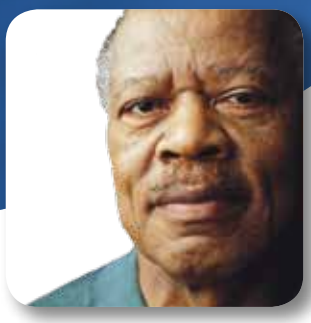
CASE STUDY

Chronic Diabetic Neuropathic Foot Ulcer



Cost Savings Through the Addition of MIST Therapy® to Standard Wound Care

Background

Neuropathic foot ulcers are a serious complication of diabetes. 24 million Americans have diabetes[1] and 15% or 3.6 million will develop a lower extremity ulcer at some time.[2]

92,000 annual amputations are due to diabetes[3]

84% ➤ Started as a simple ulcer[4]

50% ➤ Experience a second amputation within 5 years[4]

Patient Profile: 76-year-old Male[5]

Conditions: Type 1 diabetes, hypertension, peripheral artery disease, venous insufficiency, peripheral neuropathy, chronic obstructive pulmonary disease and total knee replacement (right).

Care Setting: Long-term Care

Pre-MIST Therapy

Wound: Wagner Grade III ulcer of the right plantar heel with chronic osteomyelitis that had been **non-healing for 14 years**.

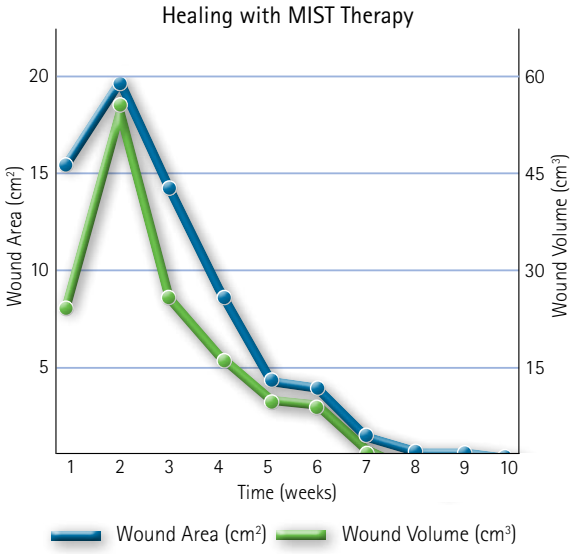
Area: 4.5 cm x 3.4 cm = 15.3 cm^2
Volume: 4.5 cm x 3.4 cm x 1.4 cm = 21.4 cm^3

Wound bed was 25% slough with bone and tendon exposure, chronic osteomyelitis and copious drainage consistent with pseudomonas.

Treatments: Compression therapy with bandages and garments, sharp and surgical debridement, negative pressure wound therapy (NPWT) and offloading shoes.

Amputation recommended by vascular and infectious disease physicians.

MIST Therapy was added to standard wound care three times a week.



