



# MIST Therapy<sup>®</sup> System: Thoughts on Therapy

*Editor's note: MIST Therapy<sup>®</sup> System: Thoughts on Therapy" is brought to you by an educational grant from Celleration<sup>®</sup>, Inc. The opinions and statements herein are specific to the author and are not necessarily those of Celleration, Inc., ECPN, or HMP Communications, LLC.*

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## CASE SERIES #8

The Gonda (Goldschmied) Vascular Center offers a continuum of care for patients with peripheral arterial disease (PAD). Persons with diabetes mellitus, high blood pressure, or high cholesterol are at increased risk of PAD. When PAD is left untreated, it can lead to gangrene or amputations. Patients with PAD often have wounds that do not heal or are very slow to heal. Successful wound healing can help to prevent amputations and additional bypass surgeries.

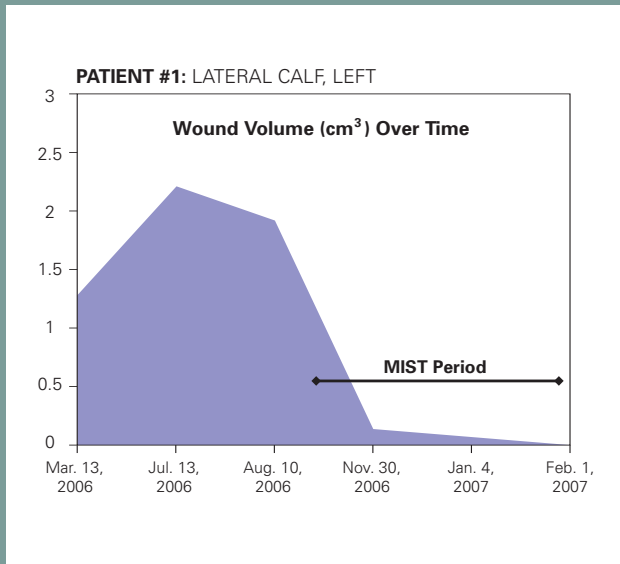
The MIST Therapy System is a noncontact, therapeutic ultrasound device cleared by the Food and Drug Administration to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudate, and bacteria. The low-frequency ultrasound waves of the MIST Therapy System are delivered via a sterile saline mist. Treatments are painless because the device does not contact the wound. We have been using MIST Therapy<sup>®</sup>

System (Celleration<sup>®</sup>, Inc.) as an adjunct to standard wound treatment for nonhealing wounds since 2006.

This is a retrospective review of the clinical effectiveness of the MIST Therapy System in 3 consenting patients with severe, nonhealing wounds and significant PAD. The patients received outpatient treatment at the Gonda (Goldschmied) Vascular Center. In these 3 patients, MIST Therapy was initiated after the majority of wound healing had already taken place and was at a point where healing was stalled with little progress being made. The patients received 3–9 minute MIST Therapy treatments 1–3 times weekly along with standard wound treatments.

In this case series, wound healing was evaluated on the basis of the wound dimensions, drainage, tissue characteristics (granulation, slough, or eschar) at various time points during treatment, and wound-related pain using a visual analog scale (VAS) that allows patients to rate pain from 0 (no pain) to 10 (extreme pain).

**PATIENT #1:** This 91-year-old woman injured her left lateral calf in an accident involving her ironing board in February 2006. Her initial treatment of wet to dry dressing was provided by home health nursing. In March 2006, her wound became necrotic and painful, so she was referred to our wound clinic. Ankle-brachial indices indicated that she had compressible vessels with waveforms consistent with advanced arterial occlusive disease. A magnetic resonance angiogram revealed significant multilevel disease with no lesion amenable to angioplasty. Given her advanced age, we decided to continue conservative treatment and monitor the wound for healing. She was initially treated with a hydrofiber dressing with silver. But due to the pain this treatment caused, the dressings were changed to a moist wound dressing, which was well tolerated. MIST Therapy was started on August 1, 2006 and given for 3 minutes 1 session per week for a total of 19 sessions. The patient rapidly responded to this treatment. In December, her wound dressing was changed to a hydrophilic dressing. She continued receiving MIST Therapy until February 2007, when the wound healed completely. Unfortunately, she suffered another trauma to her left lateral calf (just below the initial wound). This new wound is also quickly healing with MIST Therapy.



