

Case Report

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Pulsed electromagnetic field therapy for the treatment of diabetic foot complications

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Abstract

Diabetic foot ulcers and neuropathy are significant complications of diabetes mellitus, leading to substantial morbidity. Conventional treatments can be challenging, necessitating the exploration of adjunctive therapies. Pulsed ElectroMagnetic Field (PEMF) therapy has emerged as a non-invasive modality with potential benefits in managing diabetic complications. This article describes a case report and reviews the evidence regarding the application of PEMF therapy in the treatment of diabetic foot ulcers and neuropathy. Clinical trials and preclinical studies suggest that PEMF therapy may reduce pain, improve wound healing rates, and enhance microcirculation in affected tissues.

Keywords: Diabetic foot ulcer; Pulsed electromagnetic field therapy; Infection.

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Introduction

Diabetes mellitus is a growing global health concern, with an estimated 37.3 million individuals affected in the U.S. in 2023 [1]. Type 2 diabetes mellitus, the most common form, is projected to affect approximately 366 million people worldwide by 2030 [1].

Diabetic foot disease is a common and serious complication of diabetes mellitus; it encompasses a range of foot problems, from mild symptoms to severe, potentially life-threatening infections and amputations. Diabetic foot disease develops because of several factors, including peripheral neuropathy (nerve damage), poor circulation, and a weakened immune system, which are all common in individuals with poorly controlled blood sugar levels [2]. The pathogenesis of diabetic foot disease involves a complex interaction between neuropathy, vascular disease, and altered immune function. The key components are peripheral neuropathy, peripheral Arterial Disease (PAD) and immune dysfunction.

The most common complication of diabetes, distal peripheral neuropathy (DPN), occurs when elevated blood glucose levels

damage the peripheral nerves. This damage reduces sensation in the feet, preventing individuals from detecting injuries, infections, or pressure ulcers. As a result, minor injuries can go unnoticed, leading to infections and potentially severe outcomes like gangrene or amputation [3,4].

Diabetes also leads to changes in the blood vessels, resulting in impaired circulation to extremities. PAD contributes to poor wound healing, decreased oxygen delivery to tissues, and an increased risk of infections. This vascular impairment is compounded by the thickening of the basement membrane of capillaries, which hinders nutrient and oxygen supply to the skin and subcutaneous tissues [5].

Diabetes also affects the immune system, impairing the body's ability to fight infections. Hyperglycemia leads to dysfunction in neutrophils and macrophages, which are crucial for immune response. As a result, individuals with diabetes are more prone to infections, and wounds are more likely to become infected and take longer to heal [6].

Several risk factors contribute to the development of diabetic foot disease. They include high blood sugar levels (damage of

blood vessels and nerves), duration of Diabetes and previous foot ulcers or amputations, smoking and obesity, foot deformities and inadequate foot care [3,4,7,8].

Diabetic foot disease can manifest in various ways, ranging from mild symptoms to severe complications. Patients may experience tingling, numbness, or a “burning” sensation in the feet. These symptoms occur due to nerve damage and can progress to complete loss of sensation in severe cases [9]. The most common and serious manifestation, diabetic foot ulcers (DFU), are open sores or wounds that develop on the feet, often because of minor injuries or pressure. These ulcers can become infected and, without proper treatment, may lead to more serious conditions, such as osteomyelitis (bone infection) or gangrene [9,10]. Foot infections are common in individuals with diabetes, especially in those with neuropathy. Symptoms of infection include redness, warmth, swelling, and discharge from a wound. In severe cases, the infection may spread, necessitating amputation [10,11]. Diabetic foot ulceration, which can result in amputations, increased healthcare costs, and mortality [1]. Managing DFUs remains a clinical challenge, highlighting the need for effective adjunctive therapies.

Pulsed ElectroMagnetic Field (PEMF) therapy has emerged as a potential non-invasive treatment option for addressing vascular complications and wound healing in the context of the diabetic foot [1]. In this article we describe a case report in which the use of PEMF therapy was necessary to obtain definitive tissue healing in a diabetic foot.

