Retrospective analysis of combined EMTT and ESWT for hard-to-heal lower extremity ulcers: a single-centre outcome study

Objective: Hard-to-heal (chronic) lower extremity ulcers represent a significant clinical challenge with substantial morbidity and healthcare costs. Extracorporeal shockwave therapy (ESWT) has emerged as a promising adjunctive treatment modality for hard-to-heal wounds, though evidence for combined electromagnetic transduction therapy (EMTT) and ESWT remains limited. The aim of this study was to describe wound healing and pain outcomes associated with combined EMTT and ESWT, used as an adjunct to standard of care (SoC), in patients with hard-to-heal lower extremity ulcers, and to investigate whether the outcomes warrant further prospective study.

Method: This retrospective chart review analysed consecutive patients with hard-to-heal post-Mohs excisional lower extremity wounds that had failed primary closure after four weeks of SoC, treated with combined Storz Medical AG EMTT (Storz Medical AG, Switzerland) and ESWT using the Storz Medical AG ESWT with C-ACTOR device (Storz Medical AG, Switzerland) between December 2025 and March 2026. All patients received twice-weekly treatments for four weeks (eight treatments in total). Ankle–brachial pressure index (ABPI) was measured at baseline to assess arterial perfusion. Following completion of shockwave therapy, all patients underwent surgical debridement and received standardised wound dressings consisting of non-adherent foam, gauze and Conforming Stretch Gauze Bandage (Medline, US). Primary outcomes included wound surface area (WSA) reduction at weeks 4 and 8, time to complete wound closure, and pain scores at baseline, at week 4 and at wound closure.

Results: The cohort consisted of 15 patients (mean age: 82.2±7.1 years; 66.7% female; 80.0% White; 20.0% Hispanic). Mean baseline ABPI was 1.05±0.13 (range: 0.82–1.33). Mean WSA decreased from 2.89±1.08cm² at baseline to 0.88±0.93cm² at week 4 ($p<0.001$), representing a 69.5% reduction. A total of 13 patients (86.7%) achieved complete wound closure, with a mean time to closure of 5.2±1.3 weeks (range: 3–8 weeks). Visual analogue pain scores decreased from 8.1±1.2 at baseline to 2.3±0.9 at week 4 ($p<0.001$), representing a 71.9% reduction in pain severity. All patients who achieved complete wound closure reported complete pain resolution. All patients completed the full eight-treatment protocol without reported adverse events.

Conclusion: In this small, retrospective, uncontrolled, single-centre case series of 15 patients, combined EMTT/ESWT used as an adjunct to SoC was associated with wound closure (86.7%) and positive pain outcomes (71.9% reduction). Because the study lacked a comparator group, randomisation and blinding, these findings should be interpreted as a preliminary hypothesis rather than as evidence of efficacy. They warrant confirmation in prospective controlled studies.

Declaration of interest: KK is a consultant and scientific advisor for Curamedix, Lincoln, RI, US, and Storz Medical AG,Tägerwilen, Switzerland. EJL declares no conflicts of interest.

electromagnetic transduction • energy • shockwave • ulcers • lower extremity • therapeutics • wound • wound care • wound dressing • wound healing

Hard-to-heal (chronic) lower extremity ulcers affect approximately 0.3% of the global population and represent a major burden on healthcare systems worldwide.[1] These wounds are associated with significant morbidity, impaired quality of life (QoL) and substantial treatment costs. Traditional management strategies including compression therapy, wound dressings and surgical debridement often result in prolonged healing times and high recurrence rates.[2]

Extracorporeal shockwave therapy (ESWT) has emerged as a novel adjunctive treatment modality for hard-to-heal wounds. The proposed mechanisms of action include promotion of angiogenesis, recruitment of mesenchymal stem cells, enhanced cell proliferation and differentiation, anti-inflammatory effects and modulation of pain pathways.[3–6] Systematic reviews have demonstrated that ESWT significantly improves wound healing rates and reduces healing time in diabetic foot ulcers (DFUs) and other hard-to-heal wounds.[7–9]

