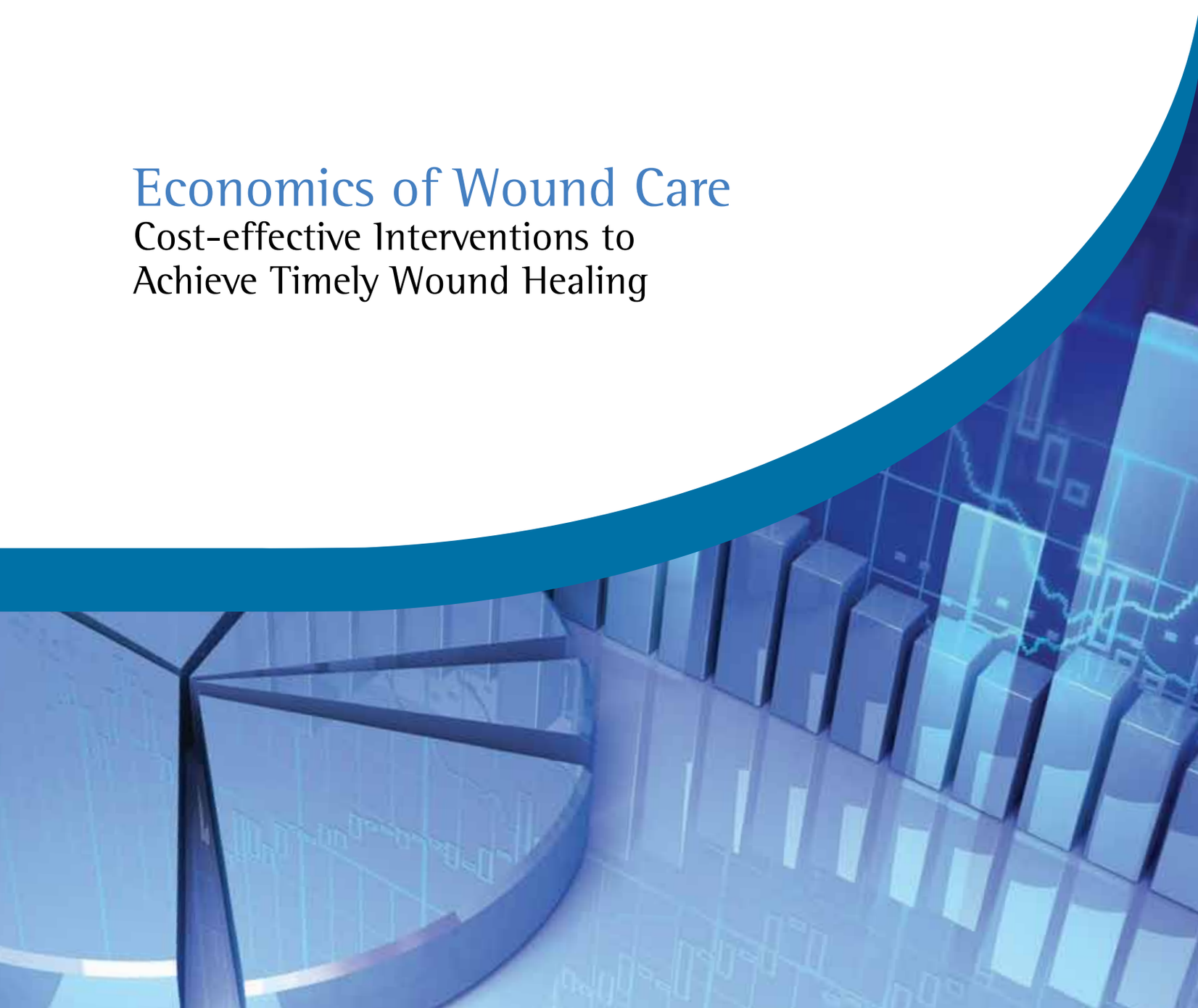
MIST™
Ultrasound Healing Therapy

Economics of Wound Care

Cost-effective Interventions to Achieve Timely Wound Healing

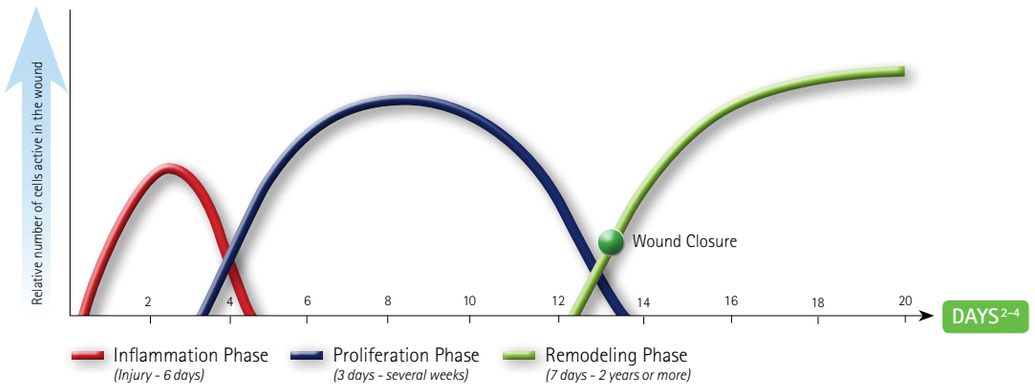


Cost-effective Wound Care

Treating non-healing wounds is costly, both in terms of time and resources required. The annual cost of chronic non-healing wounds in the U.S. can reach $25 billion.[1] In determining the most cost-effective and efficacious treatment path, it is challenging to accurately determine all costs related to non-healing wounds.

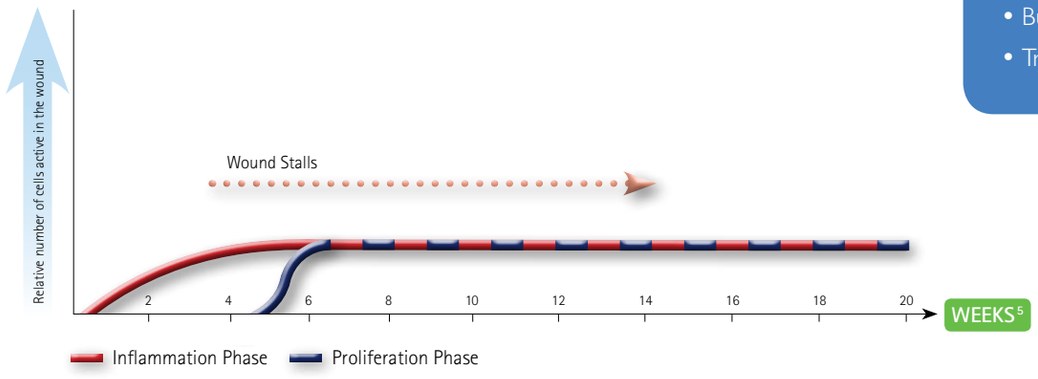
Fortunately, most wounds naturally advance through the healing process in a matter of weeks as shown directly below. However, not all wounds move through the process as expected and become non-healing wounds.

Normal Wound Healing Process



Non-healing Wounds

Many variables influence wound care costs – wound type, wound severity and patient severity. Normal wound healing progresses through a series of healing phases. However, when patients are compromised with comorbidities normal wound healing can be stalled.



Examples of Non-healing Wounds

- Dehisced Wounds
- Pressure Ulcers
- Venous Insufficient Ulcers
- Infected Wounds
- Diabetic Foot Ulcers
- Burns
- Traumatic Wounds

Factors Impairing Healing

There are a number of factors that impair wound healing leading to further therapeutic interventions.

