

Uses of Radiofrequency in Wounds, Scars, and Diabetic Foot

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Abstract

Introduction: There is evidence that electrical stimulation may result in a significantly greater reduction in the surface area and more complete healing. No conclusion on the efficacy of electrotherapy can be drawn because of significant statistical heterogeneity, small sample sizes, and methodological flaws.

Methodology: We studied 36 patients, 21 Female and 15 Male, who presented ulcers in lower limbs. 9 male and 15 female had Diabetes Mellitus. The thickness of the skin of the leg was measured using a portable ultrasonography device.

Results: For the treatment, a C200 CAPENERGY Tecar therapy device was used. A total of 10 radiofrequency sessions were applied with a periodicity of 1 time a week with a power of 60 % and a frequency of 1.2 MHz for 30 minutes once a week. Using a boot-shaped device that is specifically coupled to the RF equipment. The presence of edema, observed in 34 patients in the region of the lower limb, disappeared in 26 of the 36 patients (Wilcoxon $p = 0.003$). This result where the mean subcutaneous cellular tissue edema decreased by 0.4 mm (Friedman Test $p = 0.000$). The temperature of the area taken before and after treatment was increased by an average of 1.4° C. These differences are statistically significant (Wilcoxon $p = 0.000$).

Discussion: The results presented show the benefits of the use of radiofrequency in the treatment of ulcers in both diabetic and non-diabetic patients.

Conclusion: The greater rapidness of wound healing presented can be explained by the anti-inflammatory effect caused by the changes in the coagulation and anticoagulation systems, the improvement of microcirculation. Together, they contribute to the increase of immunological reactivity.

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Introduction

Scar formation is the ultimate outcome of wound repair in humans that takes place as a cascade consisting of overlapping inflammatory, proliferative, and remodeling phases. When the process of wound healing is uneventful after completion of the remodeling phase, the scar enters the so-called mature state according to the scheme proposed by the International Advisory Panel on Scar Management [1]. Scar has no epidermal appendages and displays a collagen pattern of densely packed fibers. The tensile strength of wounded skin at best reaches only approximately that of unwounded skin [2]. In addition, scar is brittle and less elastic than normal skin, although the regeneration of elastic fibers in the scar is still debated [3]. In addition, scars are usually hypo-pigmented after full maturation even if they can become hyper-pigmented in dark pigmented individuals or in lighter pigmented ones after exposure to UV radiation. In conclusion, the scar itself does not reproduce the features of normal skin, and therefore, it is still an unsolved functional and cosmetic issue despite the large number of treatment proposals: surgery, silicone gel sheeting, injected corticosteroids, pressure therapy, radiotherapy, laser therapy, cryotherapy, adhesive microporous hypoallergenic paper tape, and a number of miscellaneous therapies based on an anecdotal basis [1].

There is evidence that electrical stimulation may result in a significantly greater reduction in the surface area and more complete healing of stage II to IV ulcers compared with sham therapy. No conclusion on the efficacy of electrotherapy can be drawn because of significant statistical heterogeneity, small sample sizes, and methodological flaws. The efficacy of other adjunctive physical therapies as electromagnetic therapy, in improving complete closure of pressure ulcers.

To promote wound healing phases, several biophysical therapies have been utilized that employ different basic principles. Two of the biophysical techniques, microcurrent and electromagnetic fields, are based on the premise that differences in electrical potential along the different layers of the skin or mucosa are determined by the asymmetric expression of sodium and potassium ion pumps. This is termed as transepithelial potential (TEP) with the stratum corneum (outermost epithelial layer) being electronegative, while subepithelial layers are electropositive. Wound healing and tissue regeneration are driven by a closed-loop self-repair system that uses signals (electrical) to initiate repair following injury [4]. These biophysical interventions appear to modulate the disrupted endogenous electromagnetic fields and aid in reestablishment of TEP [5]. The other three biophysical therapies, namely ultrasound (US), pressure, and light therapies, have been demonstrated to have clinical benefits and their molecular mechanisms appear to involve both biophysical and biochemical perturbations. However, their precise primary biological targets remain to be fully elucidated.

