



MIST Therapy[®] System: Thoughts on Therapy

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CASE SERIES #6

At the Memorial Regional Rehabilitation Center, we have been using the MIST Therapy[®] System (Celleration[®], Inc) since February of 2006. Here we report a series of 6 consenting patients treated with MIST Therapy for wounds in which healing was inhibited by thick yellow slough, necrosis, or exposed bone or tendon. The wounds in this series originated from trauma, burns, or diabetes. These cases were selected for their educational value rather than through a systematic (ie, consecutive) selection or random assignment process.

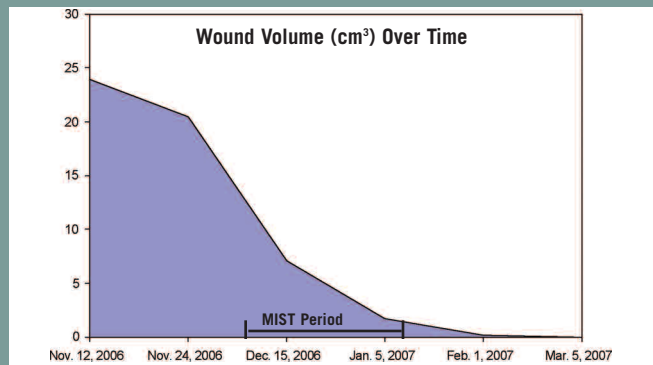
The MIST Therapy System is a noncontact, therapeutic ultrasound device cleared by the Food and Drug Administration to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudate, and bacteria. The low-frequency ultrasound waves of the MIST Therapy System are delivered via a sterile

saline mist. Treatments are painless because the device does not contact the wound.

The cases reported here reflect the initial trial of MIST Therapy at our clinic, in which we administered MIST to assist with debridement. MIST was administered until the wounds were fully granulated, at which point we stopped MIST and continued only the dressings until the wounds closed.

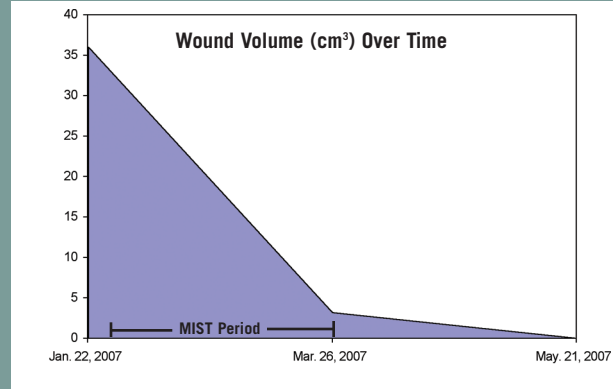
Typically, MIST Therapy is administered 2–3 times weekly for 3–5 minutes per treatment, depending on the size of the wound (ie, longer treatment times for larger wounds). In this case series, wound healing was evaluated on the basis of wound dimensions and tissue characteristics (granulation, slough, or eschar) over time. In addition, wound-related pain was evaluated using the 10-point visual analog scale (VAS) for which patients rated their pain from 0 (no pain) to 10 (extreme pain).

PATIENT #1: This 62-year-old man with a history of diabetes mellitus presented to our clinic on November 17, 2006 with chronic lateral and medial diabetic left foot ulcers of greater than 1 year of duration. The medial wound progressed well with negative pressure wound therapy (NPWT), silver dressing to reduce bioburden, and oxidized regenerated cellulose (ORC) and collagen dressing. Surgical debridement was performed on the lateral wound 1 week prior to his initial clinic visit. The incisions had dehisced, and the bone was palpable at the base of the wound; however, his diabetic neuropathy spared him wound-related pain. The depth of the wound remained unchanged after 2 months of treatment with NPWT, silver dressing, and ORC/collagen dressing. MIST Therapy was initiated on December 13, 2006 and administered 3 times per week until January 18, 2007, for a total of 13 MIST treatments. Initial treatment durations of 5 minutes were gradually reduced to 3 minutes as the wound size decreased. Once substantial granulation tissue had developed over the bone (January 18, 2007), MIST Therapy was stopped, and only the silver and collagen/ORC dressings were continued until the wound came to closure on March 5, 2007. Substantial wound volume reduction (illustrated in the graph above) was achieved during the MIST treatment period.



