

Improved Outcomes with a Microcurrent Generating Dressing on Diabetic Ulcerations in a Tribal Community Healthcare Facility

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BACKGROUND

It is well-known that patients of Native American ancestry have the highest prevalence of diabetes among all U.S. racial and ethnic groups, with staggering rates of lower extremity amputation 3 to 4 times higher than those for the general population (1-2). While research has shown that an estimated 50% of lower-extremity amputations could be prevented through the improvement of lower-extremity care in the diabetic population (3), the alarming escalation of amputation rates brings to focus deficiencies with existing standard of wound care and the unmet need for efficacious wound treatment modalities that expedite healing in diabetic ulcerations, reduce infectious complications and reduce incidence of further surgical interventions. Published literature has pointed to the benefits of electrical stimulation in the acceleration of ulcer repair (4). A microcurrent generating antimicrobial device (MCG) (a) that generates 2-10 microAmperes of current on its surface has been observed to reduce healing times in both acute and chronic wounds (5-7).

METHODS

The device was assessed in our clinic in a case series of patients presenting with wounds of varying etiology. Used as a primary contact layer, the device was secured in place with standard secondary dressings and changed 1-3 times per week. Wound healing assessments were performed at clinic visits.

RESULTS

A substantial reduction in time to healing was observed in the patients treated with the microcurrent generating dressing. Case #1 achieved complete wound closure with the MCD in 2 weeks following 4 months of standard wound management principles. Of significance, amputation was avoided in both case #2 and #3; in case #2, the wound achieved full closure in 85 days with the application of MCD in conjunction with standard care, following failure to respond to 147 days of advanced wound care modalities, including amniotic membrane, collagen matrix dressings, NPWT, etc. Case #3, a complex wound on a BKA with surrounding skin reactive to close to all secondary dressings, achieved full closure at 191 days, avoiding a scheduled AKA.

CONCLUSION

The implications and costs – both financial and social - associated with failure to intervene with efficacious wound management solutions at early stages of diabetic wound healing is far too great. Positive experience with the energy-based device in a series of patients at an Native American health facility demonstrates its potential to improve wound healing outcomes and address the unmet needs of a high risk patient population, making it a cost effective option for a new standard in wound care.

REFERENCES

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Case #1: Ulcer to the right foot TMA stump

Co-morbidities:

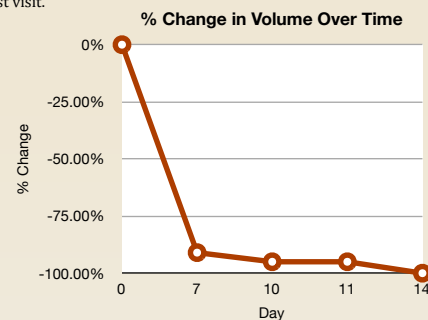
DM2 with neuropathy, HTN, TMA amputation, Atrophic kidney, CKD, Hemodialysis, Carotid artery stenosis 69%. Past history of necrotizing fasciitis on the chest.

Wound History

50 year old male presented with ulcerations 10/17/12 on the sole of the right foot, measuring 10x2x1mm and 7x9x1mm. There was malodor but no purulent drainage, edema or other signs of infection. Initial treatments included cadexomer matrix dressings (b), DSD and felt pads for offloading. The patient performed his own dressing changes and came to all of his appointments but walked at least 1.5 miles a day, and presented with filthy and thrashed outer dressings at follow-up visits. The ulcers improved by 2nd visit at day 9 and were pronounced almost healed. Patient was instructed to apply antibiotic ointment and polymeric membrane dressings (c) at home and was not seen again in podiatry until four months later, in which the wounds increased to a combined size of 60x30x2mm since his last visit.

Treatment & Outcomes

On 2/19/13, MCG was applied as sole treatment method and moistened with hydrogel. Epithelial bridge observed at day 2, with 91% reduction at day 6 and complete re-epithelialization at day 14. Patient and staff involved in his care were all surprised at the quick progress and rapid epithelialization of the wound. Patient was pleased and grateful, and stated that his ulcers in the past typically took a year to heal. To date the area has remained healed.



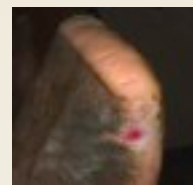
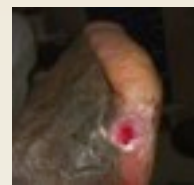
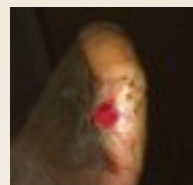
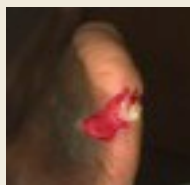
126 Days SOC

6 Days MCD

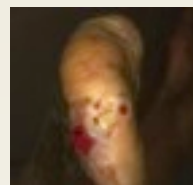
9 Days MCD

14 Days MCD

Sole to Lateral Edge



Sole to Lateral Edge Center Opening



Case #2: Ulcer to the left metatarsal head

Co-morbidities:

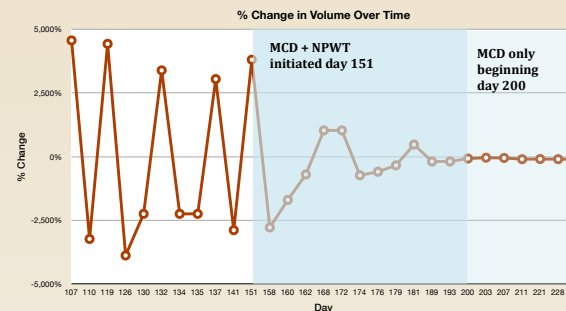
DM with neuropathy, Right TMA, recurrent recalcitrant DM foot ulcers and osteomyelitis, ischemic heart disease, HTN, kidney transplant due to renal disease, calcified PAD.