Microenvironment	Clinical Observations
Impaired Blood Flow	Bacterial Infection
Deficient Growth Factors	Moisture Imbalance
Senescent Cells	Physical Pressure
Sustained Inflammation	Inadequate Nutrition
Excessive Proteolysis	Wound Pain
Bacterial Bioburden	Patient Non-compliance

Research suggests that an uncomplicated wound might cost about $8,000.[6] Stockl reported that diabetic foot ulcers that progressed to a higher severity experienced more than $17,000 in higher costs than those that did not.[7]

Economic Consequences of Non-healing Wounds

Increasing Costs

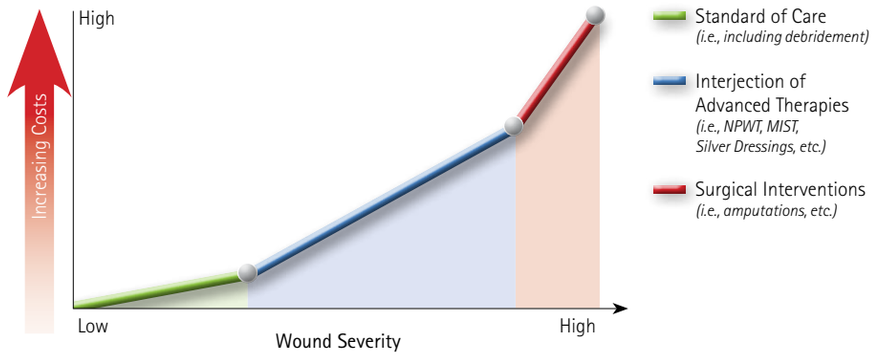
- **Length-of-stay (LOS) of patient**
- **Utilization of antibiotics, analgesics and advanced wound therapies** (i.e., NPWT, Silver Dressings, etc.)
- **Usage of biological grafts**

Increasing Costs

- **Hospital readmissions**
- **Wound recidivism**
- **Cost of care in managing the patient**
- **Surgical and diagnostic interventions**

Treatment Path/Cost Scale

The lower the wound severity, the more effective Standard of Care will be. However, as wound and patient severity increase, so does the need for additional costly therapies.



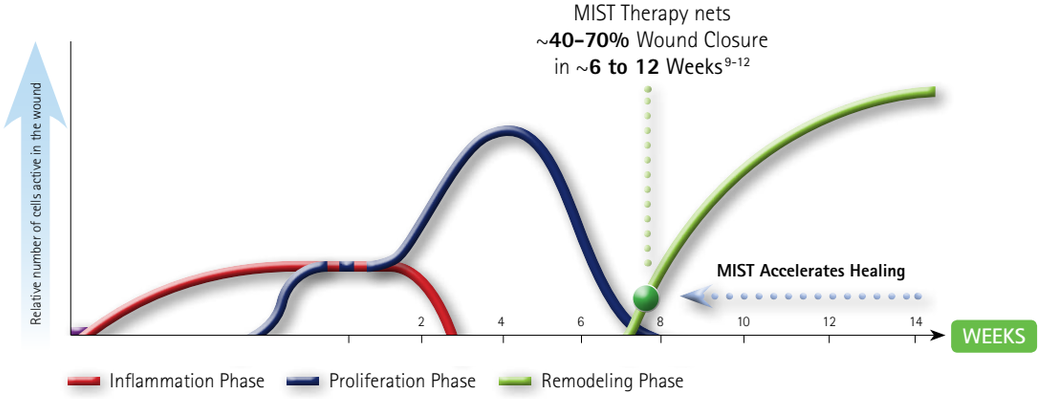
Approximately 85% of all amputations start as a simple ulcer.[8] Taking a limb costs about $45,000.[7] Up to 50% of patients undergoing an amputation will undergo a second within 5 years.[8]

Painless Accelerated Healing

To understand the economic benefits MIST Therapy® provides, it's important to first understand MIST's healing benefits.

MIST Therapy delivers a low frequency ultrasound through a saline mist to the wound bed. When combined with Standard of Care, this painless, non-contact energy delivery results in four key aspects of wound healing:

- **Active cell stimulation**
- **Decreased bioburden**
- **Increased blood flow**
- **Cleansing and gentle maintenance debridement**



Standard of Care for diabetic foot ulcers results in **24-31%** wound closure in **12-20** weeks.[5]

MIST Therapy addresses these barriers to healing by stimulating the environment, actively impacting the wound bed and accelerating healing.