Electromagnetic transduction therapy (EMTT) represents another emerging modality that may enhance wound healing through stimulation of cellular proliferation, migration and inflammatory pathway modulation.[10,11] The combination of EMTT and ESWT may provide synergistic effects on wound healing, though clinical evidence remains limited.[10,12]

This retrospective study aimed to describe the wound healing and pain outcomes associated with combined EMTT and ESWT, delivered as an adjunct to standard of

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care (SoC), in a cohort of patients with hard-to-heal lower extremity ulcers. Given the retrospective and uncontrolled design, the analysis was intended to characterise a preliminary hypothesis for prospective investigation rather than to establish efficacy.

Methods

Ethical approval and patient consent

This study was a retrospective review of existing, deidentified clinical records, and, as such, was determined to be exempt from institutional review board oversight as secondary research under the US 45 Code of Federal Regulations (CFR) part 46.104(d)(4). Specifically, the analysis met the criterion at 45 CFR 46.104(d)(4)(ii), in that the information was recorded by the investigators such that the identity of the human patients could not readily be ascertained, the investigators did not contact the patients, and the investigators did not reidentify patients. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki, and all data were handled in compliance with applicable US Health Insurance Portability and Accountability Act (HIPAA) and data-protection requirements.

Study design and patient population

This retrospective chart review included consecutive patients with hard-to-heal lower extremity ulcers treated with combined EMTT and ESWT at a single outpatient wound care centre (West Boca Center for Wound Healing, Coconut Creek, FL, US) between December 2025 and March 2026. All wounds were post-Mohs excisional surgical wounds that had failed to heal, defined as failure to achieve primary closure after four weeks of SoC therapies. This uniform aetiology reduces the wound type heterogeneity common to wound healing case series and establishes that all wounds were refractory to an initial course of SoC prior to biophysical therapy.

Inclusion criteria were:

- A hard-to-heal post-Mohs excisional lower extremity wound that had failed primary closure after four weeks of SoC
- Completion of the full eight-treatment protocol
- Availability of complete outcome data including wound measurements and visual analogue scale (VAS) pain scores.

Exclusion criteria were:

- Active infection requiring systemic antibiotics at treatment initiation
- Critical limb ischaemia (ankle–brachial pressure index (ABPI) <0.40)
- Pregnancy.

Wound depth, presence of exposed tendon or bone, and additional comorbidities such as neuropathy, renal disease, smoking status, and immunosuppression were not uniformly recorded in the medical record and could not be abstracted; this residual heterogeneity is acknowledged as a limitation.

Baseline assessment

All patients underwent comprehensive baseline evaluation including:

- Demographic data collection (age, sex, race)
- Wound location
- Measurement of wound surface area (WSA; cm^2)
- ABPI measurement to assess arterial perfusion
- VAS pain assessment (0–10 scale, where 0=no pain and 10=worst pain imaginable).

Treatment protocol

All patients received combined EMTT and ESWT during each treatment visit. The two modalities are distinct: EMTT delivers high-energy electromagnetic pulses (not mechanical shockwaves) via a magnetic applicator, whereas ESWT delivers focused acoustic (mechanical) shockwaves via a separate shockwave applicator. EMTT was delivered using the Storz Medical MAGNETOLITH system, and focused ESWT was delivered using the Storz Medical device with the C-ACTOR applicator (both Storz Medical AG, Switzerland). Accordingly, the parameter counts below are expressed as electromagnetic pulses for EMTT and as shockwave impulses for ESWT. Treatment was administered twice weekly for four weeks, totalling eight treatment sessions.

EMTT parameters (electromagnetic pulses):

- Number of pulses: 4000 per treatment session
- Intensity level: 8
- Frequency: 8Hz.

ESWT (focused shockwave) parameters (acoustic shockwave impulses):

- Energy flux density: $0.13 mJ/mm^2$
- Frequency: 4.5Hz
- Number of shocks: 1000 per treatment session
- Application area: periwound tissue and wound surface.

