

A Prospective Pilot Study of Ultrasound Therapy Effectiveness in Refractory Venous Leg Ulcers.

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OVERVIEW

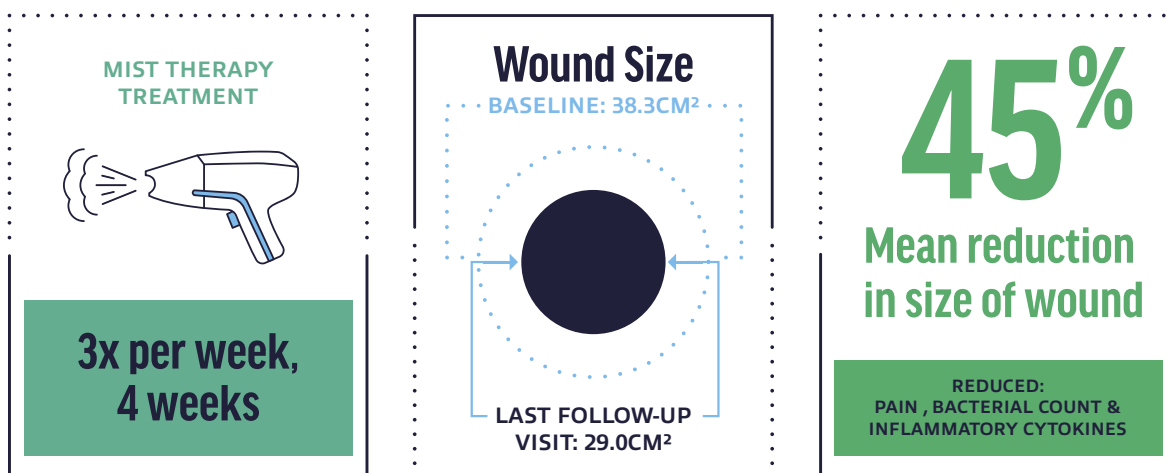
The purpose of this study was to assess the effectiveness of noncontact ultrasound therapy in healing large, chronic, refractory venous leg ulcers that had not responded to treatment with a multilayer compression bandage. The study measured wound size, bacterial burden, and pain over a four-week treatment course.

Compression therapy is the gold standard in treating VLU but compliance issues exist:

- Noncompliance rates: 9.7% - 80%
- Current healing rate: less than 70% with SOC

SOLUTION

Treatment of refractory venous ulcers with MIST Therapy* and compression therapy resulted in significant wound size reduction and healing.



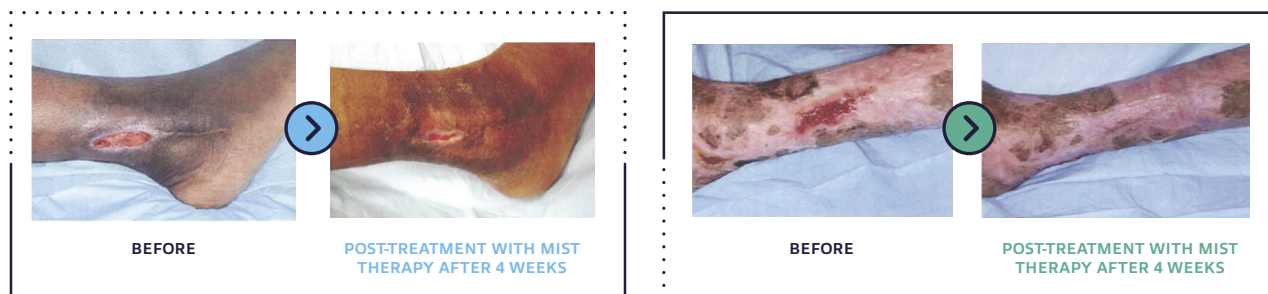
*Data was compiled utilizing MIST Therapy. UltraMIST is the next generation of MIST Therapy and maintains the same mechanism of action as the MIST Therapy used this study. *SEE PAGE 2 FOR SAFETY INFORMATION.*

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STUDY DESIGN

- A prospective, pilot study of 10 patients with large refractory (not responding to therapy) venous stasis ulcers were studied.
- Four-week treatment period, three times per week
- Biopsies were taken at baseline and three days after the four-week treatment period was completed.

BEFORE AND AFTER: NONCONTACT ULTRASOUND THERAPY



CONCLUSION

CLINICAL IMPROVEMENT: Patients treated with MIST Therapy and compression therapy showed clinical improvement over the course of four-weeks and had a decrease in inflammatory cytokines, bacterial count, and pain.

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.