Clinical Benefits of MIST Therapy = Economic Value

The clinical benefits of MIST Therapy has been **studied in over 500 patients.**
Over 35,000 patients have benefited from the healing power of MIST Therapy.



The MIST Therapy® Effect

MIST Therapy provides the benefits of painless healing with economic savings.

MIST Therapy, together with Standard of Care, decreases the need for additional therapies, decreases the number of treatment days and has been shown to reduce the risk of amputation or further surgical interventions.

The clinical benefits of MIST Therapy provide institutions treating non-healing wounds added economic benefits. Beyond the savings noted from accelerated healing, MIST Therapy also delivers potential savings in the reduction of more expensive advanced therapies, pharmaceuticals and biologics.

MIST Therapy may eliminate or reduce the need for:
↓ Usage or prolonged use of advanced therapies *NPWT*[16-17] *Silver Dressings*[16-17]
↓ Usage of advanced biologics[11-13]
↓ Usage of antibiotics (bacterial resistance)[12, 14]
↓ Usage of analgesics & pain medications[15]
↓ Usage of invasive debridement[11]
↓ Hospital readmissions[11]
↓ Wound recidivism[9, 12]
↓ Costs associated with amputations[18]

MIST Therapy may increase:
↑ Patient compliance
↑ Post surgical rehabilitation
↑ Patient's Quality of Life (QOL)
↑ Advanced biologic or skin flap acceptance[11-15]

Cost Savings with MIST Therapy®

An analysis was completed to compare the cost of care for patients with diabetic foot ulcers treated for 12 weeks with Standard of Care (SOC) only to MIST Therapy plus SOC.[19]

Research Design and Methods: Three retrospective diabetic foot ulcer studies provided SOC cost and closure rate data used to assess the cost effectiveness of MIST Therapy. The MIST Therapy randomized sham controlled clinical trial results provided the closure data for MIST Therapy.

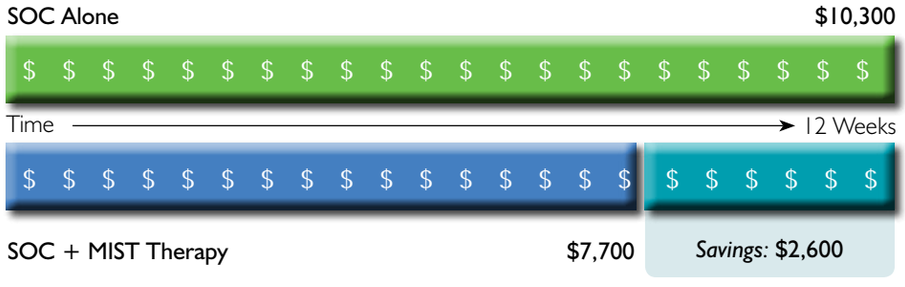
Results: A cost model was developed. These results were compared to MIST Therapy plus SOC for a case-mix adjusted cost per 1,000 patients.

Dollar Value Associated with Time Savings

	SOC Alone	MIST Therapy + SOC	
Healed/progressed towards healing	70%	91%	
Deteriorated	30%	9%	
Total cost per 1,000 patients for a 12-week episode of care	$10,351,324	$7,795,703	**Cost Savings $2,555,620**

The savings for MIST Therapy accrue because of the greater number of ulcers that heal or progress toward healing within 7-12 weeks. These savings translate to a per patient costs savings.

Per Patient Costs Savings



Such results emphasize the importance of early detection, aggressive treatment of such ulcers, and a need for effective intervention.

