is to heal by secondary intention. Standard moist wound therapy for large defects typically results in protracted periods of wound care, risk of infection and suboptimal cosmetic outcomes (5). The recent advent of a novel antimicrobial bioelectric dressing* which utilizes established principles of moist wound therapy as well as electric stimulation principles may play a significant role in addressing this unmet need for tissue replacement options (6-10).

METHODS

The following five patients were all treated with a bioelectric dressing as the primary contact layer for both acute and chronic wounds of varying etiologies and degrees of soft tissue loss.

RESULTS

All five cases successfully healed with the bioelectric dressing as the primary contact layer to the wound bed. The benefits of this modality as an alternative to the standard of care can be seen in the outstanding cosmetic outcomes and rapid wound closure, in some cases after failure of reconstructive surgery. The outcomes in these cases support the potential of this modality as an alternative to reconstructive procedures when either impractical, prohibited by excessive risk, or failure of initial attempts at closure.

CONCLUSIONS

The courses and outcomes of these cases illustrate the potential utilization of a bioelectric dressing in the management of a wide range of wound types and sizes. The bioelectric wound dressings may offer a viable option to skin replacement when initial therapy fails or in the case where recommended treatment is prohibitive due to excessive patient risk or financial constraints. The ability to avoid high cost adjuvant therapies, while reducing in-patient hospital stays, reduction of painful reconstructive procedures without sacrificing cosmetic outcomes, makes the bioelectric dressing an attractive alternative to traditional means of soft tissue replacement. Further study is warranted to determine the role of this modality in the regeneration of skin and soft tissue in both acute and chronic wound types.

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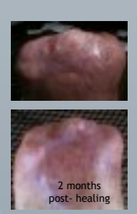
Case 1: Crushed Foot Injury –failed skin graft

49 y.o. healthy male suffered crush injury from 3000 lb. machine to distal 1/3 of left forefoot Aug. 16, 2010. Open amputation of distal forefoot Sept. 9, 2010 followed by NPWT. Prepare wound bed with bilayered skin matrix** and NPWT for eventual skin graft coverage. STSG mid-Nov. 2010. Graft slough with failure to progress after 3 months of wound care. Patient requests to begin bioelectric dressing late Feb. 2011. Following application of first dressing, marked activity in wound bed following months without progression. Dressings changed twice weekly with continued improvement resulting in complete coverage of the defect in 8 months with soft supple "skin" and preserved ambulatory function.

September 2010
Forefoot amputation & skin matrix with NPWT

Nov 2010-Feb 2011 After skin matrix (x2), STSG and moist wound care

April 2011
2 months bioelectric dressing

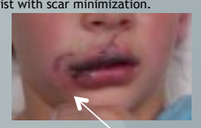


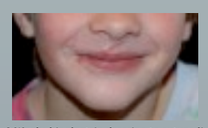
Nov 2011
8 months HEALED

Case 2: Animal Bite

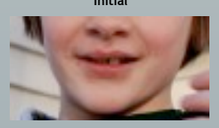
8 y.o. male following attack by a dog. Upper lip completely severed. Lower commissure partial avulsed segment. Two layer sutured repair with absorbable suture. Parents advised of a high risk of infection. Penicillin allergy –unable to use first line choice of antibiotic. 4 days IV antibiotics then d/c. Bioelectric dressing used from day 4 and continued for several weeks beyond wound healing to assist with scar minimization.

Initial

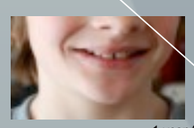


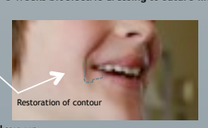


3 Weeks bioelectric dressing to suture lines



15 Weeks

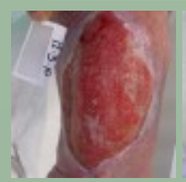




1 year follow-up

Case 3: Complex non-healing leg ulcer – Threatened limb†

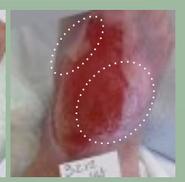
50 y.o. female with longstanding history of chronic venous insufficiency and varicosities sustained a tib-fib fracture to her right leg in 1998 requiring ORIF. Following hardware removal in late 2000, the leg became infected requiring operative debridement and NPWT. Following flap with STSG in 2001 the wound completely healed by 2003. The patient continued to experience recurrent episodes of ulceration thought to be related to venous hypertension and was treated with topical therapies including skin substitutes and compression treatment. In 2009 after a new ulcer developed on reconstructed tissue, a skin substitute*** was placed with subsequent failure to heal. Since 2010, treatments have included surgical and selective debridement, enzymatic debridement, silver products (alginate and foam), Cadexomer iodine, NPWT, and skin substitutes. Wound cultures have been significant for Staph, Pseudomonas, Enterococcus, and MRSA. Vascular consult revealed findings consistent with chronic venous insufficiency without evidence of significant PAD; pathology showed chronic ulceration without evidence of malignancy. The recommendation to consider amputation of the leg due to persistent failure to heal, prompted evaluation of the bioelectric dressing as a means to jump start the stalled wound. The bioelectric dressing twice weekly in conjunction with compression (Unna boot) therapy was started in October 2011.



