MIST Therapy® System: Thoughts on Therapy

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CASE SERIES #1

At Banner Desert Medical Center (Mesa, Ariz), we treat a variety of serious wounds, from pressure ulcers to vascular wounds and diabetic foot ulcers. Although many wound treatments are available, outcomes are not always predictable and often less than desirable.

From April through August 2006, we conducted a self-funded case series study in our transitional care unit (TCU) to evaluate the clinical effectiveness of the MIST Therapy® System (Celleration®, Inc.) in wound healing. The MIST Therapy System is a noncontact, low-intensity, low-frequency, therapeutic ultrasound device cleared by the Food and Drug Adminstration (FDA) to promote wound healing through cleansing and maintenance debridement.

The study team included physicians of various specializations and staff members from the physical therapy and wound-ostomy departments, including certified wound, ostomy and continence nurses (CWOCNs). Any patient admitted to our unit for wound care was eligible for study participation. Patients who provided informed consent were consecutively selected to participate. We chose to determine wound healing through changes in the following clinical characteristics, pre- to post-therapy:

- Wound dimensions
- Drainage amount (none to heavy)
- Tissue color (red [granulation], pink, yellow [slough], and black [necrosis])
- Patient-rated pain (visual analog scale 0–10)
- Infection (bacterial cultures).

Eight inpatients with wounds of various origins, with and without bacterial colonization, consented to participate in the MIST trial. Patients received 3–5 MIST treatments per week, for 3-20 minutes each treatment depending on wound size. Treatment continued until wounds healed completely or reached a low level of care easily managed at home.

PATIENT #1: A 54-year-old Caucasian woman with methicillin-resistant *Staphylococcus* aureus (MRSA)+ pneumonia received MIST treatment for a chronic left calf abscess of unknown origin. The patient's medical history included hepatitis C, possible liver cirrhosis, heroin abuse, bipolar disorder, jaundice, and hepatoxicity. She began treatment with an iodine packing dressing. After 10 MIST treatments over 15 days, she was discharged with a thin foam dressing to be changed every 3 days. Initially, the patient's time to discharge was estimated at 1 month; she was, however, discharged within 2 weeks.

PATIENT #1: CHRONIC LEFT CALF ABSCESS

Time point	Dimensions (cm)			Area (cm^2)	Volume (cm^3)	Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth				Red	Pink	Yellow	Black	
Start	1.5	2.5	1.5	3.7	5.6	Mild	0	90	10	0	0
End	1.2	1.1	0	1.3	0	Mild	100	0	0	0	0

PATIENT #2: A 77-year-old Caucasian woman with right cerebellar stroke, pneumonia, dehydration, and increased confusion received MIST therapy for 3 lower-extremity (LE) wounds caused by chronic cellulitis. The patient's medical history included hypertension, pulmonary embolism, deep vein thrombosis, hyperlipidemia, and basal cell skin cancer. At the initial evaluation, the projected healing time was 4–6 weeks; the wounds were, however, completely reepithelialized after 7 MIST treatments over 9 days.

PATIENT #2:											
WOUND #1: LEFT LE											
Time point	Dimensions (cm)			Area (cm^2)	Volume (cm^3)	Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth				Red	Pink	Yellow	Black	
Start	3.5	3.2	0	11.2	0	Minimal	0	80	20	0	5–6
End	0	0	0	0	0	None	Healed	0	0	0	5–6
WOUND #2: RIGHT DISTAL LE											
Start	2.0	1.6	0	3.2	0	Minimal	0	80	20	0	5–6
End	0	0	0	0	0	None	Healed	0	0	0	5–6
WOUND #3: RIGHT PROXIMAL LE											
Start	3.9	3.5	0	13.6	0	Minimal	0	80	20	0	5–6
End	0	0	0	0	0	None	Healed	0	0	0	5–6


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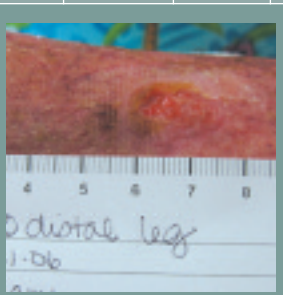
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PATIENT #3: An 83-year-old Caucasian woman received intravenous antibiotics and MIST therapy for a dehisced right medial calf wound secondary to MRSA infection. The wound, at a femoral-popliteal graft site, had been previously closed with a vacuum-assisted device. The patient's medical history included hypertension, peripheral vascular disease, and chronic atrial fibrillation. Upon admission, her estimated time to discharge was 4–6 weeks. The wound was packed with an antimicrobial dressing to control exudate. Initially, the patient required oxycodone for pain, but after 1 week of MIST treatment she was able to discontinue pain medication. Following 8 MIST treatments over 12 days, the patient was discharged with a MRSA-negative, open-to-air wound that only required bacitracin applications 3 times daily.