PATIENT #1: LATERAL LEFT FOOT							
Time point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
Lateral							
11/17/06	4.0	2.0	3.0	Moderate-maximal serosanguineous	90	10	0
12/15/06	0.8	3.0	3.0	Moderate serosanguineous	80	20	0
2/1/07	0.4	1.2	0.4	Minimal serosanguineous	90	10	0
3/5/07	Closed			None	Closed		

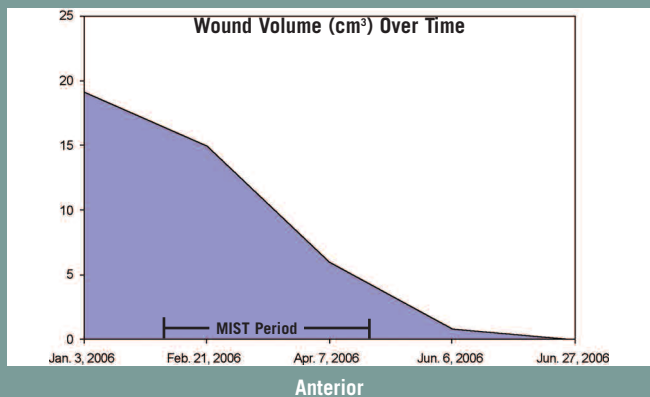
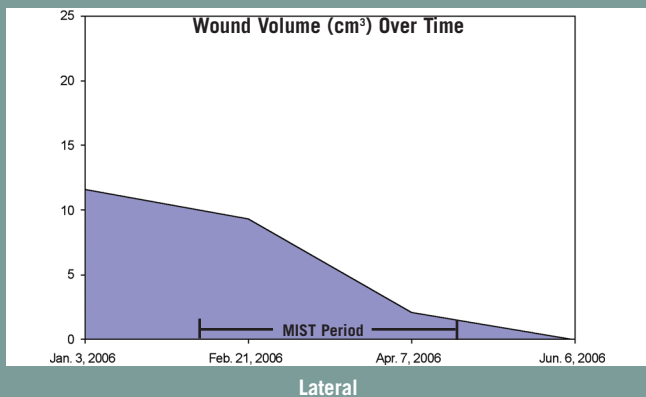
PATIENT #2: This 83-year-old female patient had diabetes mellitus and kidney failure requiring dialysis 3 times per week. Her daily medications included insulin and heparin. She presented with a large, necrotic, full-thickness wound on her right shin resulting from a fall in January of 2007. The wound was initially treated with silver sulfadiazine 1% cream and a gauze dressing but remained necrotic. On January 22, 2007, MIST Therapy was initiated at 9 minutes per session and gradually reduced to 5 minutes per session as the size of the wound decreased. On January 28, 2007, silver sulfadiazine was discontinued, and the wound was dressed with a silver alginate dressing. After a total of 23 MIST treatments over 2 months, the necrotic tissue was entirely replaced by red granulation tissue as of March 26, 2007. With wound volume substantially reduced at this point (see graph, right), MIST Therapy was stopped, and the only treatment was silver and ORC/collagen dressings through May 21, 2007, when the wound closed completely. Additionally, the patient's initial wound-related pain rating of 10 out of 10 declined to 2 out of 10 after starting MIST, and she no longer required anesthetic jelly. She reported no pain associated with MIST treatments.



