

Pilot study using EMTT and Focused ESWT post-surgery on Bone Healing: a matched analysis case-control study of foot and ankle procedures

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Purpose

To determine if adding EMTT and ESWT therapies post-operatively improve healing rates and patient outcomes.

Introduction

- The overall incidence of non-unions in the body is estimated to be about 5-10%, but according to some authors, could be as high as 50%.¹ In the foot and ankle, non-union rates have been reported between 1% and 27%, which varies based on the location and type of fracture or surgery.^{2,3}
- Osseous complications prolong the post-operative course and can delay return to work or sport. Additionally, factors such as chronic pain and the potential need for revisional surgery can impact a patient's financial, emotional, and social well-being.¹
- It was estimated that the annual costs of managing delayed fracture healing in the United States is around \$14.6 million.²
- There is a need for supplemental, low-risk, non-operative/non-invasive treatment modalities that can be implemented post-operatively that
 - (1) improve bone healing further minimizing the risk of developing a delayed union or non-union
 - (2) reduce pain and swelling thereby decreasing demand for narcotics.
- EMTT**
 - EMTT is a promising new, non-invasive, therapy which is a form of PEMF (pulsed electromagnetic magnetic field).⁵
 - EMTT was developed with a significantly greater magnetic field strength compared to PEMF, ranging between 80 to 150mT, and an increased impulse release frequency of 3Hz with an oscillation frequency greater than 100KHz.⁵ Additionally, EMTT has a shorter duration of the impulses which allows for an electrophysiological reaction to take place without increasing tissue temperature.⁶
 - The scientific premise of EMTT is based on the principle of electroporation and piezoelectric effects.^{7,8}
 - This electromagnetic energy can help facilitate the binding of calcium to calmodulin, which in turn, stimulates nitric oxide release and secretion of growth factors.⁹ Nitric oxide release not only increases blood vessel diameter, attracts immune cells, and mediates osteoblast/osteoclast differentiation; it also helps mediate inflammation, angiogenesis, and tissue remodeling.¹⁰
 - Increased expression of collagen I, alkaline phosphatase, and VEGF, which act as inducers of osteogenesis and angiogenesis.⁷
- Focused ESWT**
 - Focused ESWT (fESWT) is another non-surgical treatment option that has been shown to improve bone and soft tissue healing.
 - "single-impulse acoustic wave with high amplitude and short durations which convert electrical energy to mechanical energy".¹¹
 - fESWT is thought to promote bone healing by inducing microfracture of sclerotic bone ends and producing microfissures, thereby enhancing the blood supply to the tissue.¹¹
 - Production of small fragments of bone stimulates osteogenesis, promoting union at the fracture site.¹¹
 - Shown to stimulate cells and the extracellular matrix to induce the expression of angiogenic and osteogenic factors.¹²
 - Stimulates bone regeneration and repair through activation of angiogenic factors, integrin, and expression of BMP and TGF-beta, as well as promote neovascularization which are important for providing nutrients and oxygen required for the growth and function of reparative cells.^{13,14}
 - Other important growth and tissue repair factors that ESWT has been shown to impact include VEGF, IGF-1, TGF-beta, EGF, FGF, PDGF, PCNA, vWF, eNOS, free radicals, osteocalcin, and osteogenic growth factors.^{13,15}
 - Stimulate nociceptive c-fibers and substance P, which play a role in analgesia.¹⁶
- Some studies have shown that they can be used together and have synergistic effects to potentially provide additional clinical benefits and improve tissue healing.¹⁷

Methods

Subjects

- 24 subjects total (14F; 10M), 12 controls and 12 interventions
- Average age of control group: 48.3±15.2 years.
- Average age of intervention groups: 45.6±22.9 years.
- 18 patients who identified as "White/Non-Hispanic", two "Hispanic", two "Asian", and one each "Black/Non-Hispanic" and another as "Mixed".