Chronic arterial and venous leg ulcers can be thought of as dysregulated inflammatory processes produced by inadequate blood supply, tissue anoxia, edema, cell death, and infection, among other factors [6]. These changes alter interaction among structural components of affected tissues and between these and immune cells

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in a manner that impedes wound healing. Existing hypotheses on the pathophysiology of chronic arterial and venous leg ulceration concentrate on local effects induced by hemodynamic alterations [7-13]. Treatments at present focused on alleviating these local changes include hemodynamic preventive measures, ulcer dressings, topical treatments, and surgical or endovascular repair of the microvasculature [7,8].

A recently study revealed [14], that the changes in total-Hb were significantly greater in the Capacitive Resistive RF (CRet) and hot pack (HP) trials than in the sham trial for 30 minutes after the intervention. Oxy-Hb, which is a component of total-Hb, increased in the CRet and HP trials, whereas the deoxy-Hb decreased. This result shows that the change in total-Hb was due to the increase in oxy-Hb. An increase in oxy-Hb indicates an increase in the volume of fresh blood supplied by the arteries [15]. The mechanism of thermal effects improving blood circulation can be attributed to the direct reflective activation of vascular smooth muscles via skin temperature receptors, suppression of the sympathetic nerve system through indirect activation of local spinal reflexes, and increases in the local release of inflammatory chemical mediators such as histamine and prostaglandin, and the compound effect would result in vasodilation and increase in blood flow [16,17]. Some previous studies reported that blood circulation was improved by thermotherapy techniques such as ultrasound, shortwave diathermy, and hot pack [18,19]. These studies concluded that increases in tissues temperature caused vasodilation; hence, blood circulation was improved. In our study, the blood circulation was improved after intervention with both CRet and HP. Therefore, the present study agrees with those previous studies.

Some studies have shown that (Electric Field) ELF elicit changes in cells of the immune system through Ca signaling Cossarizza et al. [20], Matos and Cicerone [21], including up-regulated cytokine synthesis and increased cell proliferation Cossarizza et al. [20]). Hypothetically, activation of peripheral blood mononuclear cells (PBMC) could be induced in the body of patients with chronic leg ulcers by using ELF frequencies that interact with PBMC. To test this hypothesis, ELF frequencies were specifically configured to interact with PBMC obtained from normal human volunteers in vitro. Subsequently, these ELF were applied to patients with chronic leg ulcers at a site far from the lesion site. The prompt effects of this treatment on chronic leg ulcers were monitored. Systemic effects are hypothetically explained by ELF activation of PBMC and their subsequent transportation to the ulcer site via humoral route. This therapy is effective in selected patients with chronic arterial and venous leg ulcers.

Methodology

We studied 36 patients from the Hospital de Guadarrama in Madrid Spain, who presented ulcers in lower limbs. Its general characteristics are presented in Table No. 1. One male patient and four female patients had Diabetes Mellitus.

The participants of the study were duly informed about the objectives of the study, the possible risks and benefits. All of them signed the free, prior, and informed consent form as soon as they accepted to participate in the study, thus in compliance with the Declaration of Helsinki and as approved by the Research Ethics Committee of Puerta de Hierro Hospital Madrid. It was registered at ClinicalTrials.gov (NTR: 03048799) as a randomized clinical trial preceded by a pilot study.

	Female n=21	Male n=15
	Mean ± SD	Mean ± SD
Age	54.8 ± 8.2	72.6 ± 7.5
Height	160.5 ± 6.8	165.3 ± 4.1
Weight	62.4 ± 3.0	78.6 ± 4.1
D. Mellitus	9	12

Table 1: Characteristic of the sample studied.

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Results

For the treatment, a C200 CAPENERGY tecar therapy device was used. A total of 10 radiofrequency sessions were applied with a periodicity of 1 time a week with a power of 60 % and a frequency of 1.2 MHz for 30 minutes once a week. Using a boot-shaped device that is specifically coupled to the RF equipment. (C Boot Capenergy figure 1).