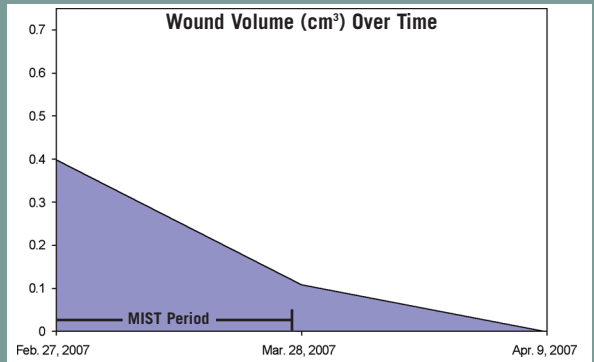
PATIENT #2: RIGHT LOWER LEG							
Time Point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
1/22/07	12.0	15.0	Necrotic	Maximal serous	0	0	100
3/26/07	2.8	5.8	0.2	Minimal serous	100	0	0
5/14/07	0.1	0.1	0.1	Scant serous	100	0	0
5/21/07	Closed			None	Closed		

PATIENT #3: This healthy 37-year-old male had 2 large wounds on his right lateral and anterior calf caused by a burn from a motorcycle exhaust pipe in December of 2005. The wounds were initially treated with silver sulfadiazine cream 1% and a gauze dressing for approximately 2 months. Substantial yellow slough, which was difficult to debride with sharps, was inhibiting wound healing. Additionally, the patient reported pain of 8–9 out of 10 that required pre-treatment with lidocaine before debridement. The wounds were treated with MIST Therapy 3 times per week from February 15 to April 28, 2006, for a total of 21 MIST treatments. Treatment durations started at 9 minutes per session and decreased to 6 minutes as wound size decreased. In addition to MIST, the wounds were dressed with silver and ORC/collagen dressings. After starting MIST Therapy, wound-related pain was reduced to 1 out of 10, and he reported no pain associated with MIST treatments. Anesthetic jelly was discontinued on March 30, 2006. Additionally, MIST Therapy loosened the yellow slough to enable removal and allow for granulation tissue to develop. When MIST was discontinued on April 28, 2006, the lateral and anterior wounds had achieved 100% and 80% granulation tissue, respectively. From this time onward, dressings consisted of silver and ORC/collagen. The wounds eventually closed on June 6, 2006 (lateral calf) and June 27, 2006 (anterior calf). As shown in the graphs below, wound volume reduction occurred primarily during the MIST treatment period.

PATIENT #3: RIGHT LATERAL AND ANTERIOR CALF							
Time point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
Lateral Calf							
1/30/06	5.8	10.0	0.2	Moderate serosanguineous	30	70	
2/21/06	5.2	9.0	0.2	Moderate	60	40	0
4/7/06	3.2	6.6	0.1	Moderate-maximal	80	20	0
6/6/06	Closed			None	Closed		
Anterior Calf							
1/3/06	16.0	6.0	0.2	Moderate serosanguineous	10	90	0
2/21/06	15.0	5.2	0.2	Moderate	Not measured		
4/7/06	13.0	4.6	0.2	Moderate-maximal	60	40	0
6/6/06	8.0	1.0	0.1	Moderate serosanguineous	90	10	0
6/27/06	Closed			None	Closed		