The wound on 11/8/06

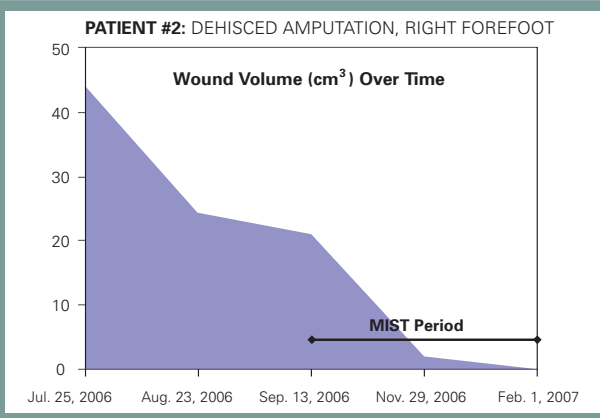


1/1/07

PATIENT #1: LATERAL CALF, LEFT

Time Point	Dimensions (cm)			Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth		Red (granulation)	Pink (granulation)	Yellow (slough)	Black (eschar)	
3/13/06	3.0	1.5	0.3	Moderate	0	70	30	0	10
7/13/06	3.1	2.5	0.3	Scant	0	60	40	0	10
8/10/06	2.8	2.4	0.3	Scant	0	70	30	0	8
11/30/06	1.0	0.7	0.2	Scant	90	0	10	0	3
12/7/06	1.2	0.8	0	Scant	90	0	10	0	2
1/4/07	0.9	0.6	0.1	Scant	90	0	10	0	1
2/1/07	0	0	0	None	Healed	0	0	0	0

**PATIENT #2:** This 65-year old man has a past medical history that includes type 2 diabetes mellitus, significant peripheral vascular disease (PVD), and, recently, multiple angioplasty revascularization and painful, ischemic ulcerations of both first toes. In June 2006, following a failed popliteal-to-peroneal artery bypass with vein graft, he underwent a trans-metatarsal amputation of his right forefoot. It was likely that future treatment would include a below-the-knee-amputation. He was treated postoperatively with a pneumatic compression device, hyperbaric oxygen, and orally administered vasodilators. In July 2006, the amputation wound dehiscenced and became necrotic. Initially the wound was treated with surgical and enzymatic debridement and alginate. The treatment was switched to topical cadexomer iodine because the wound continued to deteriorate. In September 2006, because wound healing had hardly progressed, MIST Therapy was initiated.



The patient received outpatient treatments once per week for 6 minutes per session for a total of 7 sessions. The wound responded quickly to MIST Therapy, and the patient reported decreases in pain. Follow up X-rays showed the patient had osteomyelitis at the distal edge of the 2nd and 3rd right metatarsal heads. On February 1, 2007, he returned to surgery for revision. The wound subsequently healed completely.

**PATIENT #2: DEHISCED AMPUTATION, RIGHT FOREFOOT**

Time Point	Dimensions (cm)			Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth		Red (granulation)	Pink (granulation)	Yellow (slough)	Black (eschar)	
7/25/06	3.2	8.5	1.6	Moderate	0	50	40	10	10
8/23/06	2.9	8.4	1.0	Moderate	0	80	20	0	10
9/13/06	2.5	8.3	1.0	Moderate	0	80	20	0	10
11/29/06	1.5	2.0	0.7	Moderate	90	0	10	0	7
2/1/07	0	0	0	None	Healed	0	0	0	0



The wound on 9/13/06

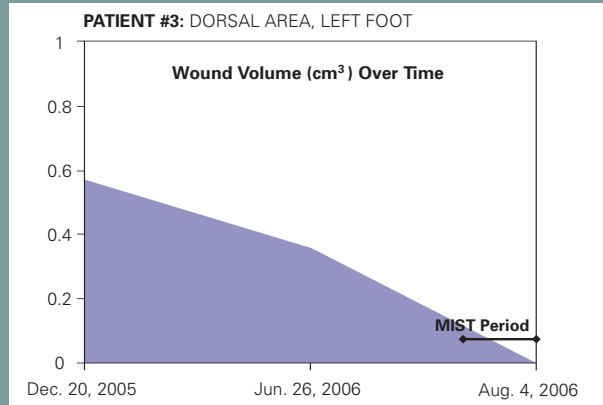
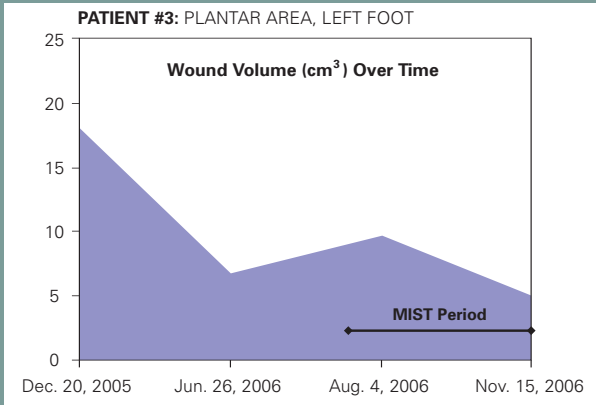


