

# Demonstration of a Bioelectric Wound Care Device for Wound Healing within a Rehabilitation Center Patient Population

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## BACKGROUND

Wound care in a rehabilitation environment is a costly and difficult problem. An IRB-approved retrospective, observational study was performed in a population of rehabilitation and long-term care patients with acute and chronic wounds of varied etiology to evaluate differences in wound healing outcomes when treated with a bioelectric wound care device<sup>a</sup> as compared to standard local wound care methods. The bioelectric device generates a microcurrent in the presence of an electrolyte such as wound exudate or sterile saline. It has been shown to facilitate wound repair (1) and has been associated with faster re-epithelialization (2) and reduced expression of inflammatory biomarkers (3) such as cytokine Interleukin-1  $\alpha$  in recent studies.

## METHODS

Data files of 38 patients who received either standard wound treatment (SOC; n=20), or were treated with a bioelectric wound device (n=18) were retrospectively reviewed. Wounds were assessed until deemed clinically to have healed with up to 100% epithelialization. All patients (18 - 99 years) with single wounds were included. Statistical analysis was performed to compare the wounds in two groups for the number of days to heal, the rate of wound volume reduction, or the monotonically decreasing, or the increasing and then decreasing characteristic of the wounds. All subjects received the best standard wound care (SOC) appropriate to their specific etiologies (i.e. antimicrobials, alginates, NPWT, etc.) alone or in conjunction with the bioelectric wound device for management of his or her wound.

## RESULTS

The wounds in the SOC group healed on average at 36.25 days (SD 28.89), while the bioelectric device group healed significantly faster in 19.78 days (SD 14.45), p=0.036. The rate of volume reduction per day was -3.83% for SOC vs. -9.82% volume reduction per day (p=0.013) for the bioelectric group. The SOC group had 50% of its wounds heal monotonically vs. 83.3% in the bioelectric device group (p=0.018).

## CONCLUSION

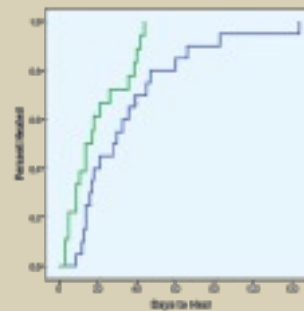
This multicenter retrospective study demonstrated a 45.4% faster, and more robust healing of wounds with the use of the bioelectric wound care device, when compared to SOC in a rehabilitation center environment, which translates to improved patient care, and potentially, significant cost savings.

## REFERENCES

- Sheftel SN. The role of a bio-electric, antimicrobial dressing in the healing of acute and chronic wounds [abstract]. Clinical Symposium on Advances in Skin and Wound Care, Las Vegas, NV. October 2008; (suppl): 217.
- Blount AL, Foster S, Rapp DA, Wilcox R. The Use of Bioelectric Dressings in Skin Graft Harvest Sites: A Prospective Case Series. *J Burn Care Res.* 2012;33(3):354-357.
- Harding AC, Gil J, Valdes J, Solis M, Davis SC. Efficacy of a Novel Bio-electric Dressing in Healing Deep Partial-thickness Wounds in a Porcine Model. *Ostomy Wound Manage.* 2012;58(9):50-55.

### Summary of patient intake data

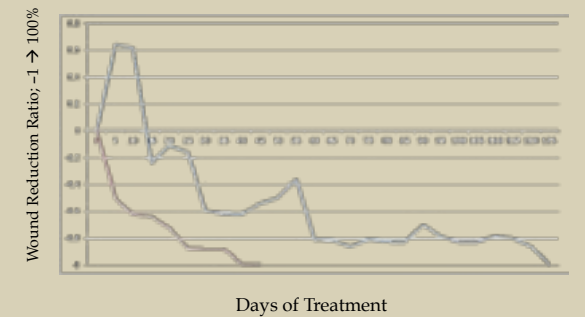
	Bioelectric Dressing	Standard of Care
Number of cases	18	20
Females	14	13
Males	4	7
Age [Years (SD)]	80.17 $\pm$ 10.24	81.5 $\pm$ 9.79
Wound size [Volume, cc]	Min 0.03 Max 224.1 Mean 21.1 $\pm$ 55.03	Min 0.01 Max 312.1 Mean 30.4 $\pm$ 74.18