Dec 2010
14.9cm x 11.6cm
3 months following skin substitute

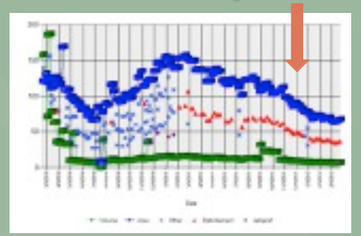
Oct 2011(10 months later)
12.4cm x11 cm
Non-healed wound nearly same size

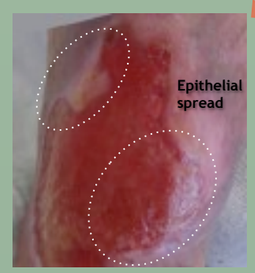
Feb 2012
10cm x 9cm
2 months bioelectric dressing



Mar 2012
9.5cm x8.4cm
4 mo. bioelectric dressing

Bioelectric dressing initiated





Case 4: Moh's resection to the scalp –Non-healing wound

83 y.o. male with past history of PVD, below knee amputation and multiple prior squamous cell cancer excisions, with radiation to scalp (risk factor for poor healing by secondary intention) (11). Prior history of non –healing wound following amputation – treated successfully with bioelectric dressing and below knee stump salvaged. Summer 2011 – Moh's resection of a squamous cell CA of the scalp with full thickness skin defect. Non-healing of the wound site with "bone visible" following good wound care with home health nursing using a hydrofiber AG dressing. Skin graft recommended by surgeon. September 2011--Family wanted to avoid skin grafting and requests to begin bioelectric dressing in view of prior successful experience. Physician approval obtained and bioelectric dressing applied and changed 2-3 times/week and covered with an absorptive secondary dressing.

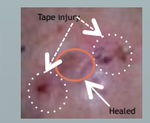
Aug 27 2011
Post-op wound dehiscence

Sep 4 2011
Day 8 of hydrofiber AG

Sep 6 2011
Day 10 of hydrofiber AG

Sep 13 -Day 3 of bioelectric dressing- (bioelectric dressing initiated Sep 10)

Week 3- Cavity completely granulated and active epithelial spread noted

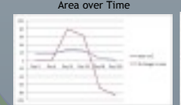


2 months Late Follow-up, Skin graft avoided. Normal appearing skin in treated area. Tape irritation to peri-wound skin

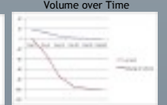
Case 5: Traumatic Scalp avulsion‡

Unrestrained, uninsured male presented with multi-trauma from MVA. The patient sustained full thickness scalp avulsion with exposed frontal bone involving a portion of hear bearing scalp. This size defect is typically managed with tissue flap to achieve a rapid closure and restore contour for cosmetic appeal. Bioelectric dressing was used when attempts to place NPWT were unsuccessful due to location of the wound and inability to maintain an airtight seal. Early robust granulation was seen and therapy was continued in the face of ongoing improvement with twice weekly dressing changes performed by the patient at home. 27 weeks of bioelectric dressing treatment lead to rapid filling of the defect and ongoing skin regeneration with excellent cosmetic results as well as regrowth of areas of normal appearing hair. (12)

Area & % Change in Area over Time



Volume & % Change in Volume over Time



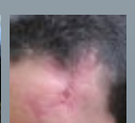
Day 0

Day 4 Base of wound covered (30% volume reduction)

Week 4
Full coverage of bone

Week 12
98% reduction in volume

Week 18



27 weeks – fully healed with normal contour and regrowth of hair bearing tissue.

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‡ Goodyear, AZ
^ Vomaris Innovations, Inc., Chandler, AZ

*Procellera® Wound Dressing, Vomaris Innovations, Inc., Chandler, AZ, USA
**Integra™ Bilayer Matrix Wound Dressing, Integra Life Sciences Corp, Plainsboro, NJ, USA
***GammaGraft ®,Promethean Health Sciences, Pittsburgh, PA, USA