11/14/06



2/2/07

**PATIENT #3:** This 57-year-old man has a significant medical history, including insulin dependent diabetes mellitus, severe PVD, congestive heart failure (CHF), renal insufficiency, lower extremity paralysis secondary to stroke, and three toe amputations (two on his right foot and one on his left foot). In December 2005, he developed two wounds on his left foot that probed to the bone. One was on the plantar surface of the 5<sup>th</sup> metatarsal heel and cuboid. The other was on the dorsal lateral area. On December 22, 2005, he was hospitalized for treatment with intravenous (IV) antibiotics and revascularization. However, the revascularization was unable to be performed because no appropriate target vessels were found. Therefore, the treatment options were limited to amputation or wound healing modalities. During this hospitalization, the patient developed a decubitus heel ulcer on his left foot. On December 26, 2005, he was discharged home on IV antibiotics and wound care with silver alginate and light compression to control the edema. The dorsal wound healed, and the plantar wound dimensions improved somewhat, but the wound still probed to the bone. In June 2006, an abscess developed on the lateral aspect of his left foot again. He was treated with cadexomer iodine, calcium alginate, gauze, and light compression dressings. The wounds on his left foot were draining copious amounts of serosanguineous fluids, and the wound beds were necrotic with exposed bone. In late July 2006, he began receiving MIST Therapy along with calcium alginate dressing, as an outpatient, 3 times per week for 9 minutes per session for a total of 36 sessions. Immediately following MIST Therapy initiation, a significant increase in granulation tissue and rapid covering of bone on the plantar foot wound was noted. The dorsal area wound on his left foot was healed by August 4, 2006, a week after his first MIST Therapy treatment. As of November 2006, the plantar wound did not heal completely; however, the exposed bone remains covered and the large tissue defect has filled in and remains healthy. The left decubitus heel ulcer was healed by December 5, 2006.



**PATIENT #3: PLANTAR AREA, LEFT FOOT**

Time Point	Dimensions (cm)			Drainage	Tissue color (%)				Pain (0-10)
	Length	Width	Depth		Red (granulation)	Pink (granulation)	Yellow (slough)	Black (eschar)	
12/20/05	6.0	3.0	1.0	Copious	30	0	70	0	Insensate
6/26/06	2.5	2.7	1.0	Moderate	30	0	70	0	-
8/4/06	3.5	2.5	1.1	Moderate	70	0	30	0	-
11/15/06	2.8	1.6	1.1	Moderate bone-covered	100	0	0	0	-



The wound on 12/23/06



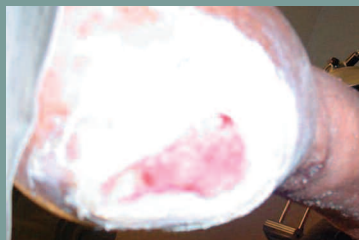
3/23/07

**PATIENT #3: DORSAL AREA, LEFT FOOT**

Time Point	Dimensions (cm)			Drainage	Tissue color (%)				Pain (0-10)
	Length	Width	Depth		Red (granulation)	Pink (granulation)	Yellow (slough)	Black (eschar)	
12/20/05	0.8	0.6	1.2	Copious	10	0	90	0	Insensate
6/26/06	1.5	0.4	0.6	Moderate	70	0	30	0	-
8/4/06	0	0	0	None	Healed	0	0	0	-

PATIENT #3: DECUBITUS ULCER, LEFT FOOT

Time Point	Dimensions (cm)			Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth		Red (granulation)	Pink (granulation)	Yellow (slough)	Black (eschar)	
6/26/06	3.4	5.0	0.5	Copious	90	0	10	0	Insensate
8/4/06	3.5	4.2	0.4	Moderate	90	0	10	0	-
11/15/06	0.7	0.5	0.3	Moderate	90	0	10	0	-
12/5/06	0	0	0	None	Healed	0	0	0	-



The wound on 9/6/06



12/28/06

**CONCLUSION**

This is a case series of 2 men and 1 woman ranging in age from 57–91 with significant medical histories that included diabetes, severe PVD, CHF, renal insufficiency, lower extremity paralysis, past amputations, and revascularization.

All of these patients presented to our center with PAD that was difficult to treat due to lack of appropriate vessels for revascularization or angioplasty and failed or potential future amputations. One complication of PAD is difficult wound healing. Each of these patients presented with recalcitrant wounds for which standard treatment had been unsuccessful. MIST Therapy was initiated for 1–3 sessions per week for 3–9 minutes per session for a total of 7–39 sessions per patient.

One of the treated wounds (on patient 1) did not heal completely after 4 months

of treatment. However, the exposed bone remains covered, the large tissue defect has filled in, and the wound remains healthy. All of the other wounds on the 3 patients rapidly and completely healed with 100% granulation and the absence of wound drainage. In addition, 2 of the 3 patients reported a decrease in pain as the wounds healed. The patient who did not report any pain associated with his wound at any of the time points was insensate.

Most importantly, it was anticipated that 2 of the 3 patients were going to require additional amputations due to their PVD and their wounds. However, through the successful and rapid wound treatment, all additional amputations and bypass surgeries were avoided.

At the Gonda (Goldschmied) Vascular Center, we have found MIST Therapy to be a valuable adjunct to standard of care treatment of patients with difficult-to-

heal wounds. As illustrated by these 3 cases, MIST Therapy was initiated when the majority of the wound healing had already occurred but at a point where progress was no longer occurring. As we become more familiar with the technology, we are learning which categories of wounds benefit most from MIST Therapy. We have also learned that no patient is a “textbook” case. MIST Therapy has shown no detrimental side effects to the wounds or the patient, so we feel comfortable utilizing this modality on wounds with a variety of etiologies.

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