Infection control

To prevent device contamination and maintain a sterile technique, the Storz C-ACTOR applicator was protected using 3M Steri-Drape, 1010 (Solventum Corp., US) during all treatment sessions. This barrier method allowed for direct application of therapeutic energy while preventing contact between the device and the wound bed.

Surgical (sharp) debridement of the wound bed to remove nonviable tissue was performed after completion of the full eight-treatment EMTT/ESWT protocol; debridement was not performed during the four-week treatment course. Week 4 WSA measurements were obtained at the final treatment visit prior to the post-protocol debridement, therefore week 4 measurements reflect the wound state before surgical debridement. SoC was implemented for all patients, consisting of:

- Non-adherent foam dressing as primary layer
- Gauze as secondary layer
- Conforming Stretch Gauze Bandage (Medine, US)
- Self-adherent wrap as outer layer.

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Dressings were changed at least twice weekly, in conjunction with each treatment visit, and wounds were monitored weekly for healing progression. Additional wound-specific care was provided according to clinical need and could include: offloading and pressure redistribution; oedema control; infection management; and glycaemic and nutritional optimisation. Notably, compression therapy was deliberately not used in any patient. Although all patients had CVI, compression was intentionally withheld so that any wound healing response could be attributed to the combined EMTT/ESWT protocol and local SoC rather than to compression-driven resolution of the venous component. This design choice allowed the biophysical intervention to be evaluated on its own, at the cost of not reflecting guideline-concordant venous ulcer management, in which compression is standard. Because the remaining adjunctive measures were applied on an individualised SoC basis rather than by protocol, their use was not uniformly standardised across patients. As discussed in the Limitations section, these cointerventions, together with the post-protocol debridement, may contribute meaningfully to the observed healing outcomes and cannot be disentangled from the independent effect of EMTT/ESWT in this uncontrolled design.

Outcome measures

Primary outcomes included:

- WSA (cm²) measured at baseline, week 4 and week 8
- Time to complete wound closure (weeks)
- VAS pain scores at baseline, at week 4 and at wound closure.

Secondary outcomes included:

- Percentage of patients achieving complete wound closure
- Percentage reduction in WSA at week 4
- Percentage reduction in VAS pain scores at week 4
- Adverse events (AEs) related to EMTT/ESWT treatment.

Table 1 shows the patient-level dataset.

Statistical analysis

Descriptive statistics were calculated for all variables. Continuous variables are presented as mean±standard deviation (SD), with ranges where appropriate. Categorical variables are presented as frequencies and percentages.

For continuous outcome measures (WSA and VAS pain scores), paired t-tests were used to compare baseline values with week 4 measurements. The Shapiro–Wilk test was performed to assess normality of data distribution. For non-normally distributed data, the Wilcoxon signed-rank test was used as a non-parametric alternative.

Percentage reduction in WSA was calculated as:

((Baseline WSA – Week 4 WSA) / Baseline WSA) × 100

Percentage reduction in VAS pain scores was calculated as:

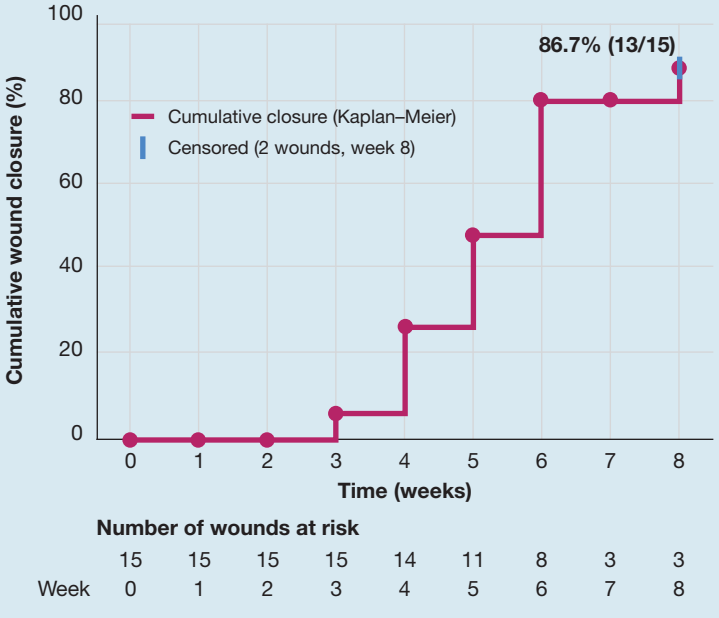
((Baseline VAS – Week 4 VAS) / Baseline VAS) × 100
where VAS=VAS pain score.