Wound History

64 year old male reported he rubbed a blister during exercise on 08/22/2012 and was first seen in our clinic on 8/23/12, with wound size 15x15x1 mm on the left metatarsal head. Patient was initially treated with hydrofiber (d), hydrocolloid dressings (e), collagen matrix dressings (f), cadexomer matrix dressings, collagenase ointment (g) and DSD, amniotic membrane allograft (h) and hydrolymer dressings (i). Patient admitted to hospital 9/20/12 for revascularization of anterior tibial artery with balloon angioplasty. On 11/8/12, wound edges approximated and sutured closed, and patient was hospitalized 4 days later due to osteomyelitis of 5th met. Resection of met head. NPWT initiated 11/22/12 but replaced with antimicrobial dressings and increased in size to 28x25x15mm. NPWT restarted 12 days later but placed on hold due to infection.

Treatment & Outcomes

Following 147 days of SOC, MCD initiated 1/21/13 in conjunction with NPWT for 43 days, with reduction in wound volume observed in 10 days. MCD and hydrogel used as sole treatment method on 3/11/13, with full closure on 4/15/13. Patient was fairly compliant with care and mostly remained non-weight bearing. Patient was so grateful amputation was avoided and was impressed with the product. Wound has remained closed to date.



110 Days SOC



130 Days SOC



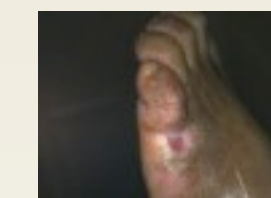
23 Days MCD



35 Days MCD



46 Days MCD



56 Days MCD

Case #3: Right side BKA non-healing wound

Co-morbidities:

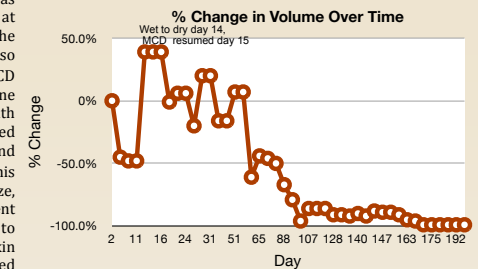
DM with peripheral vascular insufficiency and peripheral polyneuropathy, HTN, CAD (bypass x5) angioplasty, ray amputation 4th toe on the left foot.

Wound History

75 year old male had a non-healing right foot ulcer due to vascular insufficiency and infection. Patient was scheduled to have a TMA but instead underwent BKA on 12/8/12. He was admitted again to hospital again on 12/31/12 due to infection and increasing eschar and underwent a revision of the stump. Bone was exposed at the distal aspect of the tibia. The patient also had a nerve exposed in this area, which was very sensitive to dressing application. Sutures in place on 1/8/13 but wound dehiscd centrally on 2/4/13, with signs of infection present, and AKA planned. Initial wound dimensions 100x15x50mm.

Treatment & Outcomes

Despite abundant slough/fibrin mix present in wound, MCD was applied and secured in place with hydrolymer dressing and at follow-up visits, we observed fibrotic tissue flaking off as if the dressing was "debriding" the wound. Sharp debridement was also performed at each visit. NPWT applied in conjunction with MCD but was removed due to drape irritation. MCD was applied alone and in conjunction with other standard dressings on 3/6/13, with significant wound size reduction and epithelial bridge developed on 7/1/13. Medial ulcer healed 8/8/13, with lateral wound remaining at time of write-up. One of our struggles with this patient is that his skin reacted to everything, including gauze, gauze bandage rolls, elastic bandages, NPWT drape, government sock and any adhesive we tried. We constantly were battling to find a way to cover this wound and to treat the surrounding skin breakdown. The hydrolymer dressing adhesive and foam saved the day and the patient has been able to use these products successfully in combination with MCD.



Initial



Day 15 MCD



Day 62 MCD



Day 124 MCD



Day 164 MCD



Day 182 MCD

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| a. Procellera® Antimicrobial Wound Dressing, Vomarix Wound Care, Inc., Chandler, AZ | f. Biostep, Smith & Nephew, Hull, UK |
| b. Iodosorb, Smith & Nephew, Hull, UK | g. Collagenase Santyl® Ointment, Healthpoint Biotherapeutics, San Antonio, TX |
| c. Polymem®, Ferris Mfg. Corp., Fort Worth, TX | h. EpiFix®, Mimedex Group, Kennesaw, GA |
| d. Aquacel® Ag Dressing, Convatec, Skillman, NJ | i. Tielle®, Systagenix Wound Management, Gatwick, UK |
| e. DuoDERM®, Convatec, Skillman, NJ | j. V.A.C.® Drape, KCI, Inc., San Antonio, TX |