Pilot Study Investigating the Use of a Exudate Management Dressing Under Compression for the Treatment of Venous Leg Ulcers

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Background

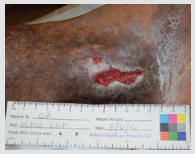
Venous leg ulcers (VLU's) are, in general, exudative wounds that require compression therapy (1) to address the increased venous hypertension (2). Dressings choice for these patient is extremely important as this must be kept on wound surface for days along with the compression wraps and it must be able to absorb the exudate and maintain moisture balance at the wound interface. The purpose of this pilot study is to describe outcomes of VLU treatment with TRITEC Silver in combination with compression. Specifically, TRITEC Silver wound dressings are a silver based antimicrobial contact layer with a unique exudate management technology. This patented exudate management technology, called Active Fluid Management (AFM), is engineered to create a unidirectional exudate transfer away from the wound interface and into a secondary absorptive dressing.

Methods

This is a 10 patients, IRB-approved, single site, open label, non-randomized, non-comparative, prospective pilot study to evaluate the study dressings used under compression for the management of VLUs. Subjects who met the inclusion and exclusion criteria were given informed consent and enrolled. Each week, the circumference of the calf and the wound measurements were recorded. The primary objective was the rate of wound closure, based on wound measurements using digital planimetry. Secondary objectives were also examined including: pain, odor, periwound skin condition, edema, and exudate amount. Digital photographs were obtained at each visit pre and post debridement with a ruler that was labeled with the day of the study and the subject number. Following the collection of data and photographs, the study dressing was applied and covered with ABD pads (to act as a secondary absorptive layer) and compression. The dressing was to be left on for 7 days between weekly visits. The subjects were followed for a minimum of 4 weeks, but could have been followed for as long as 12 weeks dependent upon wound progression.
A patient completed the study if he was healed, or if the clinician considered a different dressing a better option; as usually a near completely healed wound does not need absorptive dressings.

Patient # 8

- 50 yo male with obesity, venous HTN, poorly controlled diabetic (Hb A1c 10.9) and active smoker, previous episode ulcer same location which required 8 months treatment with multilayer wraps to heal
- Most recently, he presented at our WCC with a wound present for 4 months and treated with multilayer wraps without progress
- After starting the study dressing, he started to make progress, had improved pain, good compliance and eventually healed.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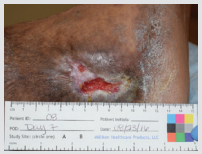
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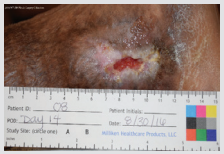
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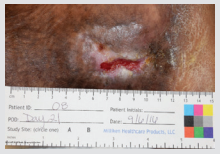
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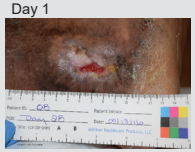
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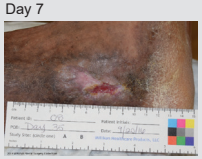
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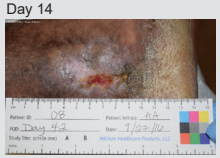
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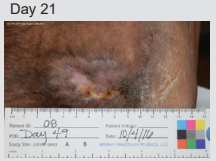
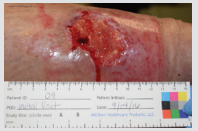

Day 49

Patient # 9

- 70 yo male with hx DM, obesity, CAD, s/p CABG, asthma, OSA, hx of resp failure episodes, chronic anticoagulation, mild protein energy malnutrition
- Admitted inpatient d/t severe cellulitis and possible necrotizing fasciitis and taken to OR for debridement 7/28/16
- Initial visit in WCC 8/31/16 with visible 2 + pitting edema, heavy drainage, significant periwound skin moisture damage especially dependent area
- After starting compression and use of the study dressing the patient demonstrated a rapid improvement in the wound bed, significant improvement of granulation quality and significant improvement of surrounding skin.
- In the ensuing weeks, he showed rapid epithelization of wound edges and the patient avoided a skin grafting process due to rapid healing.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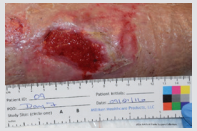
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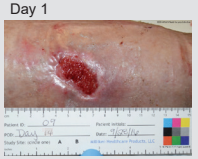
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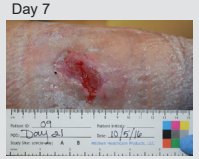
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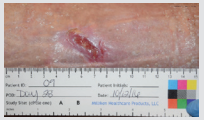
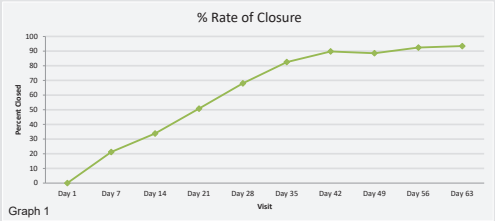
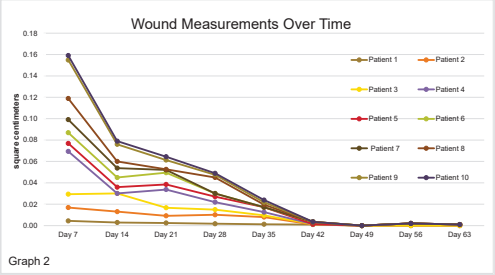

Day 28

Results

Wound surface measurements obtained using digital planimetry were plotted and rate of closure percent was calculated, see Graph 1. One patient completed trial before 4 weeks. On average, at 4 weeks a 68% reduction in wound surface was noticed. Average reduction was 0.15 sq cm/day.
In Graph 2 the wound area progression over time is displayed.
Patients were asked to numerically rate wound pain: 4 patients had decrease pain, 6 had similar levels.
Subjective assessment (scale 1-10) of exudate, periwound skin, ease of use (application and removal) and odor was favorable and rated highly by the clinicians (9 and 10)



Graph 1



Graph 2

Conclusions

The AFM technology exudate management dressing was found to be a useful strategy in conjunction with multilayer compression therapy, as outlined by the calculated rate of closure. The application, management, and removal of the dressing had positive clinical outcomes and good tolerability from both clinical and patient perspective.

References:
1. Lippmann HI, Fishman LM, Farrar RH, et al. Edema control in the management of disabling chronic venous insufficiency. Arch Phys Med Rehabil. 1994;75:436-441
2. Rudolph DM. Pathophysiology and management of venous ulcers. J WOCN. 1998;25(5):248-255

This 10 patients case series was studied under State IRB 00030790.
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