Cumulative wound survival trend as a function of Days

Group  
■ SOC  
■ Bioelectric

Cumulative average trend for percentage wound healing for the SOC and the bioelectric device group, using the 5-day interpolated values. The overall trend for the wound trajectory is much steeper for the bioelectric group compared to SOC.



## Stage II Blister

### Patient 6- Bioelectric Device

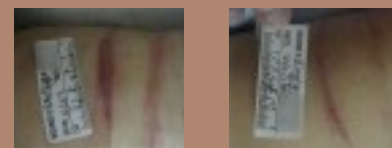
85 y/o with recent fall and non-operable fx  
 Dx: Tib/Fib and ankle fx's, dM, Peripheral Neuropathy, Coronary Arteriosclerosis, Pacemaker, HTN, chronic renal disease, COPD, CHF, MI  
 Blister completely resolved in 5 days



Initial Day 5

### Patient 9- SOC

83 y/o female  
 Right medial thigh  
 Dx's: Right TKR, chronic pain, HTN, Vitamin D def., h/o Uterine CA



Initial Day 14

## Open Hematoma

### Patient 1- Bioelectric Device

77 y/o, female  
 Dx's: Falls, DM, HTN, ESRD with hemodialysis, PVD, right AKA, depression, dementia, poor skin integrity



Initial Day 6 Day 10 Day 14

### Patient 2- SOC

70 y/o male  
 Hematoma occurred on 6/28/12, opened on 7/8/12  
 Dx's: long-term anticoagulant therapy, chronic kidney disease (stage III), coronary arteriosclerosis, CAD, CABG, pacemaker, h/o MI, AF, HTN, cerebrovascular disease, CVA, cardiac failure, DM II, depression, dependent edema, venous insufficiency, hypothyroidism, anemia, hypercalcemia, hyperlipidemia, DVT



Initial Day 9 Day 21 Day 29 Day 35

## Surgical Dehiscence

### Patient 8- Bioelectric Device

65 y/o female  
 Dx's: Intestinovesical fistula, colovesicle fistula s/p repair, diverticular bowel, left uterine stent repair, UTI, sepsis, perforation of intestine, AF, DM II, HTN, CAD, anxiety, depression, bilateral renal cysts, anemia, morbid obesity, hypokalemia, s/p polyp removal vagina, hypothyroidism, Vitamin D deficiency  
 Tx: NPWT + bioelectric device; treatment began 5/11/12 and NPWT discharged 6/8/12



Initial Day 6 Day 13 Day 23

### Patient 9- SOC

85 y/o female  
 Dx's: Surgical dehiscence with MRSA, HTN, edema, MI, immune thrombocytopenia, anemia, hypothyroidism, hyperlipidemia, renal arterial stenosis, CVA, AAA, h/o bilateral iliac occlusion with s/p stent, femoral bypass  
 Tx: NPWT + antimicrobial wound filler. Treatment began 9/8/11; discharged NPWT 9/29/11



Initial Day 7 Day 14 Day 21

## Category III Skin Tear

### Patient 15- Bioelectric Device

88 y/o female  
 Left back  
 Dx's: Hypothyroidism, DM II, hyperlipidemia, anemia, dementia, depression, HTN, coronary arteriosclerosis, congestive heart failure, AF, chronic renal disease, hypokalemia, hyponatremia, CVD, bipolar, COPD, CVD



Initial Day 5

### Patient 3- SOC

90 y/o, female  
 Dx's: Alzheimer's disease, HTN, hypothyroidism, h/o DVT, CAD, edema, depression, CVD, CVA, cerebral arteriosclerosis, falls, psychosis, senile dementia



Initial Day 3 Day 9