Figure 1: Boot shaped device for using with CAPENERGY C-200 to apply radiofrequency treatment in the diabetic foot.

The presence of edema, observed in all patients in the region of the lower limb, disappeared in 29 of the 36 patients (Wilcoxon $p = 0.004$). This result was confirmed by ultrasound measurements where the mean subcutaneous cellular tissue edema decreased by 1.73 cm (Friedman Test $p = 0.000$). In Figure 2, the evolution of edema in the echographic study can be observed. The temperature of the area taken before and after treatment was increased by an average of 1.4° C. Figure 3 These differences are statistically significant (Wilcoxon $p = 0.000$).

In Figure 4 The temperature increase before (a) and after (b) the treatment measured by thermal imaging camera is observed.

To evaluate pain, the Visual Analogue Scales [22] was used. Figure 5 shows how pain perception has decreased before starting treatment

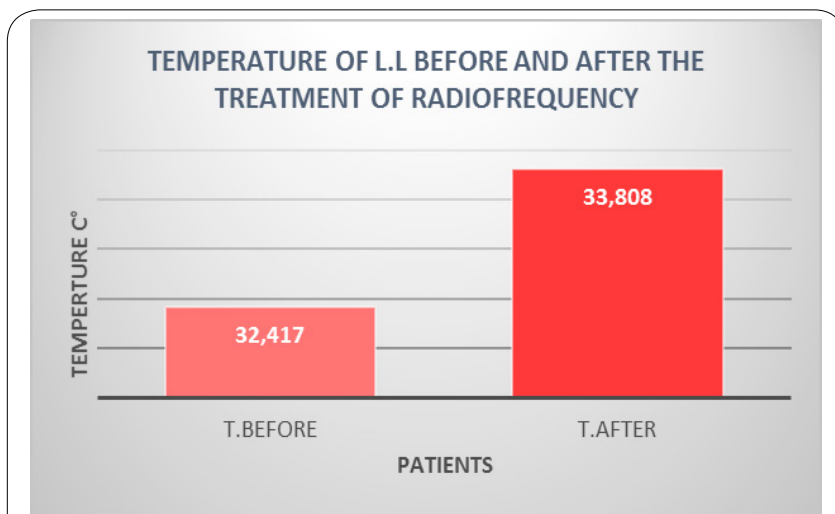


Figure 2: Changes in the temperature of the lower limb after treatment.

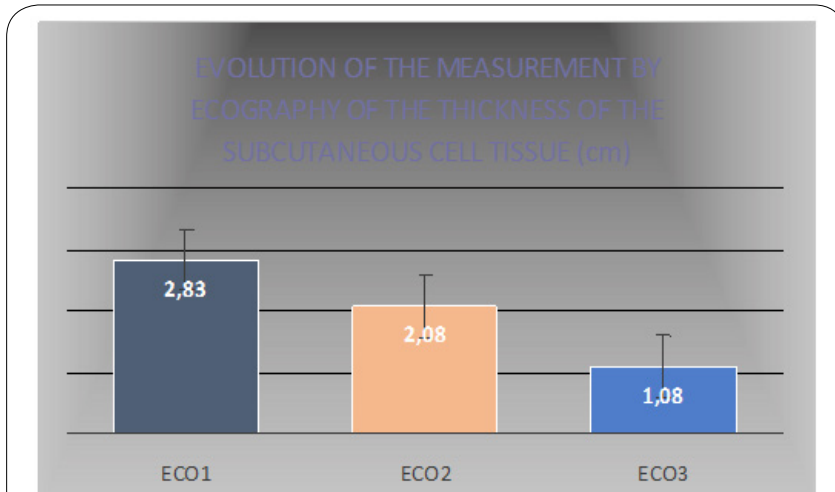


Figure 3: Evolution of the measurements of subcutaneous cell tissue by Ecography.

