

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

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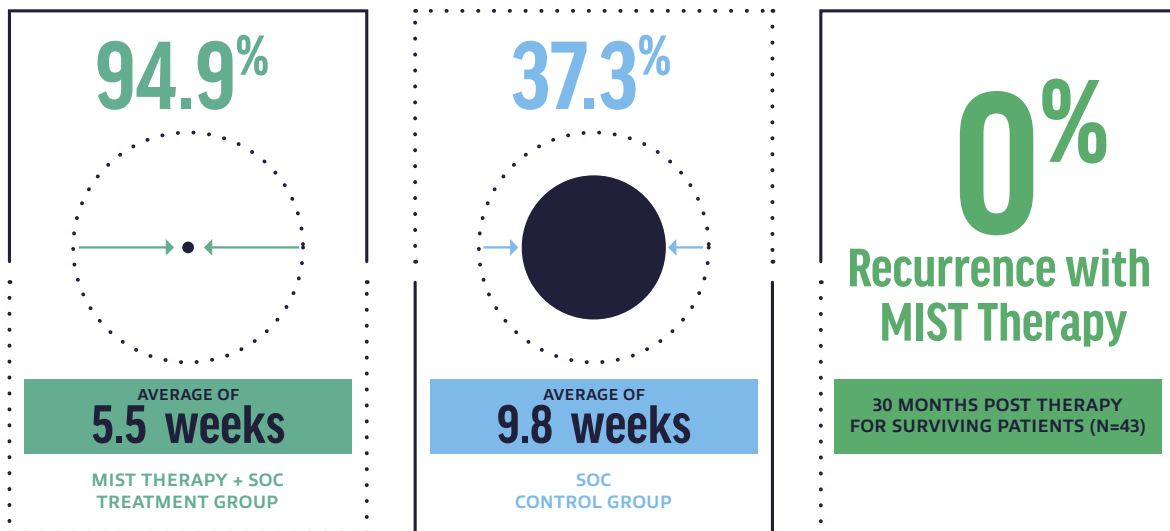
OVERVIEW

An open-label, non-randomized, baseline-controlled, single center clinical case series was conducted at the Mayo Clinic. The purpose of this study was to characterize the effects of MIST Therapy* for chronic, recalcitrant lower-leg and foot ulcerations post standard of care (SOC) treatment with non-progressing wounds.

SOLUTION

94.9% wound volume reduction in non-progressing wounds within an average of 5.5 weeks with MIST Therapy.

- **Rate of Healing and Closure:** The use of MIST Therapy improved the rate and speed of healing in non-progressing, lower-extremity ulcerations.



*Data was compiled utilizing MIST Therapy. UltraMIST is the next generation of MIST Therapy and maintains the same mechanism of action as the MIST Therapy used this study. *SEE PAGE 2 FOR SAFETY INFORMATION.*

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Additional areas showing statistically significant improvement with MIST Therapy.



No serious adverse effects were noted with the use of the noncontact low-frequency ultrasound therapy.

CONCLUSION

IMPROVED PATIENT OUTCOMES: Frequent use of MIST Therapy improves outcomes.

- 3x/week = 40% wound closure (N=15)
- 5x/week = 56% wound closure (N=36)

STUDY METHODOLOGY

- Open-label, non-randomized, baseline-controlled, single center (Mayo) clinical case series.
- The 51 patients evaluated served as their own control. Only after the wounds were no longer progressing with SOC was MIST Therapy introduced.
- The majority of patients had \geq one 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 (identified as poor responding patients).

DESCRIPTION AND INDICATIONS FOR USE

Description: The UltraMIST® System delivers low-frequency ultrasound to the treatment site using a noncontact fluid (e.g., saline).

Indications for Use: MIST Systems produce a low energy ultrasound-generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of fibrin, yellow slough, tissue exudates, and bacteria.

CONTRAINDICATIONS, POTENTIAL COMPLICATIONS, AND WARNINGS

Contraindications: Do not use near electronic implants/prosthesis (e.g., near or over the heart or over the thoracic area if the patient is using a cardiac pacemaker); on the lower back during pregnancy or over the pregnant uterus; over areas of malignancies.

Potential Complications: Tingling, redness.

Warnings: UltraMIST applicator is designed as a single patient-use disposable unit to avoid contamination. Do not re-sterilize or reuse applicators. Reusing the applicator and/or fluid may result in infection and degraded performance. Do not allow the treatment wand or applicator to contact the patient's skin directly. Risk of burns: Do not touch the metal tip of the treatment wand during operation.

Please refer to the Instructions for Use for additional information.