



Accelerated Healing. Clinically Confirmed.

Treatment of Chronic Foot and Leg Ulcerations with MIST Therapy®

Study Summary



Use of Noncontact Low-Frequency Ultrasound in the Treatment of Chronic Foot and Leg Ulcerations: A 51-Patient Analysis

Kavros SJ, Schenck EC. Journal of the American Podiatric Medical Association March/April 2007; 97(2):95-101

Study Overview:

This study was an open-label, nonrandomized, baseline-controlled clinical case series designed to characterize the effects of noncontact low-frequency ultrasound therapy for chronic, recalcitrant lower-leg and foot ulcerations after being treated with standard of care (SOC) for a period of time until wounds were no longer progressing.

Fifty-one patients were evaluated. The majority of patients had one or more of the following conditions: diabetes mellitus, neuropathy, limb ischemia, chronic renal insufficiency, venous disease, and inflammatory connective tissue disease. All patients had lower extremity ulcers, 20% had a history of amputation, and 63% had a multifactorial etiology.

Key Findings:

Overall, **94.9% Wound Volume Reduction** with

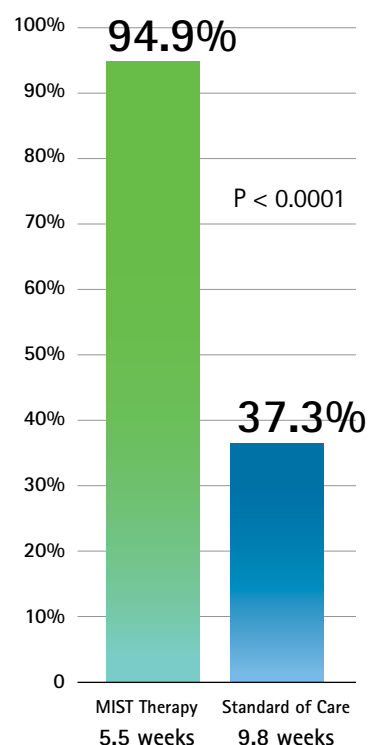
MIST Therapy plus SOC in non-progressing wounds within an average of **5.5 weeks** as compared to **37.3%** Wound Volume Reduction within an average of **9.8 weeks** with SOC alone. ($P < 0.0001$)

0% reoccurrence at the original wound site at **30 months** post therapy survey of surviving patients. Five patients developed a subsequent ulcer in a different location than the original wound site in 6 to 18 months post treatment.

Accelerating the Rate of Healing

MIST Therapy® uses low-frequency ultrasound to stimulate cells at and below the wound surface to activate healing. A painless procedure, it is the only noncontact, low-frequency ultrasound device for healing cleared by the FDA.

Significant Wound Volume Reduction with MIST Therapy



Physician Observations

"Our experience using MIST Therapy was very positive. MIST seems to be an effective modality for the treatment of wounds. This modality has demonstrated a reduction in healing time and has brought many recalcitrant wounds to closure after the standard of care regimen had failed to do so."

— Dr. Steven J. Kavros , Mayo Clinic

Before



After MIST Therapy



Patients Like Yours?

This study examined patients with multifactorial etiologies like Ben. He is 72 years old, has Type 2 diabetes and is a former smoker. He had a chronic diabetic foot ulcer (Wagner grade two) that he had endured for more than 3 months.

The study found that wounds like Ben's healed considerably faster when treated with MIST Therapy plus standard of care.

Sound Science. Strong Results.

Painless, Accelerated Healing with MIST Therapy[®]

MIST Therapy is an innovative, noncontact approach to wound healing. The system creates low-frequency ultrasound waves that produce and propel a gentle mist of sterile saline into the wound bed. The saline mist improves the transfer of ultrasound from the device without contact or pain to the patient.

MIST Therapy promotes painless wound healing through:

- Active cell stimulation
- Decreased bioburden
- Increased blood flow
- Cleansing and gentle/maintenance debridement

Results may vary based on individual patient characteristics.

For more information, contact your local
Celleration representative or call (952) 224-8700.



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MIST Therapy System FDA Clearance. 510 (k) Clearance June 2005. "The MIST Therapy System produces a low-frequency 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.