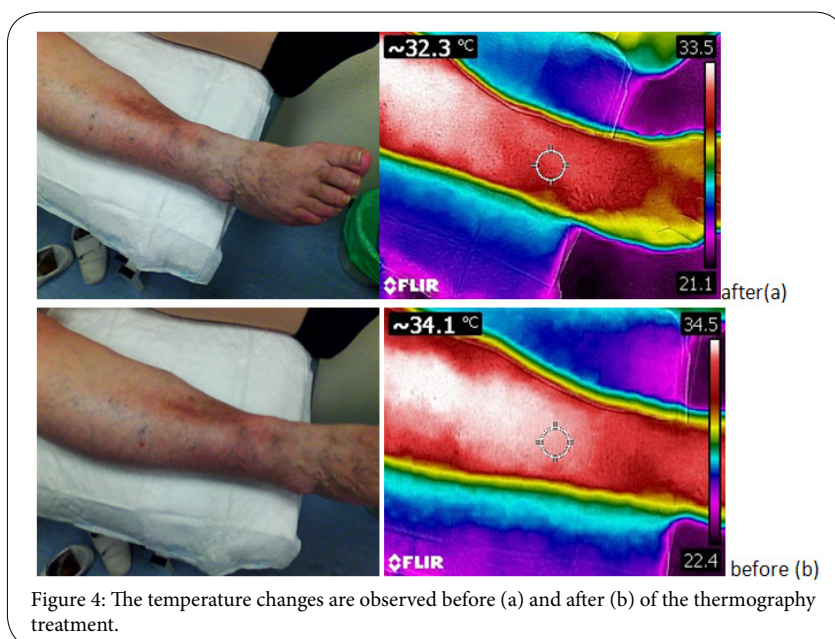


Figure 4: The temperature changes are observed before (a) and after (b) of the thermography treatment.

and at the end of these differences were statistically significant (Friedman Test $p = 0.000$).

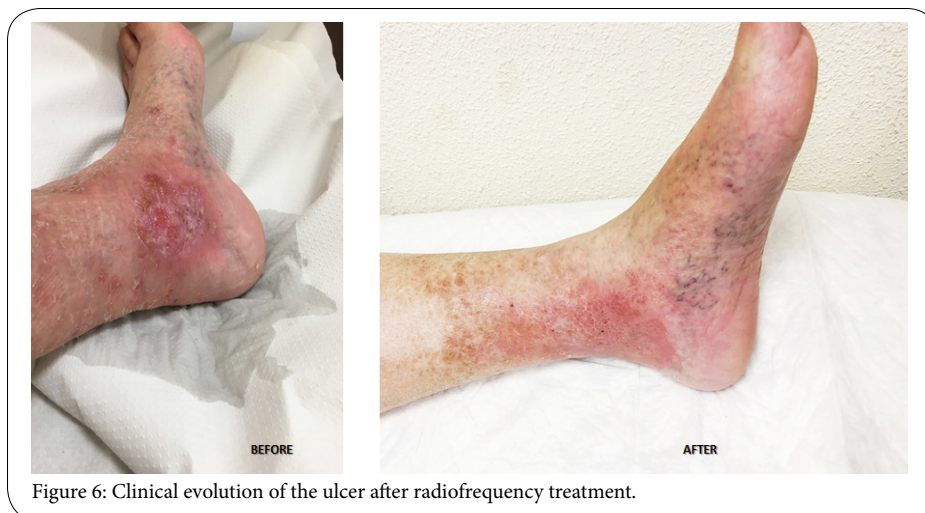
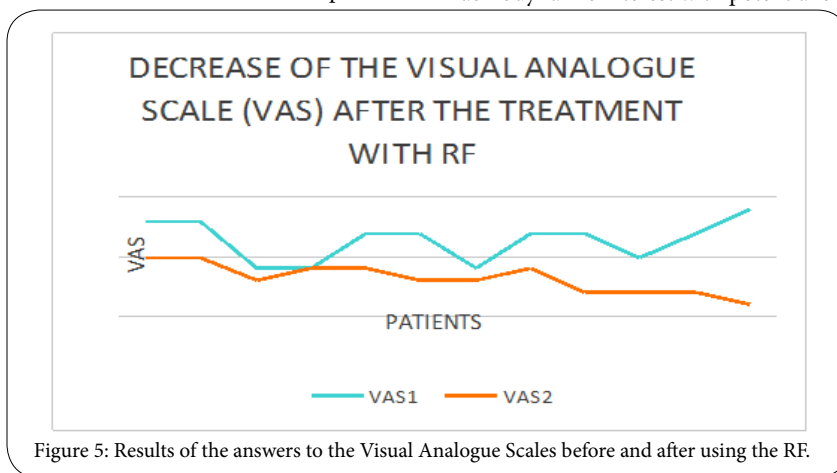
In Figure 6 and 7 it can be observed the clinical evolution of a patient's ulcer after radiofrequency treatment is observed, note the evident improvement in the lesion.