Case presentation

FGB, a 43-year-old man with a history of deep vein thrombosis due to Factor V Leiden mutation, comes to our attention for the onset of fever, redness of the forefoot, and necrosis of the fourth toe of the right foot in the absence of trauma (Figure 1). Blood tests reveal a blood glucose level of 464 mg/dL and a C-reactive protein (CRP) level of 312 mg/L. He undergoes emergency room CT angiography which does not show significant arterial obstructions (Figure 2). He is evaluated by the vascular surgeon who performs a plantar incision with drainage of purulent material (Figure 3), and empirical antibiotic therapy with ampicillin/sulbactam and clindamycin is initiated. The following day, in the operating room, surgical debridement is performed: dorsal incision with drainage of foul-smelling purulent material (sent for culture, positive for *Enterococcus faecalis* and *Bacteroides distasonis*), amputation of the necrotic fourth toe of the foot, resection of the head of the fourth metatarsal for decompression purposes, and revision of the plantar wound (Figure 4). A drain is placed and removed within the next 72 hours. Hypoglycemic and antihypertensive therapy is initiated due to the incidental finding of type II diabetes mellitus and arterial hypertension.

Antibiotic therapy is changed to daptomycin and metronidazole in the following days due to the appearance of a skin rash. After 10 days of surgery, due to wound dehiscence (Figures 5,6), a foot MRI is performed, revealing small fluid collections (Figure 7). Antibiotic therapy is modified by continuing daptomycin and adding meropenem.

Advanced wound care of the surgical wounds with Hydro-fiber dressing is initiated with local improvement (Figure 8),

and toe-touch weight-bearing with a heel shoe is allowed. One month after the surgery, according to the difficult soft tissue healing, local PEMF therapy (Biostim® IGEA SpA, Carpi (Mo), Italy) was indicated 8 hours/die for 40 days, during the daytime or night-time; the patient was to be alert to any undesirable events or symptoms including burning sensation or signs of skin rash, which would indicate immediate interruption of the treatment. The dedicated coil was placed on the foot and powered by the PEMF generator system, which delivers a pulsed signal with a peak magnetic field intensity of 2.5 ± 0.1 mT and a frequency of 75 Hz.

Advanced wound care continues. The plantar wound closed 50 days after surgery, while the dorsal wound closed at the end of treatment with Biostim®. The plantar wound closes 50 days after the surgery. A new MRI performed 3 months after the surgery showed no signs of osteomyelitis (Figure 9). At 4 months, there is complete resolution of the cutaneous condition (Figure 10). Free ambulation with footwear including a custom-made insole is resumed.



Figure 1: Foot presentation at emergency department.

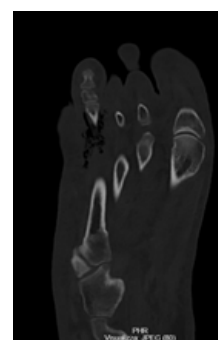


Figure 2: MCT angiography.



Figure 3: Plantar incision.



Figure 4: Surgical debridement.



Figure 5: Dorsal wound dehiscence.



Figure 6: Plantar wound dehiscence.

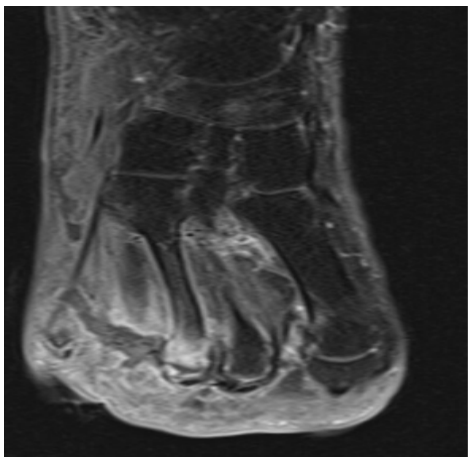
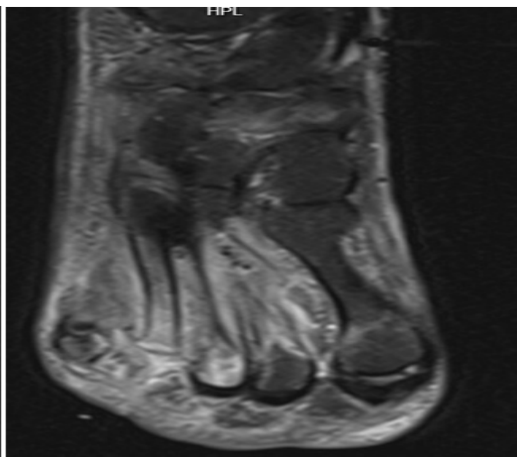


Figure 7: MRI 10 days after surgery (small fluid collections).



Discussion

Diabetic foot problems can often go unnoticed in the early stages due to the lack of pain perception, and this delayed diagnosis can lead to severe consequences. Therefore, it is essential to raise awareness, emphasize the importance of regular foot care, and understand the effective treatments and preventive measures available [12].