Exclusions: Smokers, DM, Rheumatoid/Immunocompromised, revision cases, Worker's Comp/Industrial cases

Control group (12 patients): Contralateral limb or individuals with same procedure

Intervention group (12 patients)

- 1 session of focused ESWT ("Duolith™", Storz Medical AG, Tägerwil, CH)
 - Performed within 3 weeks of surgery/injury to surgical site
 - Up to 0.35mJ/mm²
- 2 sessions of EMTT ("Magnetolith™", Storz Medical AG, Tägerwil, CH)
 - Performed within 3 weeks of surgery/injury
 - 6000 pulses; 8 Hz, power level 8

Analysis

- Excel™ (Redmond, WA, USA and STAT SAK® (G Dallal, Andover, MA, USA). P&T
- 0.05 was required for Student's-T and Fisher's Exact tests, which were two-tailed.

Outcome measures:

- Primary: VAS score at time of weightbearing
- Secondary: Radiographic healing via plain radiographs by independent radiologist at 4 weeks post-index procedure and time to RTA

Results

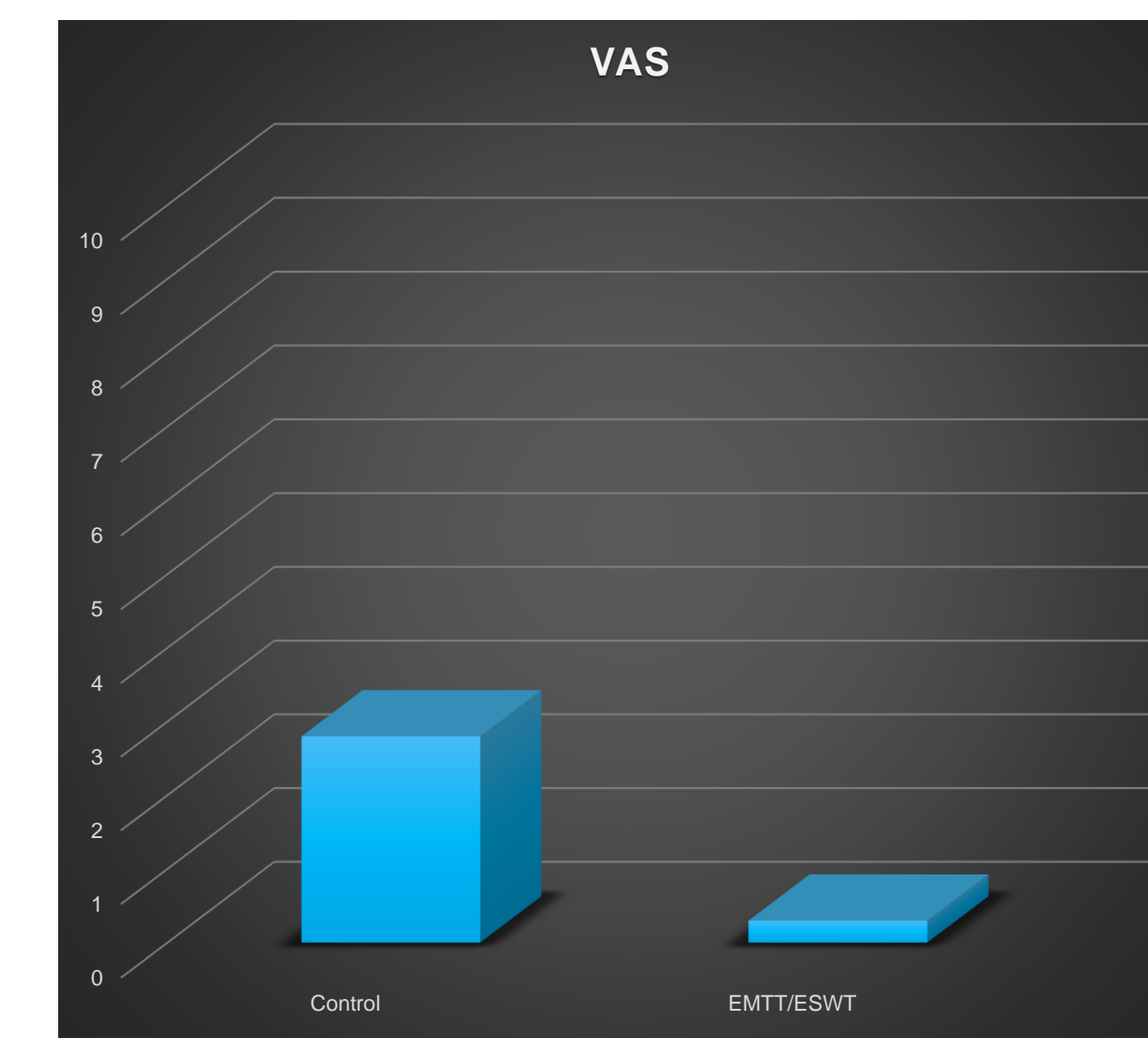
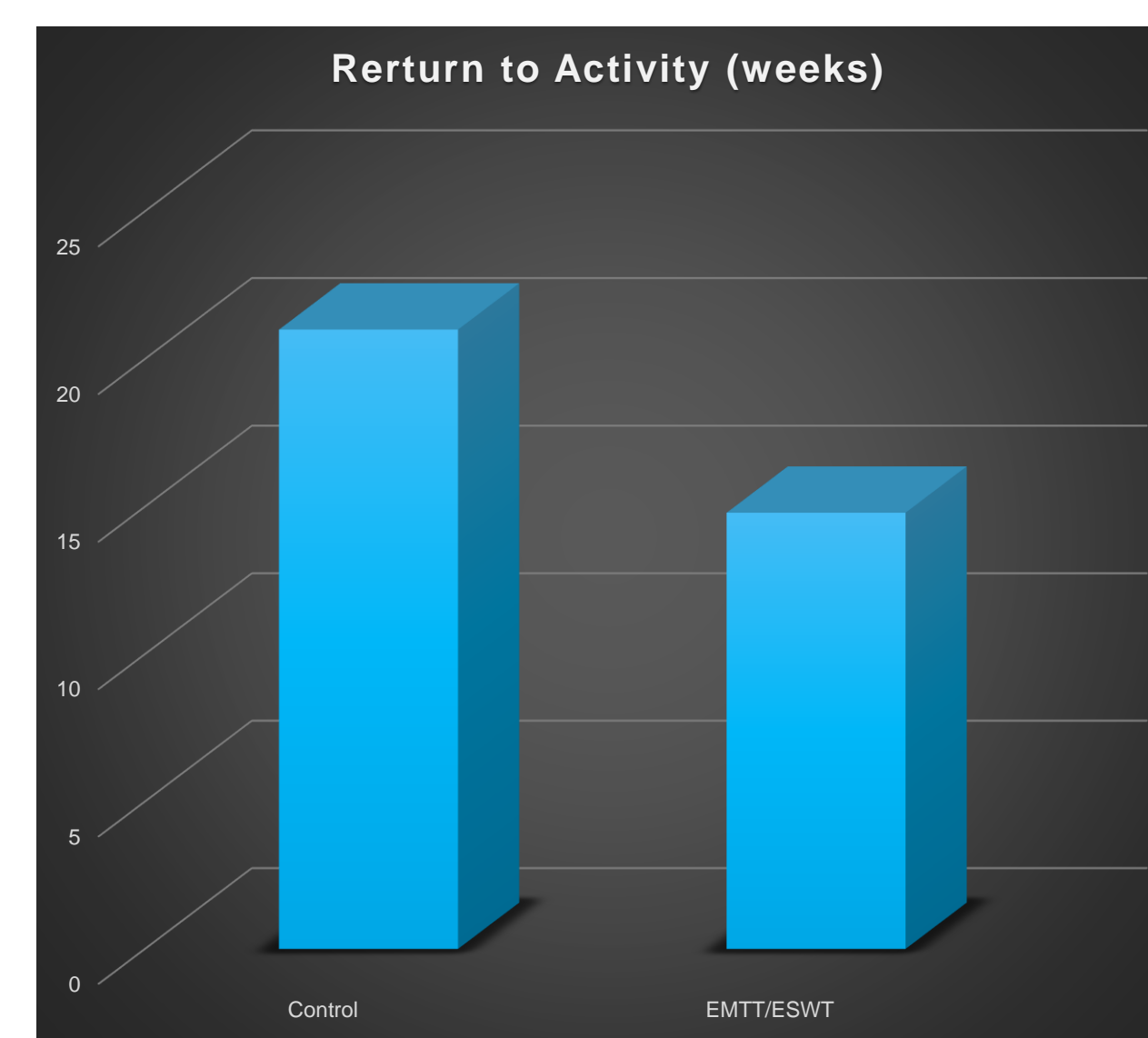
- Matched analysis on foot and ankle procedures from June 2022-April 2023
- There was no difference in age between the two groups, P=0.49.
- Average VAS scores post-treatment effect size between the controls (2.8±1.5) and intervention (0.3±0.9) groups was significantly better, 2.5 (1.4 to 3.6, 95%CI), P=.0001.
- Radiographic healing noted at four weeks during treatment between the controls (2/12) versus intervention (8/12) was significantly more for those who had EMTT, P=.04.
- Average RTA was faster by 6.2 weeks for the EMTT group, 14.8±4.5 weeks versus the controls, 21.0±9.0 weeks (0.18 to 12.2, 95%CI), P=.04.