Discussion

The results presented show the benefits of the use of radiofrequency in the treatment of ulcers in both diabetic and non-diabetic patients.

An important characteristic is that it is not invasive, it is not painful, it is well tolerated and the results are evident the improvements of the lesion and the improvement of the quality of life of these patients.

The 20-minute treatment 10 using the manual mode with a capacitive electrode at a frequency of 1.5 MHz over the area of the ulcer followed by 10 minutes with the use of the c-Boot, followed by a lymphatic drainage followed by placing the active plate in the sole of the foot and the passive in the lumbar region have given surprising results. The magnetic characteristic of blood in arteries is of great haemodynamic interest with potential clinical implications. Previous



in-vivo investigations which substantiated the beneficial effects of an external magnetic field on blood flow haemodynamics [23]. An study demonstrated that a static magnetic field induces some small but significant changes in microcirculation and skin temperature in anesthetized animals [24], what can explain the great improvement of these patients, along with the mobilization of Ca^{2+} , vascular and epithelial growth factors, that have an important role in the healing of the diabetic foot.

Future Perspectives

Employment of EMF in regenerative medicine opens a new avenue for treatment of various diseases. Due to its non-ionizing and non-invasive nature, the use of EMF has evident advantages compared to current chemical, biological and physical methods of tissue regeneration and wound healing. Electric and magnetic components of EMF could be employed separately or in combination for different therapeutic purposes. Both components have demonstrated a capability for stimulating cell proliferation and differentiation.

EMF has great potential to be harnessed for wound treatment in combination with metal nanoparticles of noble metals. Gold and silver have been credited with antimicrobial properties for many centuries. Modern technology allows fabrication of stable gold and silver nanoparticles with desired size and shape [25-27]. Particle size can provide the possibility of enlarging contacting area, which leads to an increase in anti-bacterial activity and speeding up processes of wound healing [28]. Noble nanoparticles might be incorporated into wound dressings made of various types of materials such as polymer films, hydrogels, composites and alginates. EMF can be applied externally and non-invasively to wound dressings containing the noble nanoparticles to enhance their antimicrobial action. This approach might serve as a foundation for developing a completely new type of wound dressing.

Conclusion

To summarize, taking into account the great clinical potential of EMF, we can expect a rise in new techniques for tissue regeneration and wound healing in close perspective. Such strategy allows combining EMF with various chemical, physical and biological modalities to provide desired synergistic bio-effects and enhanced treatment efficacy.

The greater rapidness of wound healing presented can be explained by the anti-inflammatory effect caused by the changes in the coagulation and anticoagulation systems, the improvement of microcirculation and the hormonal excretion. Together, they contribute to the increase of immunological reactivity.

The influence of the magnetic field on the microcirculatory system can be used to explain the often cited fact that magnetic fields have anti-oedematous, analgesic and anti-inflammatory effects, which is one of the reasons for their wide application in surgery.

Competing Interests

The authors declare that they have no competing interests.

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