

Use of low frequency ultrasound therapy in the treatment of recalcitrant leg ulcers: case series

This series of case reports looks at the efficacy of low frequency ultrasound using the MIST Therapy® System in the treatment of four problematic leg ulcers. The debridement and healing profiles observed during treatment demonstrate how the therapy was able to stimulate the wound healing process and reflect international study results, with wound reduction rates of between 41–73% over the 10–14-week treatment period. Clinicians found the system easy to use with minimal training. It was also non-invasive, pain-free and did not result in discomfort or side-effects for the patients.

Ray Norris, Rachel Henchy

KEY WORDS

Debridement
Ultrasound therapy
MIST Therapy®
Leg ulcers

Chronic, non-healing wounds present many clinical challenges and cause a great deal of distress to patients (Posnett and Franks, 2008). While the impact on patients' quality of life is difficult to quantify, the costs to the NHS are huge. Chronic wounds represent a significant burden to the NHS, which during 2005 was estimated at between £2.3bn–£3.1bn (Posnett and Franks, 2008).

It is estimated that between 70,000 and 190,000 individuals have a venous leg ulcer at any one time (Moffatt et al, 2004), with leg ulcers costing the

NHS up to £600m each year (Health Commission, 2004). The risk of infection means that the average cost of a hard-to-heal wound is between £5,000 and £9,818 (Wound Solutions, 2010). The MIST Therapy® System (Celleration Inc) uses ultrasound technology to atomise saline and deliver it as a continuous vapour 'mist' to the treatment site. The vapour generated has a relatively uniform droplet size and this acts as a conduit, transmitting ultrasonic energy to the treatment site and supporting energy transfer to a depth of between 2–3.5mm (dependent upon the condition of the skin), both to reduce bioburden and stimulate cell activity.

'Barriers to healing' is a term associated with the management of chronic, non-healing wounds. Debridement of non-vital tissue is seen as a problem when trying to successfully heal these wounds. Removal of non-vital or necrotic tissue can be achieved surgically or autolytically and dressing products are used to promote autolysis (Cutting, 2008). Ultrasound therapy offers a new, alternative solution, which is explored in the case reports in this article.

The low energy ultrasound-generated by MIST Therapy promotes wound healing through wound cleansing and maintenance debridement, removing yellow slough, fibrin tissue, exudate and bacteria.

MIST Therapy is effective in wound healing, as the ultrasound penetrates into the hypodermis and stimulates the wound bed (www.celleration.com). Several studies have demonstrated the effect of ultrasound (Thawer and Houghton, 2004; Lai and Pittelkow, 2007; Kozak and Goral, 2008), and MIST Therapy has been shown to have an anti-inflammatory effect in wounds with chronic inflammation (Kozak and Goral, 2008), stimulating the production of chemical mediators which in turn activate fibroblasts (Thawer and Houghton, 2004) and provide early release of growth factors (Lai and Pittelkow, 2007).

MIST Therapy also increases the deposition of blood vessels, providing stronger, more natural collagen in granulation tissue (Thawer and Houghton, 2004) and increased blood flow (Leidl and Kavros, 2001). It is also effective in decreasing bioburden through mechanical stress, which breaks down rigid bacterial cell walls, including methicillin-resistant *Staphylococcus aureus* (MRSA), *Vancomycin-resistant enterococcus* (VRE) and *Pseudomonas aeruginosa* (Serena et al, 2009).

International studies have shown that MIST Therapy increases closure of wounds by 40–61% within 12 weeks through wound acceleration (Ennis et al, 2005; Kavros and Schenck, 2007). In chronic foot and leg ulcerations,

Ray Norris is Tissue Viability Nurse, South West Essex Primary Care Trust, Rachel Henchy is Sister, Day Care Unit, Brentwood Community Hospital

studies have shown a 94.9% reduction in wound volume within 5.5 weeks (Kavros and Schenck, 2007).

The following case reports examine the use of MIST ultrasound therapy on non-healing leg ulcers and are the first to be done in the UK. The authors work for South West Essex Community Services and the patients were seen in their local leg ulcer clinic. MIST Therapy was evaluated specifically on patients with sloughy, non-healing leg ulcers. Consent was obtained from all patients and wounds were photographed and measured on a regular basis using a grid measurement tool to record the surface area, the widest points are also recorded within the article. Two of the patients were new to the leg ulcer clinic and had previously been receiving care in the community. The remaining two patients had been receiving care in the clinic for a number of weeks, but their healing had stalled.