Control Group

- 1-Talar microfracture
- 1-Fifth metatarsal fx ORIF
- 1-Medial malleolar fx ORIF
- 1-Midfoot fusion
- 1-Triple arthrodesis
- 1-Lapidus
- 2-Talar retrograde drilling
- 3-Ludloff osteotomy

Intervention Group

- 1-Talar retrograde drilling
- 1-Lapidus
- 1-Ludloff osteotomy
- 1-Fifth metatarsal fx ORIF
- 1-Midfoot fusion + triple arthrodesis
- 1-Triple arthrodesis
- 2-Talar microfractures
- 4-Medial malleolus fx ORIF



Pre-op Intervention



4 wks Post-op

Discussion

Outcome:

- Pain Reduction: Decreased pain levels in patients undergoing the combined therapy after ankle and foot procedures
- Accelerated Bone Healing: X-Ray four weeks post-procedure showed that the combined therapy positively impacts the healing process
- Quicker Return to Activity: Patients in the intervention group exhibited a significantly shorter time to return to activity (RTA) compared to the control group, highlighting the potential for a faster recovery and improved quality of life

Complementary Mechanisms

- EMTT and ESWT have complementary mechanisms of action, with EMTT promoting osteogenesis, angiogenesis, and inhibiting osteoclast formation, while ESWT enhances osteogenesis, blood supply, and angiogenesis, contributing to bone healing
- Non-Invasive and Side-Effect-Free: Both EMTT and ESWT are non-invasive therapies without known side effects, making them promising options for bone healing disorders

Reference to the current state of research:

- Our study aligns with prior research demonstrating the effectiveness of the combined EMTT and ESWT therapy in cases of non-unions, reinforcing its potential as a standard treatment option

Conclusions

- Significant Improvement:** The combination of EMTT and ESWT offers a promising therapeutic option, significantly enhancing bone healing outcomes after ankle and foot procedures
- Clinical Relevance:** The observed reductions in pain levels, accelerated bone healing, and quicker return to activity times underscore the clinical relevance of this non-invasive and side-effect-free treatment approach
- Reduced Healthcare Burden:** Faster healing times and improved outcomes can reduce the economic burden associated with prolonged healing, additional surgeries, and complications, benefiting both patients and healthcare systems
- Future Research:** Acknowledging the need for further research, particularly in optimizing stimulation protocols for different diagnoses and anatomical locations

The synergistic effects of Electromagnetic Transduction Therapy (EMTT) and Extracorporeal Shockwave Therapy (ESWT) represent a promising and non-invasive approach to significantly enhance bone healing and surgery, potentially revolutionizing the treatment landscape for orthopaedic patients undergoing ankle and foot procedures. Further research in these and other anatomic regions is warranted.

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