Clinical Studies and Case Stories

MIST™
Ultrasound Healing Therapy

References

1. Staylor, A. Wound Care Devices: Growth Amid Uncertainty. MedTech Insight. 2009;11(1):32-47.
2. Krasner DL, Kane D. Chronic Wound Care: A Clinical Source Book for Healthcare Professionals. 2nd ed. Wayne, PA: HMP Communications; 1997:1-4.
3. Hahler B. Surgical Wound Dehiscence. MedSurg Nurs. 2006 Oct;15(5):296-300.
4. Mercendetti M, Cohen AJ. Wound Healing, Healing and Repair. eMedicine.medscape.com. March 2008; Article #128129.
5. Margolis DJ, Kantor J, Berlin JA. Healing of Diabetic Neuropathic Foot Ulcers Receiving Standard Treatment – A Meta-Analysis. Diabetes Care 1999;22(5).
6. Kruse I, Edelman S. Evaluation and Treatment of Diabetic Foot Ulcers. Clinical Diabetes. 2006;24 (2):91-93.
7. Stockl K, et al, Costs of Lower-Extremity Ulcers Among Patient with Diabetes. Diabetes Care 27:2129-2134, 2004.
8. Reiber, GE, Boyko EJ, Smith DG. Lower Extremity Foot Ulcers and Amputations in Diabetes. In Diabetes in America, 2nd edition. Bethesda, MD; National Diabetes Data Group, National Institutes of Health, NIDDK NIH Publication No. 95-1468, 1995.
9. Ennis WJ, Formann P, Mozen N. Ultrasound Therapy for Recalcitrant Diabetic Foot Ulcers: Results of a Randomized, Double-Blind, Controlled Multicenter Study. Ostomy Wound Management 2005;51(8):24-39.
10. Cole PS, Quisberg J, Melin MM. Adjuvant Use of Acoustic Pressure Wound Therapy for Treatment of Chronic Wounds. J Wound Ostomy Continence Nurs. 2009;36(2) In press.
11. Ennis WJ, Valdes W, Gainer M, Meneses P. Evaluation of Clinical Effectiveness of MIST Ultrasound Therapy for the Healing of Chronic Wounds. Adv Skin Wound Care 2006;19:437-46.
12. Kavros SJ, Schenck EC. Use of Noncontact Low-Frequency Ultrasound in the Treatment of Chronic Foot and Leg Ulcerations: A 51 Patient Analysis. J Am Podiatr Med Assoc 2007;97(2):95-101.
13. Kavros SJ, Liedl DA, Boon AJ, Miller JL, Hobbs JA, Andrews KL. Expedited Wound Healing with Noncontact, Low-frequency Ultrasound Therapy in Chronic Wounds; A Retrospective Analysis. Adv Skin Wound Care 2008, 21(9):416-23.
14. Serena T, Lee SK, Lam K, Attar P, Menses P, Ennis W. The Impact of Noncontact, Nonthermal, Low-Frequency Ultrasound on Bacterial Counts in Experimental and Chronic Wounds. Ostomy Wound Management 2009;55(1):22-30.
15. Gehling ML, Samies JH. The Effect of Noncontact, Low-intensity, Low-frequency Therapeutic Ultrasound on Lower-Extremity Chronic Wound Pain: A Retrospective Chart Review. Ostomy Wound Management 2007;53(3):44–50.
16. Howell-Taylor M, Hall Jr MG, Brownlee WJ, Taylor M. Combined Use of Negative Pressure Wound Therapy and Acoustic Pressure Wound Therapy to Prepare Infected, Open Postsurgery Wounds for Secondary Surgical Closure, Poster Presentation, 2007 SAWC.
17. Thurman K, MIST Therapy System: Thoughts on Therapy, ECPN, January/February 2007.
18. Eingle, J. Closure of a 14-year Chronic Diabetic Foot Ulcer with the Adjunctive Use of a Acoustic Pressure Wound Therapy, Poster Presentation May 2008.
19. Carr P, Bieber J. Cost Effectiveness of MIST Therapy System 5.0 for the Treatment of Diabetic Foot Ulcers. White Paper.

For more information, contact your local Celleration representative or call (952) 224-8700.

10250 Valley View Road, Suite 137
Eden Prairie, MN 55344
phone: 952.224.8700
fax: 952.224.8750
customer service: 866.307.MIST (6478)
email: info@celleration.com

www.celleration.com

MIST Therapy System FDA Clearance. 510 (k) Clearance June 2005. "The MIST Therapy System produces a low energy ultrasound-generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue, exudates and bacteria."

Please see full package insert for additional information on indications, contraindications, warnings, precautions, and side effects.

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