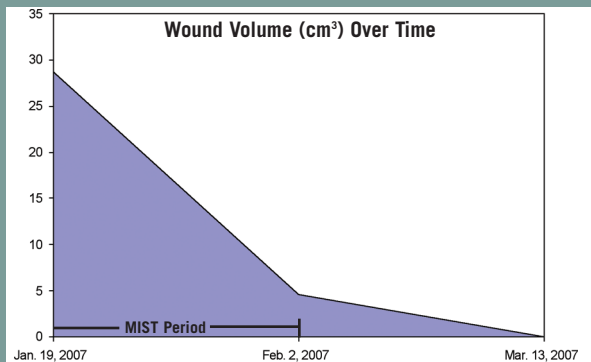
PATIENT #4: This patient was a 44-year-old woman with no significant medical history. She presented with a full-thickness burn wound on her left thigh in late January of 2007. Over the course of 1 month, the wound was treated with silver sulfadiazine cream 1% and a gauze dressing. Attempts at sharp debridement were unsuccessful due to thick yellow eschar and complaints of severe pain (8 out of 10). On February 27, 2007, MIST Therapy was initiated twice per week for 3 minutes per session. The thick yellow eschar loosened and was removed, which had not been possible with sharp debridement. The wound dressing was changed to foam dressing only on March 5, 2007. Additionally, the patient reported a modest reduction in pain to 5 out of 10; however, the use of anesthetic jelly throughout treatment likely influenced her pain scores. With 9 MIST treatments over a period of 1 month, granulation tissue developed over 95% of the wound as of March 28, 2007. At this point, MIST Therapy was discontinued, and only foam dressing was applied until the wound closed completely on April 9, 2007. Wound volume reduction is illustrated in the graph above.



PATIENT #4: LEFT THIGH

Time point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
2/27/07	1.0	2.0	0.2	Moderate serosanguineous	0	100	0
3/28/07	1.0	1.1	0.1	Minimal serosanguineous	95	5	0
4/9/07	Closed			None	Closed		

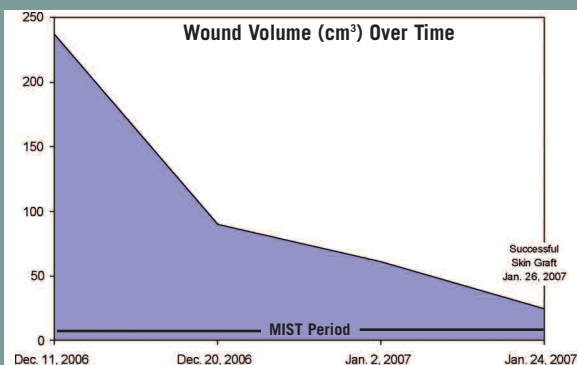
PATIENT #5: This 91-year-old woman sustained a large, full-thickness wound to her right lower shin in December of 2006 when a bookshelf fell on her right leg. Her medical history included hypertension and irregular heart-beat, and medications included verapamil and digoxin. Initially, the wound was treated with antimicrobial silver/alginate dressing and sharp debridement. The wound had become necrotic and was covered completely with black eschar. Her pain was severe (10 out of 10) and required narcotic medications for pain relief. MIST treatments for 5 minutes per session twice per week were initiated on January 19, 2007. During this time, the wound was dressed with silver and matrix metalloproteinase-inhibiting dressings. Sharp debridement was continued with MIST to remove yellow slough build-up. The black eschar was replaced by 100% red granulation tissue after a total of 6 MIST treatments over 3 weeks. MIST was discontinued on February 2, 2007. The reduction in wound volume over time (shown in the graph above) was primarily achieved during MIST Therapy. After starting MIST Therapy, the patient no longer needed lidocaine jelly for sharp debridement, and her pain score was reduced to 2–3 out of 10. It is not known whether she discontinued narcotic pain medication. At her last visit on March 13, 2007, the wound was nearly closed. In a follow-up call 1 week later, the patient reported the wound was closed.



PATIENT #5: RIGHT LOWER LEG

Time point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
1/19/07	18.4	3.9	Necrotic	Moderate purulent	0	0	100
2/2/07	11.5	1.0	0.4	Minimal serosanguineous	100	0	0
3/13/07	0.2	0.2	0.2	None	100	0	0
3/20/07	Closed			None	Closed		