Case report one

Mrs B is a 90-year-old female who lives alone and has reduced mobility and bilateral lower limb oedema. She had been receiving treatment for her ulcer from her practice nurse for approximately seven months. On initial assessment she presented with an ulcer on her left gaiter region that measured 4.5x3.5cm in size and was covered with a thick layer of 100% yellow/green slough (Figure 1). There was a small amount of purulent exudate with slight malodour. A Doppler assessment was performed and the right ankle brachial pressure index (ABPI) measured 1.18, and the left 1.05. This patient was considered suitable for compression bandaging, therefore low level compression was applied as appropriate. Initially, the ulcer was dressed with an antimicrobial and foam dressing to treat the localised infection and absorb the exudate. In spite of two dressing changes and a reduction in ankle circumference of 5cm, the wound remained covered in 100% sloughy tissue.

The decision was made by the authors to start MIST Therapy. This treatment was provided for six minutes, in accordance with the recommended

treatment algorithm provided by the manufacturer for a wound of this size. The patient stated that there was no discomfort throughout the treatment. The compact portable unit was both easy to assemble and use. Despite more frequent treatments being recommended, the wound was only treated once a week with MIST Therapy, which proved to be successful.

After two MIST Therapy treatments



Figure 1. Ulcer on left gaiter region before first treatment with MIST Therapy.



Figure 2. After four sessions of MIST Therapy (29th March, 2010), the wound was covered in 100% healthy granulation tissue.



Figure 3. After 10 weeks' treatment, the wound had almost healed and the patient was ready to progress to compression hosiery.

the wound bed was covered in approximately 80% granulation tissue. It was noted that there was some mild re-sloughing on the wound bed between treatments. The primary dressing was changed to sorbion sachet S (H&R Healthcare Ltd) to prevent further re-sloughing.

After four MIST Therapy treatments, Mrs B's wound had reduced in size, measuring 4x3cm and was covered in 100% healthy granulation tissue (Figure 2). At this time, MIST Therapy was no longer required and treatment of Mrs B's wound continued with sorbion sachet S and 3-layer compression for the next six weeks. During this time the level of exudate and size of the wound continued to decrease. After 10 weeks of treatment, Mrs B was measured for compression hosiery as the wound had almost healed (Figure 3) and measured 1.75x1 cm.

Case report two

This 87-year-old female (Mrs S) lives alone and has reduced mobility. She presented at the authors' clinic in June 2009 with a large (approximately 67cm², 12x8cm), infected, sloughy ulcer to her right medial malleolus. The wound had a copious amount of malodorous creamy exudate. Mrs S required opioid analgesia regularly and at dressing changes, as her pain score was 8-9 on a visual analogue scale (VAS). She had been having the ulcer

dressed in the community for the last four years, and stated that it had only briefly healed during this period.

A Doppler assessment was performed. Her right ABPI was 0.96, and her left was 0.98. The wound was dressed with a silver antimicrobial dressing with 3-layer compression bandaging. Initially, significant progress was made and the pain, volume of exudate and wound size decreased. In January 2010, after seven months of treatment, the total wound size had reduced by half with an approximate measurement of 8.5x4.5cm. However, the rate of improvement had slowed down and there was a large amount of fibrous slough on the wound bed.



Figure 4. Wound covered in a layer of fibrous slough before first MIST Therapy (8th February, 2010).



Figure 5. After 10 weeks of therapy, the volume of exudate had decreased and the pain reduced (15th March, 2010).

