

MIST Therapy[®] System: Thoughts on Therapy

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CASE SERIES #5

At the Archbold Center for Wound Management, we began using the MIST Therapy[®] System (Celleration[®], Inc.) in late 2004 for a variety of wounds, especially those that were painful or complicated by bacterial infection, deep tissue problems (ie, infection or edema), or comorbid conditions. This retrospective review of the clinical effectiveness of MIST Therapy focuses on atypical wounds with a variety of complicating factors known to inhibit wound healing. These 6 consenting patients were nonrandomly selected to provide a varied sample of exceptionally recalcitrant wounds with complicating factors likely to severely delay or even prevent healing. The wounds in this case series originated from a variety of etiologies, including trauma, surgery, arterial or venous insufficiency, hidradenitis, and necrobiosis lipoidica diabetorum (NLD).

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.

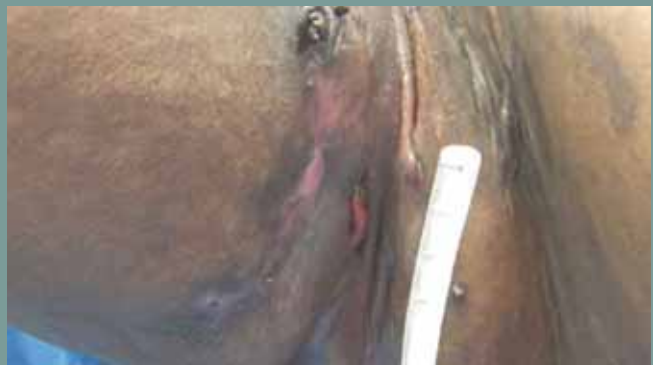
Most clinical reports of MIST Therapy describe treatment times of 3–5 minutes, 2–3 times weekly, in ulcers of pressure, venous/arterial insufficiency, or diabetic origin, which, though recalcitrant, have typically been relatively uncomplicated. For the challenging wounds in this series, we often administered MIST Therapy (in addition to the standard of care) for longer durations, and, on average, these wounds required more total MIST treatments than did the less-complicated wounds described in previous reports. Wound healing was evaluated on the basis of increases in granulation tissue across wound beds in addition to a reduction in wound dimensions. There was also a secondary benefit in the reduction in wound-related pain using the 10-point Visual Analog Scale (VAS), for which the patients rated pain from 0 (no pain) to 10 (extreme pain).

PATIENT #1: This 39-year-old African-American woman had hidradenitis, a chronic disease of the apocrine glands that causes plugging of the glands and subsequent development of acne-like, pus-filled lesions on the axilla or groin/thigh areas. A hidradenitis lesion on her upper right axilla had become ulcerated. The wound had existed for several months and had been treated with iodine and extra-absorbent pads. At presentation to our center, the wound was approximately 90% granulating tissue and 10% slough. In an attempt to reduce bacterial load, drainage, and odor, MIST treatment for 12 minutes per session was initiated on March 29, 2005, and the wound was dressed with extra-absorbent pads. After 14 MIST treatments over 2 months, the wound closed completely. MIST Therapy was discontinued on May 27, 2005.

PATIENT #1: RIGHT AXILLA AND UPPER ARM							
Time point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
3/29/05	7.1	1.7	0.1	Moderate	90	10	0
5/27/05	Closed			None	Epithelial tissue		



The wound on 3/29/05



5/27/05

PATIENT #2: This 53-year-old Caucasian woman with lupus erythematosus presented June 25, 2005 with a right anterior shin wound from a skin tear that occurred during surgery at another facility. Though initially treated with a combination of a prescribed ointment, nonadherent dressings, and a wrap, wound healing was not progressing, most likely due to complications associated with lupus. On July 15, 2005, MIST treatments were initiated for 4 minutes per session in addition to enzyme and silicone foam dressings. Over the course of 19 MIST treatments, the wound progressively improved to closure with new epithelial tissue. MIST treatment was discontinued on September 6, 2005.

PATIENT #2: RIGHT ANTERIOR SHIN							
Time point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
7/15/05	7.0	3.3	0.3	Moderate serous	35	65	0
9/6/05	3.5	1.1	0.1	Moderate serous	100	0	
9/16/05	Closed			None	Epithelial tissue		



The wound on 7/15/05



9/6/05



9/16/05

PATIENT #3: This 69-year-old Caucasian woman had bilateral circumferential wounds of the lower legs resulting from NLD and chronic venous insufficiency. The wounds, which had been present for more than 6 years, required daily pain medication and limited her mobility to a very slow cadence with a rolling walker. Prior to being referred to our wound center, the patient had been treated with vinegar whirlpool, multilayer compression bandage, and various anti-inflammatory ointments. She reported occasional improvements of short duration. On May 20, 2005, she began receiving treatment at our wound center. Precise wound dimensions were not obtained due to the irregular shape and circumferential involvement. The patient rated her pain as 10 out of 10 on the VAS scale. MIST treatments were initiated for approximately 24 minutes per session in addition to silver dressings and multilayer compression bandages. After approximately 3 weeks of MIST treatment, she reported a decrease in her pain score to 3 out of 10 and a reduction in pain medication, which eventually was no longer needed for wound-related pain. The secondary gains were even greater in that the patient's functional mobility improved to where she started driving herself to her appointments and improved to a sassy cadence in her new tennis shoes with no assistive device. The duration of the MIST treatments was reduced in relation to the size of open areas but returned to longer duration upon noticeable deterioration of closed areas. Over the course of 194 MIST treatments and nearly 2 years, both legs significantly improved with a preponderance of epithelial tissue and rapid reversal of areas of deterioration. The patient is still undergoing care.