PATIENT #6: This healthy 56-year-old woman suffered a crush injury to her left arm and hand in a car accident on November 17, 2006, resulting in degloving of her left hand. In spite of treatment with NPWT and sharp debridement, the wound became necrotic, a tendon was exposed dorsally, and the wound emitted a strong odor suggestive of bacterial infection. Pulsatile lavage for 1–2 weeks was unsuccessful in debriding the wound. She was a clear candidate for a skin graft, so the goal of therapy was to reduce bioburden and promote the growth of enough granulation tissue to cover the exposed tendon and allow for skin grafting. Prior to starting MIST treatment, the patient's pain was mild at rest (1–2 out of 10) and severe during NPWT treatments (8–10 out of 10). On December 11, 2006, MIST Therapy (13 minutes per session) was initiated adjunctively 3 times per week for 6 weeks to reduce the odor/infection and promote growth of granulation tissue over the exposed tendon. The patient reported no pain associated with MIST treatments and discontinued use of topical anesthetic 11 days after starting MIST Therapy. Complete coverage of the tendon with granulation tissue was achieved by January 5, 2007. The wound was successfully grafted on January 26, 2007. Actual wound volume reduction during the MIST Therapy period is shown in the graph above.



The patient reported no pain associated with MIST treatments and discontinued use of topical anesthetic 11 days after starting MIST Therapy. Complete coverage of the tendon with granulation tissue was achieved by January 5, 2007. The wound was successfully grafted on January 26, 2007. Actual wound volume reduction during the MIST Therapy period is shown in the graph above.

PATIENT #6: LEFT UPPER EXTREMITY

Time point	Dimensions (cm)			Drainage	Tissue color (%)		
	Length	Width	Depth		Red/Pink (granulating)	Yellow (slough)	Black (eschar)
12/11/06	27.0	22.0	0.4	Moderate serous	75	25	0
1/2/07	17.0	12.0	0.3	Minimal serous	95	5	0
1/24/07	12.0	10.5	0.2	Minimal serous	100	0	0
1/26/07	Patient treated with successful skin graft surgery						

CONCLUSION

In this case series, 4 women and 2 men with chronic wounds originating from trauma, burns, and diabetes were treated with MIST Therapy in an attempt to promote healing that had been inhibited by either thick yellow slough, necrosis (eschar), or exposed bone or tendon. Patients ranged in age from 37–91 years. MIST treatments were administered 2–3 times per week for 4–9 weeks. Duration of each treatment session ranged from 3–13 minutes. Substantial granulation tissue was achieved in no longer than 9 weeks. Furthermore, all wounds (with the exception of the wound requiring a skin graft) came to complete closure within 6–20 weeks. For the 1 patient who was destined for a skin graft, granulation tissue covering the exposed tendon developed within 4 weeks of initiating MIST Therapy, adequately preparing the wound for a successful graft procedure.

Additionally, no patient reported pain associated with MIST treatments. In fact, all patients who reported wound-related pain (5

of 6) reported substantially lower pain scores after starting MIST Therapy. Four of these patients were able to discontinue use of topical anesthetics.

The wounds in this series were treated with MIST until substantial (90–100%) granulation tissue had developed. This strategy of treating to full granulation rather than closure was based on three main factors: our primary objective of debridement; granulation tissue formation as a reliable indicator of healing progression; and the cost associated with a new, non-reimbursable modality for which we did not yet have objective evidence of efficacy. As shown in the case graphs, the bulk of wound volume reduction occurred during the MIST treatment periods. Since beginning to experiment with MIST Therapy in February of 2006, we have had numerous opportunities to utilize it with a variety of patients and wound types, and we now administer MIST until closure. MIST Therapy has helped to loosen adherent yellow and black eschar, particularly in patients suffer-

ing from burns. MIST accelerated or initiated granulation tissue formation and increased cell growth for our more recalcitrant wounds and those for which healing progression had stalled. In our experience, MIST has been an effective adjunct therapy to improve granulation tissue formation, especially over exposed tendon and bone where other modalities have not been as beneficial. In our clinical experience, MIST Therapy also appears to alleviate pain associated with chronic open wounds, especially during sharp debridement. We have also noticed a reduction in usage of narcotics and topical analgesics among the patients we have treated with MIST. ■

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