Time to complete wound closure was analysed using Kaplan–Meier survival analysis, with wounds that did not achieve complete closure by week 8 censored at their last follow-up visit.

Pearson correlation coefficients were calculated to assess relationships between baseline ABPI and wound healing outcomes, as well as between baseline wound size and time to closure.

Statistical significance was set at $p<0.05$ (two-tailed). All statistical analyses were performed using SPSS version 27.0 (IBM Corp., US). Given the small, uncontrolled sample (n=15), p-values comparing baseline with follow-up are reported as exploratory only and are not intended to support causal inference; emphasis is placed on descriptive patient-level outcomes, effect sizes and confidence intervals. The Kaplan–Meier analysis is presented as a cumulative closure estimate; a Kaplan–Meier closure curve with the number at risk at each timepoint is provided in Fig 1.

Fig 1. Kaplan–Meier estimate of cumulative wound closure based on confirmed complete re-epithelialisation (n=15). The number of wounds at risk is shown at each weekly timepoint. Cumulative closure reached 86.7% (13/15) by week 8. The two wounds not achieving confirmed closure by week 8 were censored at week 8; both subsequently achieved confirmed complete closure by week 12



Results

Patient characteristics

The study cohort consisted of 15 patients with a mean age 82.2±7.1 years (range: 69–92 years). The majority were female (66.7%, n=10) and White (80.0%, n=12), with 20.0% (n=3) identified as Hispanic. Ulcers were

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Table 1. Patient-level dataset (all patients had post-Mohs excisional, hard-to-heal wounds)

Patient	Wound side	Sex	Age, years	Race	Type 2 diabetes	Hypertension	Chronic venous insufficiency	ABPI	Baseline wound area, cm²	Week 4 wound area, cm²	Week 8 wound area, cm²	Closure status	Confirmed closure week	C-ACTOR treatments	VAS baseline	VAS week 4
1	Right	F	92	W	No	Yes	Yes	0.99	4.2	3.1	0	Not closed	—	8	8	4
2	Left	F	85	W	Yes	Yes	Yes	1.04	2.6	0	0	Closed	4	8	9	3
3	Left	M	78	W	No	Yes	Yes	1.1	5.7	0.5	0	Closed	5	8	8	3
4	Right	F	90	W	No	Yes	Yes	1.03	3.2	0.3	0	Not closed	—	8	8	2
5	Right	F	83	H	Yes	Yes	Yes	0.92	3.3	1.2	0	Closed	6	8	10	3
6	Left	F	88	W	Yes	Yes	Yes	0.96	2.2	0	0	Closed	4	8	9	3
7	Left	M	69	W	Yes	Yes	Yes	0.82	1.5	0	0	Closed	3	8	7	2
8	Right	F	73	W	No	Yes	Yes	1.2	2.26	0	0	Closed	4	8	6	1
9	Left	F	81	W	Yes	Yes	Yes	1.14	2.1	0.4	0	Closed	5	8	6	1
10	Right	M	72	H	Yes	Yes	Yes	1.33	2.8	0.9	0	Closed	5	8	8	2
11	Right	F	79	W	No	Yes	Yes	1.03	2.4	1.3	0	Closed	6	8	8	1
12	Left	F	82	W	No	Yes	Yes	1.12	2.3	0.8	0	Closed	6	8	7	1
13	Right	M	91	W	Yes	Yes	Yes	0.89	3.2	2.1	0	Closed	8	8	9	2
14	Right	M	82	W	Yes	Yes	Yes	0.99	2.87	1.1	0	Closed	6	8	9	3
15	Left	F	88	H	Yes	Yes	Yes	1.21	2.66	1.5	0	Closed	6	8	9	4
Mean/n			**82.2**		**Type 2 diabetes (n=9)**			**1.05**	**2.89**	**0.88**		**13/15**			**8.1**	**2.3**