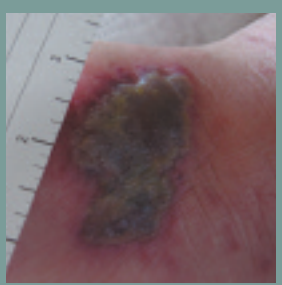
PATIENT #3: RIGHT MEDIAL CALF											
Time point	Dimensions (cm)			Area (cm^2)	Volume (cm^3)	Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth				Red	Pink	Yellow	Black	
Start	5.0	1.0	2.0	5.0	10.0	Moderate	0	80	20	0	3–4
End	1.3	0.3	0.5	0.4	0.2	None	100	0	0	0	0

PATIENT #4: An 80-year-old Caucasian man with altered consciousness received MIST therapy for a right heel wound with a history of MRSA infection. The patient's medical history included early osteomyelitis, moderate chronic plantar fascitis, mild generalized atherosclerotic disease at the right LE, *Clostridium difficile* (C. difficile) colitis requiring intravenous antibiotic treatment, acute renal failure, dehydration, diabetes mellitus, hypertension, chronic lower back pain, hyperlipidemia, diabetic neuropathy, cerebrovascular attack, and a 50-year history of smoking. Hypergranulation tissue developed after 18 MIST treatments over 29 days, resulting in discontinuation of treatment.

PATIENT #4: RIGHT HEEL										
Time point	Dimensions (cm)			Area (cm^2)	Volume (cm^3)	Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth				Red	Pink	Yellow	Black	
Start	5.0	4.0	0.5	20.0	10	Moderate	0	5	95	0	0
End	4.2	4.5	0	18.9	0	Moderate	95	0	5	0	0

PATIENT #5: A 49-year-old Caucasian woman received MIST therapy for 2 left LE wounds secondary to venous insufficiency (wound #1) and cellulitis (wound #2). She had a 4-day history of fever and 1-day history of erythema preceding admission. The patient's medical history included diabetes mellitus, obesity, anemia, nonocclusive thrombus in the left popliteal vein, and a previous cellulitis wound on her right LE requiring extensive inpatient care. Her projected time to discharge was 4 weeks. In 2.5 weeks, after 12 MIST treatments, her wounds progressed to open-air status and 100% granulation. The patient was discharged with a dressing of petrolatum gauze and a synthetic wrap.

PATIENT #5:											
WOUND #1: LEFT FOOT, DORSUM											
Time point	Dimensions (cm)			Area (cm^2)	Volume (cm^3)	Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth				Red	Pink	Yellow	Black	
Start	2.5	5.0	0	12.5	0	Minimal	0	0	100	0	6
End	0.8	2.0	0	1.6	0	None	Thin scab remained over wound				0
WOUND #2: LEFT LATERAL CALF											
Start	7.4	11.0	0	81.4	0	Minimal	0	0	100	0	6
End	5.0	4.0	0	20.0	0	None	100	0	0	0	0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PATIENT #6: A 53-year-old Hispanic man with increased white blood cells received intravenous antibiotics and MIST therapy for 2 MRSA+ perirectal abscesses that had undergone previous incision and drainage surgeries. The patient's medical history included T5 paraplegia since 1996, uncontrolled diabetes mellitus, and spinal fusion. He was wheelchair-bound and had been gel cushion noncompliant for weeks. At his initial evaluation, the buttocks wound had undermining of 3.8 cm at 2 o'clock. An alginate dressing controlled the heavy exudate. Following 1 MIST treatment, 85% of yellow slough was removed with sharp debridement. After 24 MIST treatments over 36 days, undermining was gone and exudates decreased. A thin foam dressing was applied with change orders for alternate days. His left lateral malleolus wound closed completely after 4 MIST treatments.

