



MIST Therapy[®] System: Thoughts on Therapy

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Pamela Cole, MSPT, CWS

CASE SERIES #3

We have used the MIST Therapy[®] System (Celleration, Inc.) as an adjunctive treatment for nonhealing wounds in Methodist Hospital's wound clinic for more than 3 years. The MIST Therapy System is a noncontact, low-frequency ultrasound device that has been cleared by the Food and Drug Administration (FDA) to promote the healing of wounds. It cleanses, debrides, and stimulates the cells of wound healing by delivering therapeutic ultrasound waves via a sterile saline mist. The device does not contact the wound; therefore, MIST Therapy is pain-free.

This is a retrospective review of 6 consenting outpatients with recalcitrant wounds to demonstrate the clinical efficacy of the MIST Therapy System in wounds of various etiologies. The following parameters were used to determine the clinical effectiveness: reductions in wound area and volume; amount of drainage; signs and symptoms of infection; subjective wound-related pain (using a visual analog scale, rated 0-10, where "0" is no pain and "10" is extreme pain); and changes in wound bed composition (eg, percentage of granulation tissue, slough, and eschar). Patients were treated until their wounds closed.

PATIENT #1: W.L. was a 56-year-old Caucasian man with type 2 diabetes mellitus who smoked cigarettes. He injured his left foot in a boating accident and developed osteomyelitis, resulting in the amputation of his left 5th toe. He presented to the wound clinic a month after surgery and after undergoing an incision and drainage procedure. The patient received MIST Therapy every 3–4 days as an outpatient after the wound became infected and dehisced. During this time, he also received a polyvinyl alcohol sponge with methylene blue and gentian violet, which later transitioned to bovine collagen. He was issued a pneumatic walking boot but was noncompliant with it. After 2 days of MIST treatment, granulation tissue markedly increased. We noted substantial improvement at each clinic visit thereafter. One month after MIST Therapy initiation, the wound epithelialized in the center, leaving 2 smaller wounds that were 90% granulated (see the “10-20-06” entry in the table below). His wounds closed in 2 months after 17 MIST treatments despite limiting factors of smoking, infection, and low albumin.

PATIENT #1: LEFT 5TH TOE AMPUTATION SITE

Treatment	Dimensions (cm)			Drainage	Tissue color (%)			Pain
	Length	Width	Depth		Red/Pink (granulation)	Yellow (slough)	Black (eschar)	
9-15-06	5.4	1.7	1.0	Moderate	50	50	0	0
10-20-06	1.2	0.5	0.3	Minimal	90	10	0	0
	0.4	0.2	0.4					
11-13-06	0	0	0	None	-	-	-	0



The wound on 9-15-06



10-18-06



11-13-06

PATIENT #2: H.P. was an 81-year-old Caucasian man with many comorbidities, including type 2 diabetes mellitus, paroxysmal ventricular tachycardia, hypertension, obstructive sleep apnea, angina pectoris, asthma, chronic obstructive pulmonary disease, peripheral vascular disease, bilateral lower extremity (LE) distal bypass grafts, chronic kidney disease, benign prostate hypertrophy, ischemic heart disease, congestive heart failure, coronary artery bypass graft, and diastolic dysfunction. He had been treated for bilateral heel ulcers due to osteomyelitis, but the right heel never fully closed due to further osteomyelitis of the calcaneus. Subsequently, he underwent a partial calcanectomy of the right foot and was referred to the wound clinic for aggressive care of his surgical wound. His prognosis was poor due to the extent of his wound, which exposed the bone and decreased blood flow to his right foot. We believed that MIST Therapy was the last treatment option to save his limb from a below-the-knee amputation. After 38 MIST Therapy treatments and silver- and vancomycin-soaked moist dressings, his wound was healed in 4 months despite his many comorbidities and limiting factors. Surprisingly, this wound healed in less time than his previous, less-extensive foot wounds had.