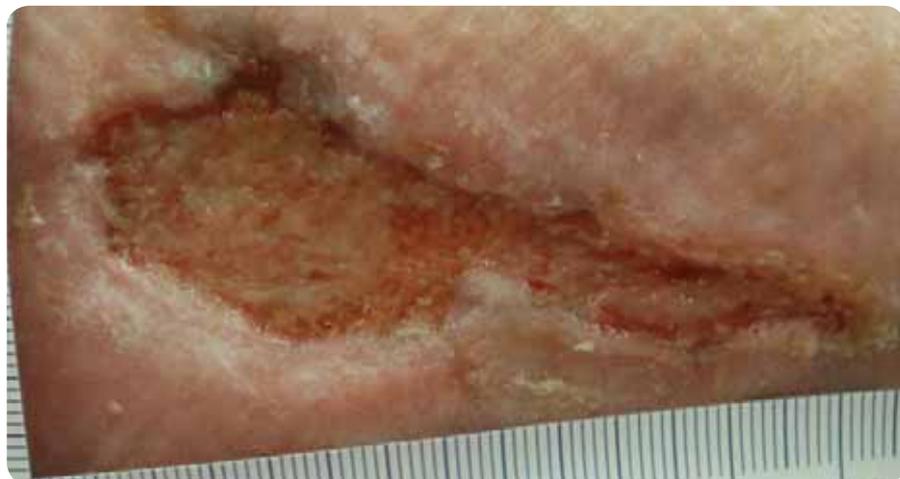


Figure 6. Photograph taken on 17th May 2010, week 14 of MIST Therapy (wound size 6.5x2.5cm).

Despite receiving appropriate treatment, this patient's wound had stalled and was no longer progressing to healing. Therefore, Mrs S was started on MIST Therapy. The wound was covered in a thin layer of fibrous slough (Figure 4). Initially, MIST therapy was administered twice a week.

After five weeks of treatment the ulcer had decreased in size from 34cm² to 24cm², the peri-ulcer skin appeared healthier and the wound bed was more vascular, although some of the wound remained covered in yellow slough. A reduction in pain was reported (4–5 on a VAS), along with a decrease in odour.

After nine weeks of MIST Therapy the decision was made to increase from two to three treatments a week. No other factors with regard to this patient's care were changed over the following weeks. The patient's general health and choice of dressing remained the same throughout. The patient did not report any pain or discomfort throughout the treatments.

By mid-March, after 11 treatments with MIST Therapy, the volume of exudate from the wound had decreased, and her level of pain was now 3–4 on the VAS, the wound bed appeared more vascular and there were islands of epithelising cells forming (Figure 5). By mid-May, after 14 weeks of MIST Therapy, the wound size had reduced to 9cm² (Figure 6). MIST Therapy was continued, the patient was

measured for compression hosiery and the wound continues improving to time of publication.

Case report three

Mr E presented at the leg ulcer clinic in September 2009. He was an active, independent 84-year-old male who lived alone. A plan of care was agreed by the authors that would allow Mr E to be seen twice a week at clinic and to continue his regular once a week swimming session. This was an important part of his regular exercise regimen which he was keen to continue. Mr E stated that he first developed an ulcer in 1998, which, despite having a graft to the wound, had never fully healed.

Doppler assessment showed his right ABPI to be 1.02, and his left, 1.07. He had an ulcer above his left medial malleolus, measuring 12x9cm which was covered in 100% sloughy tissue. The ulcer was oozing a large amount of purulent exudate and the peri-ulcer area was macerated. Mr E's ulcer was treated with a silver antimicrobial dressing for two weeks, until the signs of infection had abated. Compression bandaging was started in October once Mr E's antihypertensive medication had been altered and his blood pressure was slightly better controlled. After one month's treatment with compression therapy, the level of exudate had decreased and the condition of the peri-ulcer skin had greatly improved. By the start of January 2010, Mr E's ulcer had reduced in size to 11x7cm and was covered in 50% sloughy tissue.

As further significant progress had not been achieved by the end of January and his blood pressure had stabilised on the new antihypertensive medication, the decision to increase Mr E's level of compression bandaging to full compression was taken. To enable Mr E's swimming activities and retain his quality of life, the treatment was carried out weekly following his swimming session. During this short break in compression therapy, the bandages were removed and an occlusive dressing was utilised before returning to the leg ulcer clinic for the reapplication of compression bandaging.

By mid-February, 2010 the ulcer remained at 11x6.5cm (57cm²) and the ulcer bed was covered in approximately 80% thick, yellow slough (Figure 7). The decision was made to start MIST Therapy, which was performed twice a week. The appearance of Mr E's wound was recorded by photographs. The appearance varied as he continued to go swimming once a week.