ABPI—ankle–brachial pressure index; C-ACTOR—Storz Medical device with the C-ACTOR applicator (Storz Medical AG, Switzerland); F—female; H—Hispanic; M—male; VAS—visual analogue scale for pain; W—White

distributed between right (53.3%, n=8) and left (46.7%, n=7) lower extremities. All 15 wounds were post-Mohs excisional surgical wounds that had failed primary closure after four weeks of SoC. Every patient had hypertension and CVI, and nine (60.0%) patients had type 2 diabetes.

Mean baseline ABPI was 1.05±0.13 (range: 0.82–1.33), indicating adequate arterial perfusion in the majority of patients. One patient had an ABPI of 0.82, suggesting mild peripheral artery disease (PAD), while another patient had an ABPI of 1.33, potentially indicating arterial stiffness or medial arterial calcification.

Wound healing outcomes

Mean WSA at baseline was 2.89±1.08cm² (range: 1.5–5.7cm²). Following four weeks of treatment, mean WSA decreased significantly to 0.88±0.93cm² (range: 0–3.1cm²), representing a 69.5% mean reduction in wound size (exploratory p<0.001, paired t-test). The mean absolute reduction in WSA was 2.01±0.98cm² (95% confidence interval (CI): 1.47cm², 2.55cm²).

For this analysis, complete wound closure was defined as 100% re-epithelialisation of the wound with no drainage, confirmed on clinical examination; a recorded WSA of 0cm² at a given visit was taken to represent complete re-epithelialisation at that visit. Individual patient WSA reduction at week 4 ranged from 26.2–100.0%, with 10 (66.7%) patients achieving ≥50% WSA reduction. A WSA of 0cm² at the week 4 visit was recorded in four (26.7%) patients (Patients 2, 6, 7 and 8); consistent with the closure definition above, all four were counted as confirmed closures, one at week 3 and three at week 4. This accounts for the relationship between the number of wounds with a week 4 WSA of 0cm² and the confirmed closures shown in the closure-timing distribution below.

Complete wound closure was achieved in 13 of 15 patients (86.7%; 95% CI: 59.5%, 98.3%). Among patients who achieved closure, the mean time to complete healing was 5.2±1.3 weeks (range: 3–8 weeks; median 6 weeks). The distribution of healing times was as follows:

- Week 3: 1 patient (6.7%)
- Week 4: 3 patients (20.0%)
- Week 5: 3 patients (20.0%)
- Week 6: 5 patients (33.3%)
- Week 8: 1 patient (6.7%).

By week 8, two patients (13.3%; Patients 1 and 4) did not achieve confirmed complete re-epithelialisation and so were counted as not closed. Both nonetheless demonstrated WSA reduction over the study period, with week 4 WSA reductions of 26.2% and 90.6% from baseline, respectively; although their week 8 residual WSA approached zero on measurement, complete re-epithelialisation was not confirmed, and they were therefore censored rather than counted as closures.

Based on confirmed complete re-epithelialisation, Kaplan–Meier analysis demonstrated a cumulative closure probability of 6.7% by week 3, 26.7% by week 4, 46.7% by week 5, 80.0% by week 6, and 86.7% by week 8, with the two wounds that did not achieve confirmed closure (Patients 1 and 4) censored at week 8 (Fig 1). The four wounds with a recorded WSA of 0cm² at the week 4 visit were all counted as confirmed closures within this estimate, and so the cumulative week 4 closure figure (26.7%, 4 of 15) is concordant with the number of week 4 zero-area wounds.

There was no significant correlation between baseline wound size and time to closure (Pearson r=0.18; p=0.54), suggesting that larger wounds did not necessarily require longer healing times. Similarly, baseline ABPI did not significantly correlate with wound healing outcomes (r=0.12; p=0.67).