PATIENT #2: RIGHT HEEL

Treatment	Dimensions (cm)			Drainage	Tissue color (%)			Pain
	Length	Width	Depth		Red/Pink (granulation)	Yellow (slough)	Black (eschar)	
5-30-06	3.0	1.4	0.4	Moderate	20	80	0	0
7-24-06	1.2	0.4	0	Minimal	80	20	0	0
9-26-06	0	0	0	-	-	-	-	-



The wound on 6-7-06



8-11-06



10-2-06

PATIENT #3: K.H. was a 59-year-old Caucasian man with a history of type 2 diabetes mellitus, deep vein thrombosis, degenerative joint disease, obesity, venous hypertension, and recalcitrant wounds who was treated in our clinic. In June of 2006, he developed a venous hypertensive ulcer on his right medial LE that did not respond to home care with debridement ointment and silver dressings. On July 30, 2006, MIST Therapy was initiated twice weekly along with moist dressings and compression wraps. During MIST Therapy, he reported no pain, but sharp debridement was painful, even when using 4% lidocaine-soaked gauze before the procedure. This very fibrotic wound quickly granulated and reepithelialized after MIST Therapy was initiated. In about 2 months and 20 MIST treatments, the wound closed. The patient subsequently underwent radio-wave frequency ablation for improved venous return and wound prevention.

PATIENT #3: RIGHT MEDIAL LOWER EXTREMITY								
Treatment	Dimensions (cm)			Drainage	Tissue color (%)			Pain
	Length	Width	Depth		Red/Pink (granulation)	Yellow (slough)	Black (eschar)	
7-30-06	3.0	2.2	0.5	Minimal	20	80	0	3
10-6-06	0	10.0	0	None	-	-	-	0



The wound on 7-30-06



10-6-06

PATIENT #4: V.L. was a 63-year-old Caucasian woman who developed a sacral pressure ulcer in December of 2005 during inpatient treatment for aspiration pneumonia and malnutrition due to dysphagia. The patient had multiple sclerosis with quadriplegia, necessitating the use of an electric wheelchair with custom seating. Her medical history included hypertension, osteoporosis, gallstones, recurrent urinary tract infections, and a Foley catheter. In January of 2006, she began receiving negative pressure wound therapy (NPWT) in our clinic. The following month, a percutaneous endoscopic gastrostomy tube was installed to help increase her caloric intake. In June of 2006, NPWT was discontinued because she developed coccygeal osteomyelitis. She was treated with intravenous vancomycin and daily silver dressing changes. Despite these therapies, the rate of wound healing plateaued. On September 22, 2006, MIST Therapy was initiated along with non-thermal infrared treatments. The patient had 20 MIST Therapies over 13 weeks. Her wound closed on January 2, 2007.

PATIENT #4: SACRAL PRESSURE ULCER								
Treatment	Dimensions (cm)			Undermining (cm)	Tissue color (%)			
	Length	Width	Depth		Red/Pink (granulation)	Yellow (slough)	Black (eschar)	
1-17-06	2.0	2.1	0.9	1.0 @ 12:00 1.4 @ 3:00 0.6 @ 6:00	40	60	0	
9-8-06	1.0	0.4	1.1	1.1 @ 12:00	60	40	0	
11-7-06	0.7	0.5	1.0	0	80	20	0	
12-12-06	0.7	0.2	0.4	0	90	10	0	
1-2-07	0	0	0	0	-	-	-	



The wound on 1-17-06



3-3-06



11-7-06

PATIENT #5: D.S. was an 82-year-old Caucasian man who was malnourished and received MIST Therapy for several pressure ulcers that developed during a long hospitalization for pneumonia. Some of his wounds were deep, probing close to the bone. His other treatments included sharp debridement, papain-urea ointment, collagen, silver, and moist dressings. He had a heel-relief splint and a pressure-relief mattress but no pressure-relief cushion. The patient reported no pain with MIST Therapy, but he did report pain with sharp debridement. Overall, he received a total of 33 MIST Therapy treatments: 8 for a lumbar spine wound, 17 for a heel wound, 6 for a right malleolus wound, and 2 for sacrum-area wounds. All wounds closed in less than 4 months despite the patient's malnutrition and lack of pressure-relief cushion.