DPN is characterized by sensory alterations due to damage to myelinated and unmyelinated nerve fibers [1]. Degeneration of small unmyelinated fibers can cause foot pain, while larger fiber involvement leads to numbness and loss of protective sensation, increasing ulceration risk [13]. A double-blind, random-

ized, sham-controlled trial investigated the efficacy of PEMF therapy in reducing DPN-associated pain [1]. The study found that patients in the active PEMF arm showed a clinically significant 30% reduction in pain compared to the sham group [13]. Although not statistically significant, a trend towards improved skin perfusion pressure was observed in the active group [6]. The authors concluded that PEMF therapy appears effective as a non-pharmacologic approach for reducing pain in diabetic peripheral neuropathy and shows promise for enhancing vascular physiology in microcirculatory dysfunction associated with diabetic peripheral arterial disease (PAD) [1]. This suggests that PEMF therapy can be a valuable tool in managing the debilitating pain associated with DPN.



Figure 8: Local improvement after advanced wound care.



Figure 9: PMRI 3 months after the surgery (no signs of osteomyelitis).



Figure 10: Complete resolution of the cutaneous condition.

The mechanisms of action by which PEMF promotes healing and pain reduction have been widely studied in vitro and in vivo experiments. Several studies demonstrated that PEMF exposure induces a marked upregulation of A2A and A3 adenosine receptor (AR) subtypes across multiple cell types and tissues, concomitantly resulting in the downregulation of key proinflammatory cytokines. Notably, PEMFs act as modulators of adenosine, enhancing the efficacy of the endogenous ligand through enhanced receptor responsiveness. The stimulation of A2A and A3ARs implied a significant reduction in the release of inflammatory mediators such as PGE₂, IL-6, IL-8 and resulted in a significant inhibition of NFκB and the reduction of proinflammatory cytokines including TNF-α and IL-1β and other mediators involved in joint inflammation and joint pain [14,15]. In ad-

ditional experiments, wounded monolayer cultures of human immortalized keratinocytes (HaCaT) were observed at various time points following exposure to PEMF and Sham conditions. Levels of IL-1β, TNF-α, IL-18, and IL-18BP were measured to assess their production and expression. The findings demonstrate that PEMF can modulate inflammatory mediators and influence keratinocyte proliferation and migration, underscoring its significant role in promoting wound healing [16]. Evidence from both animal and human studies supports the adjunctive use of PEMF therapy for managing diabetes-related complications such as wounds, chronic pain, and neuropathy. These non-invasive treatments appear promising, with no known reports of adverse effects [17].

For these reasons, before considering further surgery, we considered conservative treatment combining drug therapy with PEMF to be a valid solution. The patient showed a marked improvement in the healing of the plantar wound within the first month of therapy and complete healing of the dorsal wound at the end of the 2 months of PEMF. Four months after surgery, the patient had completely regained his walking ability.

The literature suggests that another interesting treatment for diabetic feet could be implemented with pulsed radiofrequency energy (PRFE) device. A case report examined the use of a PRFE device in treating recalcitrant ulcers, including diabetic foot ulcers [28]. Four patients with ulcers present for over 3 months that had failed conventional treatment were included. Three patients had diabetic neuropathic ulcers, and one had a venous stasis ulcer. After one week of PRFE therapy (6-8 hours daily), all patients exhibited improvement and a decrease in wound size. Two patients with diabetic ulcers achieved complete healing after 3 weeks of treatment, while the other two showed significant ulcer size reduction by the end of the 6-week study and continued to heal with ongoing PRFE use. The study indicated that PRFE can be promising in treating chronic, recalcitrant wounds like DFUs. PRFE therapy has been shown to upregulate gene families involved in tissue repair and increase fibroblast growth factor-2 (FGF-2), a key molecule in wound healing that promotes angiogenesis and granulation tissue formation [17].

Overall, the evidence suggests that PEMF or PRFE holds potential for addressing various complications of diabetes beyond foot ulcers and neuropathy, although more rigorous clinical trials are necessary [17-19].

Conclusion

PEMF therapy represents an emerging and promising treatment modality in the management of diabetic foot ulcers and soft tissue healing. By promoting faster wound healing, improving circulation, and reducing inflammation, it complements conventional treatments and can be particularly useful in managing chronic wounds that are resistant to other forms of therapy. As further research is conducted and more evidence accumulates, this physical care may become an integral part of the multidisciplinary approach to diabetic foot care.

Compliance with ethical standards: The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript. The patient provided informed consent to the publication of the case report.

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