Pain outcomes

VAS pain scores demonstrated substantial and statistically significant improvement throughout the treatment course. Mean baseline VAS score was 8.1±1.2 (range: 6–10), indicating severe pain. By week 4, mean VAS score decreased to 2.3±0.9 (range: 1–4; exploratory p<0.001, paired t-test), representing a 71.9% mean reduction in pain severity (95% CI: 64.2%, 79.0%). The mean absolute reduction in VAS score was 5.8±1.1 points (95% CI: 5.2, 6.4 points).

All 15 (100.0%) patients experienced clinically meaningful pain reduction (defined as a ≥2-point decrease on the VAS scale) by week 4. Furthermore, all patients who achieved complete wound closure reported complete pain resolution (VAS=0) at the time of closure.

There was a significant positive correlation between WSA reduction and VAS pain score reduction at week 4 (Pearson r=0.68; p=0.005), indicating that greater wound healing was associated with greater pain relief.

Safety

All 15 (100.0%) patients completed the full eight-treatment protocol without discontinuation. No AEs related to EMTT/ESWT treatment were documented in the medical records, including no reports of treatment-related pain exacerbation, bleeding, infection, skin breakdown or other complications. No patients required hospitalisation or additional interventions due to treatment-related AEs during the study period.

Discussion

This retrospective chart review clinical paper describes encouraging outcomes associated with combined EMTT and ESWT, used as an adjunct to SoC, in patients with hard-to-heal lower extremity ulcers. Given the retrospective, uncontrolled design, these outcomes should be interpreted as preliminary hypotheses rather than definitive evidence of efficacy. The independent contributions of the intervention to wound closure, time to healing, pain reduction, recurrence and patient-reported outcomes cannot be determined from this study and remain to be defined. With that framing,

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the 86.7% complete-closure rate and the observed pain reduction (71.9%) are consistent with the range reported in the published ESWT wound healing literature,[9,11,12] and represent a clinically meaningful signal worthy of prospective evaluation.

The treatment parameters used in this study (ESWT at 0.13mJ/mm², 4.5Hz, 1000 shocks; EMTT at 4000 shocks, level 8, 8Hz) fall within the range of energy densities reported in the literature for hard-to-heal wound treatment. Published studies have used ESWT energy densities ranging from 0.08–0.58mJ/mm², with frequencies between 4–8Hz, demonstrating efficacy across this spectrum.[4,5] The wound healing outcomes align with systematic reviews demonstrating that ESWT significantly improves healing rates in hard-to-heal wounds. A 2024 meta-analysis of ESWT for DFUs reported a risk ratio of 1.57 for complete healing compared to controls,[6] while a 2017 systematic review found that ESWT increased wound healing rates by 1.86-fold and reduced healing time by 19 days.[2] The 69.5% reduction in WSA at four weeks and 86.7% complete closure rate observed in the present study are consistent with, and in some cases exceed, these findings.

The reduction in WSA from baseline to week 4 (exploratory $p<0.001$) was observed in the context of a combined EMTT/ESWT protocol delivered alongside SoC; because the design was uncontrolled, this change cannot be attributed to the intervention alone. The mean absolute reduction of 2.01cm² nonetheless represents a substantial descriptive improvement, particularly given the hard-to-heal nature of these wounds. The finding that 66.7% of patients achieved ≥50% WSA reduction by week 4 is noteworthy, as this threshold is often used as a predictor of eventual complete healing in hard-to-heal wound studies.[13]

The addition of EMTT to the treatment protocol represents a novel aspect of this study. Electromagnetic field therapy has been shown to modulate cellular proliferation, migration and inflammatory pathways, potentially providing complementary mechanisms to ESWT.[10–12] The high-frequency electromagnetic pulses (8Hz) delivered at level 8 intensity may enhance the angiogenic and regenerative effects of mechanical shockwaves through upregulation of vascular endothelial growth factor and mitogen-activated protein kinase pathways,[6] though the specific contribution of EMTT to the observed outcomes cannot be isolated in this retrospective analysis. It should be emphasised that the wound-specific clinical evidence base for ESWT is considerably more developed than that for EMTT, for which the wound healing evidence in humans remains limited and is largely extrapolated from musculoskeletal applications. Any synergy between the two modalities is therefore best regarded as biologically plausible and hypothesis-generating rather than established, and the present uncontrolled data cannot confirm an additive or synergistic effect.