After 10 weeks and 21 MIST Therapy treatments, the wound had reduced to 40cm², the volume of exudate and percentage of slough had decreased and the wound bed appeared more healthy and vascular. Despite regular breaks in treatment to accommodate the patient's lifestyle, a wound that had failed to heal over several years was now healing. By 11th May 2010, after 26 MIST treatments, the wound bed was approximately 95% covered in healthy granulating tissue and the wound measured 10x4cm (Figure 8). MIST Therapy and standard care continues and the wound progresses towards healing.



Figure 7. Ulcer bed covered in approximately 80% thick, yellow slough before starting MIST Therapy.

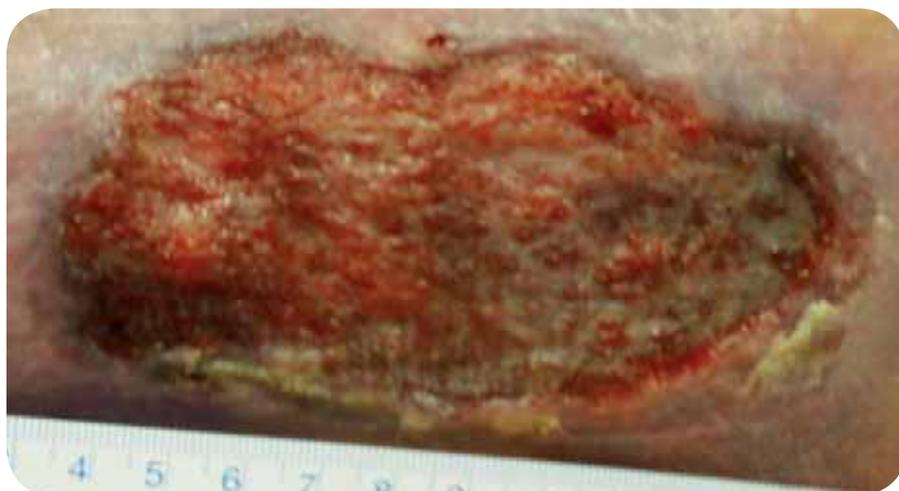


Figure 8. After 26 treatments of MIST Therapy the wound bed was approximately 95% covered in granulating tissue (11th May, 2010).

Case report four

Mrs B is an active 81-year-old female with a long history of multiple leg ulcers, stretching back over more than 10 years. She presented to the clinic towards the end of January 2010 with a sloughy, wet almost circumferential ulcer by her right ankle. It was difficult to measure this wound accurately due to its irregular shape. The wound bed appearance was approximately 5% necrotic tissue, 60% infected green slough, 30% yellow slough and approximately 5% granulating tissue. There was a large volume of malodorous purulent exudate from the wound and there were signs of cellulitis extending out from the wound margins. The peri-ulcer skin was also macerated. The ulcer had been present for over five years and her dressings had been attended to by community nurses. This patient had only recently been prescribed compression bandaging, but this had not been tolerated due to the pain of cellulitis.

Oral antibiotics were prescribed to treat Mrs B's cellulitis. Assessment confirmed multiple allergies, including latex and metals. Therefore, a non-metallic antimicrobial dressing was used with a calcium alginate, plus sorbion sachet S to manage the large volume of exudate and prevent further maceration and damage to the peri-ulcer skin.

A Doppler assessment was performed; right ABPI was 1.07 and left 1.06. As Mrs B found compression bandaging painful, the authors agreed



Figure 9. Medial aspect of right leg before MIST Therapy on 19th February, 2010 after eight treatments.



Figure 10. Lateral aspect of right leg before MIST Therapy on 19th February, 2010 after eight treatments.

to apply reduced compression until the pain from the cellulitis had subsided. Latex-free Profore® 1, 2 and 4 bandages (Smith & Nephew) were applied.

After two weeks the cellulitis had resolved but the wound remained almost 100% covered in slough. On 3rd February 2010, the decision was taken to start MIST Therapy and increase compression to one layer of inelastic bandaging now that the painful cellulitis had improved.

The extensive wound size meant it was necessary for MIST Therapy to be performed for 18 minutes per treatment. The wound was treated three times a week and the treatment time was reduced as the wound size decreased. The wound was photographed regularly to monitor progress. On 19th February, after only eight MIST treatments, the volume of exudate had started to reduce and there was an approximate 20% reduction in yellow slough (Figures 9 and 10).