PATIENT #3: RIGHT LOWER LEG WOUNDS							
Time point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
5/20/05	Circumferential right lower leg			Moderate	35 (+ 40% epithelium)	20	5
6/10/05	Circumferential right lower leg			Light	40 (+ 40% epithelium)	15	5
3/20/07	Anterior shin			Light	5 (+ 95% epithelium)	0	0



The wounds on 5/20/05



6/10/05



5/20/05



6/10/05



3/20/07

PATIENT #4: This 74-year-old African-American man had a history of diabetes, chronic venous insufficiency, osteomyelitis, and heterotopic calcification with multiple fistula tracts that communicated. The wounds on his right lower leg, present since October 2003, included a main wound measuring 9.0 x 6.6 x 0.7 cm in addition to multiple tunnel regions that were difficult to measure. While the large open area eventually closed with surgical debridement, negative pressure wound therapy, silver dressings, and compression wraps, we continued to struggle for months with multiple eruptions of calcium deposits and resultant deep tracts. On November 1, 2004, a trial of MIST therapy was initiated for 12 minutes per session in addition to an oxidized regenerated cellulose (ORC) matrix, silver dressings, and compression wraps. Although eruptions continued to occur, they were less purulent and easier to manage than they were prior to initiating MIST. The number of concurrent tracts gradually reduced. MIST treatment was discontinued on January 2, 2007. After 178 MIST treatments over slightly more than 2 years, all tracts closed, and his skin has remained intact for more than 3 months.

PATIENT #4: RIGHT LOWER LEG							
Time point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
11/1/04	9 tracks of varying depth			Light	100	0	0
1/2/07	Closed			None	Epithelial tissue		



The wound on 11/1/04



1/16/07

PATIENT #5: In 2003, this 82-year-old Caucasian woman with severe arterial disease presented to our clinic with 3 stage 3 pressure ulcers on her right lateral foot/ankle and a stage 4 ulcer at her Achilles tendon. She was told she needed a below-the-knee amputation due to the severity of her arterial disease. She refused the amputation and was treated with moist wound healing and pressure relief. Seventeen months later, 3 of the pressure ulcers had healed, but the malleolar ulcer had gradually deteriorated. On November 10, 2004, MIST treatment for 9 minutes per session was initiated in addition to standard of care. Her pain before starting MIST treatments was 8 out of 10, and she routinely took narcotic pain medication. After a few weeks of MIST treatment, her pain was reduced to 0 out of 10, and pain medications were only administered as necessary. Although the treatment duration was lengthy, this patient was adamant that staying with the MIST treatment would bring her to total closure. During the course of 205 MIST treatments over nearly 2 years, the patient's pain was kept manageable, the wound gradually progressed to closure, and the patient was spared amputation below the knee. MIST therapy was discontinued on March 1, 2007.



The wound on 11/10/04



3/8/07

PATIENT #5: RIGHT LATERAL MALLEOLUS							
Time Point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
11/10/04	3.0	2.6	0.3	Light	60	40	0
3/8/07	Closed			None	Epithelial tissue		

PATIENT #6: This 79-year-old Caucasian woman had a recalcitrant postoperative wound resulting from an unhealed incision for lumbar laminectomy on March 15, 2006. Despite treatment with topical iodophor microbicide 3 times per day and iodoform packing, the incision dehiscenced and became infected with *Clostridium perfringens*. On March 30, 2006, the patient was referred to our wound center, and MIST therapy was initiated for 5 minutes per session in addition to dressings of ORC/collagen matrix, silver, and 4 x 4 cm gauze. After 32 MIST treatments over 2 months, wound size decreased to near closure. MIST treatment was discontinued on June 16, 2006. Visit frequency was reduced with dressing changes done by the patient's spouse.

PATIENT #6: LUMBAR LAMINECTOMY INCISION

Time point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
3/28/06	3.0	1.2	1.7	Moderate	50	50	0
4/17/06	1.6	1.5	2.4	Moderate	25 (+ 10% tendon)	65	0
6/19/06	0.3	0.1	1.6	Light	100	0	0



The wound on 3/28/06



4/17/06



6/19/06

CONCLUSION

Five women and 1 man with complicated wounds of varying etiologies and durations were treated with MIST Therapy as an adjunct to the standard of care. Four patients were Caucasian and 2 African American, ranging in age from 39–82 years. These patients had wounds that were complicated by factors more challenging than most typical wound care patients, including lupus erythematosus, osteomyelitis, calcification with communicating fistula tracts, hydradenitis, and NLD. Treatment durations tended to be longer, in some cases markedly longer, than those used for patients with typical pressure, diabetic, or venous/arterial

insufficiency ulcers. Overall, patients had from 14–205 MIST Therapy treatments with durations ranging from 4–24 minutes per session. Wounds were treated to the development of substantial granulation tissue, reduction in wound size, and even closure. The process took anywhere from 2 months to more than 2 years. The two patients with wound-related pain reported improvement of pain following MIST Therapy initiation, and one returned to a level of functional independence that had been lost for approximately 6 years.

At the Archbold Center for Wound Management, we have found MIST Therapy to be a beneficial modality in

the treatment of wounds. While it has been shown that MIST Therapy can accelerate healing in the diabetic foot ulcer, we have also found it to be effective in reducing pain and improving the condition of periwound tissues. We have found it to be the best treatment option when dealing with the difficulty of acute or chronic inflammation areas under and around partially intact tissues. ■

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