The substantial pain reduction observed in this study (mean decrease of 5.8 points on the VAS scale; exploratory $p<0.001$) represents an important clinical benefit beyond wound healing. Hard-to-heal wound-related pain significantly impairs QoL, and the rapid pain relief achieved with EMTT/ESWT may reflect both direct analgesic effects of shockwave therapy through modulation of nociceptive pathways and improved wound healing with reduction of inflammatory mediators. The significant positive correlation between WSA reduction and pain reduction ($r=0.68$; $p=0.005$) supports the hypothesis that pain relief is at least partially mediated by improved wound healing, though direct neurological effects of shockwave therapy cannot be excluded.

The mean time to complete wound closure of 5.2 weeks in this study compares favourably with published literature. Omar et al.[4] reported a mean healing time of 64.5 days (approximately nine weeks) in ESWT-treated DFUs, while the present study cohort achieved healing in approximately five weeks. This difference may reflect the combined EMTT/ESWT approach, the specific patient population, or the integration of surgical debridement following shockwave therapy.

The use of the 3M Steri-Drape as a barrier between the treatment applicator and the wound bed represents an important infection control measure. This approach allows for direct energy transmission while preventing device contamination and maintaining an aseptic technique, which is critical when treating open wounds. No wound infections or treatment-related complications were observed in this cohort, supporting the safety and feasibility of this barrier method.

The baseline ABPI measurements in this cohort (mean: 1.05±0.13) indicate that most patients had adequate arterial perfusion, which is an important consideration for wound healing potential. Current guidelines recommend ABPI assessment in all patients with hard-to-heal lower extremity ulcers to identify those with PAD who may require revascularisation.[14] The lack of significant correlation between baseline ABPI and wound healing outcomes ($r=0.12$; $p=0.67$) suggests that within the range of adequate perfusion (ABPI: 0.8–1.3), arterial flow did not limit the effectiveness of EMTT/ESWT therapy. However, this finding should be interpreted cautiously given the small sample size and the exclusion of patients with critical limb ischaemia.

The inclusion of surgical debridement following EMTT/ESWT treatment and standardised wound dressings represents best practice wound care and likely contributed to the favourable outcomes observed. The temporal sequence of shockwave therapy followed by debridement may optimise wound bed preparation by first stimulating cellular proliferation and angiogenesis, then removing nonviable tissue to allow for re-epithelialisation.

Limitations

This study has several important limitations that must be acknowledged. As a small, retrospective, uncontrolled

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clinical chart review, it does not establish efficacy. It is important to distinguish between efficacy (the effect of an intervention under controlled experimental conditions), effectiveness (performance under real-world clinical conditions), and an early clinical signal—the present data, at most, provide preliminary hypotheses. The retrospective design and absence of a control group, sham comparator, randomisation and blinding limit causal inference. Without a comparison group receiving SoC alone, it is impossible to definitively attribute the observed outcomes to EMTT/ESWT therapy versus the natural wound healing trajectory or the effects of concurrent cointerventions, including post-protocol surgical debridement, standardised dressings, offloading, oedema control, infection management, and glycaemic and nutritional optimisation, none of which were controlled or standardised by protocol (compression therapy was not used in any patient). Although the cohort was homogeneous with respect to wound aetiology (all post-Mohs excisional hard-to-heal wounds) and shared comorbidities (universal hypertension and CVI, with 60% having type 2 diabetes), other potentially relevant characteristics, including wound depth, wound duration and additional comorbidities, were not uniformly recorded, and the study was not powered for aetiology- or comorbidity-stratified analysis. The small sample size (n=15) limits statistical power and generalisability, and p-values are therefore reported as exploratory only. The single-centre design may have introduced selection bias and limited external validity.