The volume of slough then decreased rapidly and the wound bed appeared more vascular with both granulation tissue and islands of epithelial cells forming. There was still a moderate amount of exudate from the wound, but the volume had reduced significantly and the purulence had changed to normal, serous exudate. A thin layer of yellow slough was re-forming on the wound bed between dressing changes

but, following discussions with the MIST distributors (H&R Healthcare Ltd), after five weeks of therapy the dressing was changed to sorbion sachet S alone, despite the level of exudate. The result of this change was to improve the quality of the response to treatment with a further reduction in the amount of slough evident and improved control of exudate (Figures 11 and 12).

After 21 treatments over seven weeks (Figure 13), the wound was almost slough free, the wound bed was healthy in nature and the wound had reduced in size to 69cm². MIST Therapy was discontinued after 25 treatments, as the wound bed was slough-free, with reduced levels of exudate, no signs of infection and a healthy, healing wound. Treatment with sorbion sachet S has continued and the wound continues to make progress.



Figure 11. Medial aspect of right leg after approximately five weeks of MIST Therapy.



Figure 12. Lateral aspect of right leg after approximately five weeks of MIST Therapy.



Figure 13. Lateral aspect of right leg after seven weeks (21 sessions) of MIST Therapy.

Conclusion

The MIST ultrasound debridement system was successful in improving healing outcomes for these four patients. The results are promising and similar to those of international studies that support the MIST Therapy system (Ennis et al, 2005; Kavros et al, 2007). The debridement and healing profiles demonstrate and reflect stimulation of the wound healing process.

The system was easy to use with minimal training necessary for healthcare professionals. Patients reported no pain or discomfort and no side-effects were observed. The non-invasive nature of MIST therapy offers an easy to use debridement system for healthcare practitioners involved in wound management. The significant improvements to the wound bed in all four cases indicate that MIST offers a further advance in therapies available to treat long-term, chronic wounds. **WUK**

References

- Cutting K (2008) Optimal exudate management in a dressing. *J Community Nurs* 22(11): 21
- Ennis WJ, Foremann P, Mozen N (2005) Ultrasound therapy for recalcitrant diabetic foot ulcers: results of a randomised, double blind controlled multi-centre study. *Ostomy/Wound Management* 51(8): 24–39
- Kavros SJ, Schenck EC (2007) Use of noncontact low-frequency ultrasound in the treatment of chronic foot and leg ulcerations: a 51-patient analysis. *J Am Podiatr Med Assoc* 97(2): 95–101
- Kozak S, Goral J (2008) The effects of MIST Ultrasound Therapy on Inflammatory Responses of Macrophages, 2008 Poster Presentation at Midwestern University
- Lai JY, Pittelkow MR (2007) Physiological effect of ultrasound mist on fibroblasts. *Int J Dermatol* 46(6): 587–93
- Leidl DA, Kavros SJ (2001) The effect of mist ultrasound transport technology on cutaneous microcirculatory blood flow. Abstract. Presented at Symposium on Advanced Wound Care and Medical Forum, Florida, USA
- Moffatt CJ, Franks PJ, Doherty DC, et al (2004) Prevalence of leg ulceration in a London population. *Q J Med* 97: 431–7
- Posnett J, Franks PJ (2008) The burden of chronic wounds in the UK. *Nurs Times* 104(3): 44–5
- Thawer HA, Houghton P (2004) Effects of ultrasound delivered through a mist of saline to wounds in mice with diabetes mellitus. *J Wound Care* 13(5): 1–6
- Serena T, Lee SK, Lam K, Attar P, Menses P, Ennis W (2009) The impact of noncontact, nonthermal, low-frequency ultrasound on bacterial counts in experimental and chronic wounds. *Ostomy Wound Management* 55(1): 22–30
- Wound solutions (2010) Available online at: www.woundsolutions.com/market [last accessed 15.05.10]

Key points

- ▶▶ Chronic, non-healing wounds present many clinical challenges and cause a great deal of distress to patients.
- ▶▶ While the impact on patients' quality of life is difficult to quantify, the costs to the NHS are huge.
- ▶▶ MIST Therapy has been proven effective in wound healing, as the ultrasound penetrates into the hypodermis and stimulates the wound bed.
- ▶▶ The non-invasive element of MIST therapy offers an easy to use debridement system for healthcare practitioners involved in wound management.