PATIENT #6:											
WOUND #1: LEFT DISTAL BUTTOCKS											
Time point	Dimensions (cm)			Area (cm^2)	Volume (cm^3)	Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth				Red	Pink	Yellow	Black	
Start	1.5	2.5	2.1	3.7	7.9	Heavy	0	0	100	0	0
End	1.0	0.5	1.2	1.5	0.6	Mild	100	0	0	0	0
WOUND #2: LEFT LATERAL MALLEOLUS											
Start	3.0	0.4	0	1.2	0	Mild	10	0	90	0	0
End	0	0	0	0	0	None	Healed	0	0	0	0

PATIENT #7: A 66-year-old Caucasian man received MIST treatment for 14 LE wounds due to pressure and bilateral cellulitis; 11 wounds were of partial thickness. The 3 detailed below were full-thickness wounds. The patient's medical history included brain trauma resulting in right hemiparesis with some spasticity, alcohol abuse, peripheral vascular disease, and treatment noncompliance. At admission to the unit, he had a 2-month history of right LE swelling and redness. The patient was diagnosed with severe cellulitis of the entire right leg. He had full-thickness pressure ulcers on his right lateral malleolus, right 5th metatarsal head, right lateral to medial heel, and the dorsum of his left foot. Because of the extensiveness of the wounds, the attending physician initially considered amputation but decided to try MIST therapy first. Assuming that the patient was able to heal, the projected time to healing was between 6 months and 1 year. In 8 weeks, following 59 MIST treatments, all 14 wounds had progressed to low-level care status. The MIST treatments saved this patient's leg from amputation.

PATIENT #7:											
WOUND #1: RIGHT LATERAL MALLEOLUS											
Time point	Dimensions (cm)			Area (cm^2)	Volume (cm^3)	Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth				Red	Pink	Yellow	Black	
Start	2.7	3.0	n/a	8.1	n/a	Moderate	0	0	0	100	7
End	0	0	0	0	0	None	Healed	0	0	0	0
WOUND #2: RIGHT 5TH METATARSAL HEAD (LATERAL FOOT)											
Start	4.5	3.0	n/a	13.5	n/a	Moderate	0	0	0	100	7
End	2.2	2.4	0	5.3	0	Minimal	75	0	25	0	0
WOUND #3: RIGHT HEEL											
Start	7.5	11.1	n/a	83.2	n/a	Moderate	0	0	0	100	7
End	4.8	4.8	0	23.0	0	Minimal	100	0	0	0	0
n/a = not available											

PATIENT #8: An 82-year-old American Indian man with increased white blood cells and a urinary tract infection (UTI) received MIST therapy in conjunction with intravenous vancomycin for an acute MRSA+ perineum abscess. The patient's medical history included diabetes mellitus, chronic renal insufficiency, chronic hypertension, and anemia. At the initial assessment, undermining of 2.5 cm was present at 12 o'clock, 2.2 cm at 6 o'clock. At discharge, undermining was reduced to 1 cm and 0 cm, respectively. After 9 MIST treatments over 15 days, the patient was discharged with a dry dressing and minimal wound packing. The patient's estimated time to discharge of 4–6 weeks was reduced by at least half.

PATIENT #8: MRSA+ PERINEUM ABSCESS

Time point	Dimensions (cm)			Area (cm^2)	Volume (cm^3)	Drainage	Tissue color (%)				Pain (0–10)
	Length	Width	Depth				Red	Pink	Yellow	Black	
Start	4.1	0.5	3.0	2.0	6.1	Mild	0	90	10	0	"Little"
End	4.0	0.2	2.0	0.8	1.6	None	100	0	0	0	0

CONCLUSION

Our evaluation of the MIST Therapy System in 8 inpatients with serious wounds of various origins, with and without bacterial colonization, found healing rates increased by 50% or more of predicted rates. In all patients, MIST Therapy substantially reduced wound area and the bacterial burden of infected wounds. It also effectively debrided wounds of the yellow slough and black necrosis that impedes healing. Finally, MIST Therapy promoted the development of red granulation tissue across wound beds (ie, it helped wounds transition from a chronic state to an inflammatory state, which is a necessary step for wound closure in chronic wounds).

MIST Therapy was pain-free for all patients, and several patients reported that treatments brought soothing relief to wounds. Changes in wound-related pain scores pre- to post-treatment varied. Of the 4 patients with pre-treatment pain, 3 reported lower to no post-treatment pain scores; 1 patient with a history of neuropathy reported no change in pain. The painless nature of the MIST Therapy encouraged patient compliance with wound care.

Based on the positive results of our study and the MIST Therapy System's ease of use, we now highly recommend MIST Therapy for almost all pressure ulcers (especially stage 3 and 4), vascular wounds, diabetic foot ulcers, and painful wounds. We have also found that MIST has important economic benefits. In addition to reducing time-to-healing compared with other standard treatments, MIST reduces medication usage (eg, narcotic analgesics and intravenous antibiotics) and more costly therapies and dressings (eg, negative pressure wound therapy, pulsed lavage, enzymatic debriding agents, and silver dressings).

In summary, our results showed that the MIST Therapy® System rapidly promoted healing and appeared to reduce wound pain, bacterial burden, and the overall cost of care. ■

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