Although the cohort was uniform in wound aetiology, the small sample size and absence of a comparator prevent subgroup analysis, including whether the 60% of patients with type 2 diabetes responded differently to those without. The combined EMTT/ESWT protocol prevents determination of the individual contribution of each modality to the observed outcomes. A factorial design comparing EMTT alone, ESWT alone, combined therapy, and SoC would be needed to elucidate synergistic effects.

A deliberate design decision in this series warrants specific comment. Although every patient carried a diagnosis of CVI, compression therapy was intentionally withheld. This was done to avoid confounding the outcomes with compression-driven healing of the venous component, so that any observed wound healing response could be more clearly associated with the combined EMTT/ESWT protocol and local wound care. The trade-off was twofold. First, this approach does not reflect guideline-concordant management of venous disease, in which compression remains the SoC; the results should therefore not be read as an argument against compression or as evidence that biophysical therapy should replace it. Second, and importantly, these findings should not be interpreted to mean that EMTT/ESWT alone can treat underlying venous disease or serve as monotherapy for venous leg ulcers (VLUs). The role of the venous component in these post-Mohs excisional wounds cannot be isolated from this study, and no conclusion about the treatment of venous pathology itself can be drawn. Determining whether combined EMTT/ESWT confers benefit specifically in cases of venous ulcer, and how it compares or combines with compression, would require dedicated prospective trials enrolling a defined subset of patients with VLUs, ideally comparing biophysical therapy plus compression against compression alone.

The relatively short follow-up period (maximum eight weeks) does not capture long-term outcomes, such as recurrence rates, which are critical for assessing the durability of wound healing. The lack of blinding and potential for selection bias inherent in retrospective studies must be acknowledged. Additionally, the older patient population (mean age 82.2 years) may limit generalisability to younger patient cohorts.

Future directions

Prospective randomised controlled trials are needed to definitively establish the efficacy of combined EMTT and ESWT in the treatment of hard-to-heal lower extremity ulcers. Future studies should include: appropriate control groups receiving SoC alone; separate treatment arms for EMTT alone and ESWT alone to determine individual and synergistic effects; longer follow-up periods (minimum 6–12 months) to assess durability of healing and recurrence rates; stratification by wound aetiology and severity to identify optimal patient selection criteria; standardised treatment protocols with clearly defined parameters; patient-reported outcome measures beyond pain scores, including QoL assessments; and cost-effectiveness analyses, given the resource-intensive nature of hard-to-heal wound management.

Additionally, investigation of optimal treatment parameters (energy density, frequency, number of shocks, treatment intervals) for different wound types would help establish evidence-based protocols. Mechanistic studies examining biomarkers of angiogenesis, inflammation and tissue regeneration, before and after EMTT/ESWT therapy, would provide valuable insights into the biological mechanisms underlying clinical improvements.

Conclusions

In this small, retrospective, uncontrolled, single-centre chart review of 15 patients with hard-to-heal lower extremity ulcers, combined EMTT and ESWT used as an adjunct to SoC was associated with encouraging wound closure and pain outcomes. The treatment protocol used specific parameters with appropriate infection control measures. Complete wound closure was achieved in 86.7% of patients; WSA decreased by 69.5% at week 4 and VAS pain scores decreased by 71.9% at week 4. The protocol was well tolerated, with no treatment-related AEs recorded. Because the study lacked a comparator group, randomisation and blinding, and cannot separate the intervention from

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concurrent SoC, these findings should be interpreted as a preliminary hypothesis rather than as evidence of efficacy. They warrant confirmation in prospective controlled studies that include appropriate control arms, separate EMTT and ESWT arms to define the individual and combined contributions of each modality, wound aetiology stratification, and longer follow-up to assess durability and recurrence. JWC

Reflective questions

- Describe the rationale and treatment protocol for combining electromagnetic transduction therapy (EMTT) with extracorporeal shockwave therapy (ESWT) in hard-to-heal lower extremity ulcers.
- Interpret the wound healing and pain outcomes reported in this study.
- Evaluate the methodological limitations that constrain the conclusions of this study.

AI statement of use

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