PATIENT #5: LEFT HEEL									
Treatment	Dimensions (cm)			Drainage	Tissue color (%)			Pain	
	Length	Width	Depth		Red/Pink (granulation)	Yellow (slough)	Black (eschar)		
5-8-06	2.9	1.9	0	Minimal	20	70	10	0	
7-10-06	0	0	0	None	-	-	-	0	
RIGHT LATERAL MALLEOLUS									
5-8-06	0.3	0.4	0.1	Minimal	0	100	0	0	
6-26-06	0	0	0	None	-	-	-	0	
SACRUM, RIGHT (R) AND LEFT (L)									
5-8-06	R	2.8	0.9	0.1	Minimal	0	100	0	0
	L	3.1	1.8	0.2	None				
6-22-06	R	0	0	0	None	-	-	-	0
9-5-06	L	0	0	0	None	-	-	-	0
LUMBAR SPINE									
5-8-06		1.5	0.4	0.1	Minimal	0	100	0	0
6-2-06		0	0	0	None	-	-	-	0



The left heel wound on 5-8-06



The left heel wound on 8-3-06



The sacrum wound on 5-8-06



The lumbar spine wound on 8-15-06

PATIENT #6: C.B. was a 65-year-old Caucasian man with type 2 diabetes mellitus who was receiving kidney dialysis. His medical history included a coronary artery bypass graft and LE bypass. In June of 2005, he received standard of care modalities for a painful, bone-exposing, infected (*E. coli*, *M. morgani*, *P. aeruginosa*) diabetic foot ulcer secondary to arterial insufficiency. Wound healing did not adequately progress, however, so MIST Therapy began in July of 2005. He was also treated with debridement ointments, antibiotic solution, silver mesh dressings, and moist dressings. Despite extreme wound-related pain, he reported no pain with MIST Therapy. With 20 MIST treatments over 10 weeks, his wound healed significantly despite the exposed bone, infection, multiple comorbidities, and reluctance to eliminate weight bearing at the wound site.

PATIENT #6: LEFT HEEL								
Treatment	Dimensions (cm)			Drainage	Tissue color (%)			Pain
	Length	Width	Depth		Red/Pink (granulation)	Yellow (slough)	Black (eschar)	
6-14-05	4.3	4.0	1.5	Minimal	10	40	50	10
9-25-05	2.6	1.5	0.5	Minimal	70	30	0	0



The wound on 6-14-05



8-5-05



9-25-05

CONCLUSION

In this retrospective case series study, patients with serious comorbidities and recalcitrant wounds of various etiologies healed faster with MIST Therapy than would be anticipated with other wound treatments based on our clinical experience. In all 6 cases, MIST Therapy rapidly reduced wound size, drainage, clinical signs of infection, and wound-related pain. It also stimulated granulation and reepithelialization across wound beds, which led to wound closure for all patients.

We began using the MIST Therapy System during our clinic's participation in a randomized, double-blind clinical trial on diabetic foot ulcers.¹ During the trial, we were impressed by its results and ease of use. Three years later, the MIST Therapy System is widely used in our clinic as an adjunctive modality to standard of care treatments. We now have 2 MIST Therapy

System units to help us keep up with the demand for treatment.

Our clinic prefers MIST Therapy over many other modalities for several reasons. First, MIST Therapy is easier to use than other physical agents and modalities used in our clinic. It is even preferred to MHz ultrasound, which requires hydrogel or film dressing before treatment. Because MIST Therapy is a noncontact treatment, it is less time-consuming than other physical agents and modalities. Finally, MIST Therapy has the unique benefit of stimulating the cells responsible for wound healing.

In economic terms, we have found MIST Therapy to be similar in cost to the kits for pulsatile lavage with suction and less costly than NPWT for both the rental of the unit and the dressing and canister kits, based on the frequency and duration of MIST Therapy and other treatment modalities. MIST Therapy may also be an affordable advanced

therapy for some patients (eg, those with pressure ulcers who might benefit from biologics but do not have the appropriate diagnosis and ICD-9 code for reimbursement).

All told, the benefits of MIST Therapy increased our patients' wound and functional outcomes while creating a powerful and effective use of our time in the clinic. ■



Pamela Cole, MSPT, CWS, is a clinical specialist for the wound clinic at the Methodist Hospital/Park Nicollet Health Services (St. Louis Park, Minn). She is a consultant for Celleration®, Inc., but received no funding for this article.

Reference

1. Ennis WJ, Formann P, Mozen N, Massey J, Conner-Kerr T, Meneses P. Ultrasound therapy for recalcitrant diabetic foot ulcers: results of a randomized, double-blind, controlled, multicenter study. *Ostomy Wound Manage.* 2005;51(8):24-39.

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