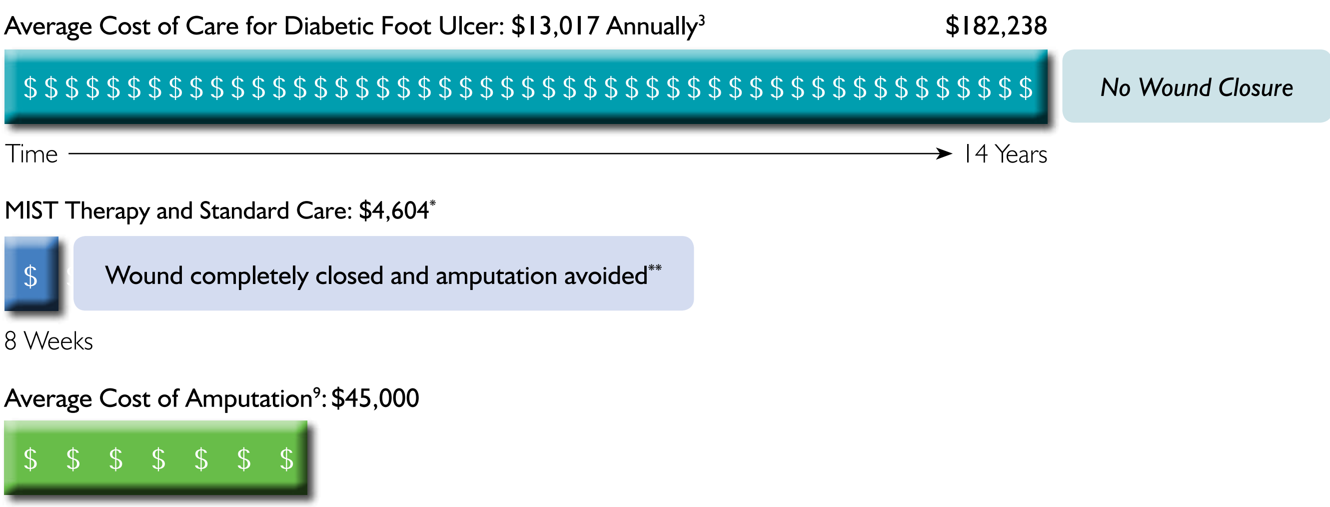
Post-MIST Therapy

Outcomes: After 26 MIST Therapy treatments over 8 weeks the **wound closed completely**. The patient was able to return home independently with his limb intact.

Infection can be a barrier to wound healing. The mechanical stress of the MIST Therapy sound waves on the bacterial cell membrane has resulted in cell death for a wide range of bacteria, including MRSA, VRE and Pseudomonas.[6-8]

The costs and cost savings depicted in this case study are illustrative only and represent the types of costs that may be incurred by a health care institution. They will vary for each institution, care setting, patient type, treatment course, etc., but provide an outline for consideration and discussion.

Potential Cost Savings†



The addition of MIST Therapy to the treatment of a non-healing diabetic foot ulcer results in significant cost savings. Not only did this wound heal after 14 years of standard wound care failed, but an amputation was avoided.

* Cost was determined using $565/week ($60 canisters, $36 for dressings, $469 rental) for negative pressure wound therapy (NPWT) and enzymatic debridement ($36) for 4 weeks (assumes 3 dressing changes per week) and $275/week was added for MIST Therapy ($150 for applicators, $125 rental) for 8 weeks. ***Cost of extended care and infection treatment not included in this analysis.***

** Results with MIST Therapy are not necessarily representative of and may vary with each patient.

† This economic analysis is based upon empirical evidence and has not been derived from a formal cost effectiveness study.

For more case stories related to this topic and others, please contact your local Celleration representative or call (952) 224-8700.

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2. Ennis WJ, Formann P, Mozen N. Ultrasound Therapy for Recalcitrant Diabetic Foot Ulcers: Results of a Randomized, Double-Blind, Controlled Multicenter Study. Ostomy Wound Management 2005;51(8)24-39.
3. Stockl K, et al, Costs of Lower-Extremity Ulcers Among Patient with Diabetes. Diabetes Care 27:2129-2134, 2004.
4. Lai JY, Pittelkow MR. Physiological Effect of Ultrasound Mist on Fibroblasts. Int J Dermatol. 2007;46(6):587-593.
5. Eingle, J. Closure of a 14-year Chronic Diabetic Foot Ulcer with the Adjunctive Use of a Acoustic Pressure Wound Therapy, Poster Presentation at WCC, May 2008.
6. Wagner SA, Kavros SJ, Vetter EA, Cockerill FR. The Effect of Mist Ultra-Sound Transport Technology on Common Bacterial Wound Pathogens. Abstract. Presented at Symposium on Advanced Wound Care, 2001.
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8. Serena, T. et al. The Impact of Noncontact, Nonthermal, Low-Frequency Ultrasound on Bacterial Counts in Experimental and Chronic Wounds. OWM 2009;55 (1).
9. Kruse I, Edelman S. Evaluation and Treatment of Diabetic Foot Ulcers. Clinical Diabetes. 2006;24 (2):91-93.

MIST Therapy System FDA Clearance. 510 (k) Clearance June 2005. "The MIST Therapy System produces a low energy ultrasound-generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue, exudates and bacteria."

Please see full package insert for additional information on indications, contraindications, warnings, precautions, and side effects.

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