ACTA SCIENTIFIC MEDICAL SCIENCES (ISSN: 2582-0931)

Volume 4 Issue 2 February 2020

Research Article

Treatment of Diabetic Foot Ulceras Using Technology with A C-Boot Device

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DOI: 10.31080/ASMS.2020.04.0518

Received: December 10, 2019

Published: January 06, 2020

Abstract

Introduction: It is known that the application of Radiofrequency in wounds, improves vascularization and oxygenation of tissues, it has also been shown to increase the Epidermal and Vascular Growth Factors. It is known to be a safe and well tolerated treatment by the patient. In order to know the effect of this treatment on the Diabetic Foot Ulcers, this study was carried out, incorporating a C-Boot, designed to apply the radiofrequency treatment with a C 100 CAPENERGY for application in the foot ulcers.

Methodology: Four patients were treated with one or several ulcers where 10 minutes of capacitive electrode treatment was first applied in the area of the ulcer at a power of 50% of that delivered by the team. Then it was applied 20 minutes using the C-Boot with active and passive plate. The treatment was applied once a week. Ecosonography was performed to evaluate subcutaneous edema and a Visual Analogue Pain Scale.

Results: All patients noticed a decrease in the symptoms of edema and a decrease in pain from the first weeks, at the end of the treatment the ulcers were closed, improving the quality of life of these patients. Conclusions: The application of Tecarterapia with the use of C-Boot has proven to be an effective treatment for the treatment of ulcer in the Diabetic Foot.

Keywords: Treatment; Technology; boot

Introduction

The formation of scars is the final result of wound repair in humans that takes place as a cascade consisting of the superimposition of inflammatory, proliferative and remodeling phases. When the wound healing process takes place without incident after the completion of the remodeling phase, the scar enters the so-called state of maturity according to the scheme proposed by the International Consultative Panel on Scar Management [1]. Scar has no epidermal appendages and shows a collagen pattern of densely compacted fibers. The tensile strength of the injured skin reaches, at best, only approximately that of the non-injured skin [2]. In addition, the scar is brittle and less elastic than normal skin, although regeneration of elastic fibers in the scar is still discussed [3]. In addition, the scars are usually hypopigmented after full maturation, even if they can hyperpigment in dark pigmented individuals or lighter pigments after exposure to UV radiation. In conclusion, the scar itself does not reproduce the characteristics of normal skin and, therefore, remains an unsolved aesthetic and functional problem, despite the large number of treatment proposals: surgery, silicone gel sheets, injected corticosteroids, pressotherapy, radiotherapy, laser. therapy, cryotherapy, microporous adhesive hypoallergenic paper tape and a series of miscellaneous therapies based on an anecdotal basis [1].

Chronic arterial and venous ulcers can be considered as deregulated inflammatory processes caused by an inadequate blood

supply, tissue anoxia, edema, cell death and infection, among other factors [4]. These changes alter the interaction between the structural components of the affected tissues and between them and the immune cells in a way that prevents wound healing. The existing hypotheses about the pathophysiology of chronic arterial and venous ulceration of the leg focus on local effects induced by hemodynamic alterations [5-11]. The treatments that currently focus on alleviating these local changes include preventive hemodynamic measures, ulcer dressings, topical treatments and surgical or endovascular repair of the microvasculature [5,6].

Electromagnetic energy has been used for the treatment of ulcers, [12], Radiofrequency has demonstrated effects on tissue repair. One study revealed [13] that the changes in total Hb were significantly greater in the RF tests for capacitive resistance (CR et) and in hot packs (HP) than in the simulated trial for 30 minutes after the intervention. Oxy-Hb, which is a component of total Hb, increased in the CR et and HP trials, while 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 [14]. The mechanism of thermal effects that improve blood circulation can be attributed to direct reflexive activation of vascular smooth muscles through skin temperature receptors, suppression of the sympathetic nervous system through indirect activation of reflexes local spinal and increased local release of inflammatory chemical mediators such as histamine and prostaglandin, and the compound effect would result in vasodilation and increased blood flow [15,16]. Some previous studies reported that blood circulation improved with thermotherapy techniques with shortwave diathermy associated with the use of hot packets [17,18]. These studies concluded that increases in tissue temperature caused vasodilation. Therefore, blood circulation was improved. In our study, blood circulation improved after the intervention with CRet and HP. Therefore, the present study agrees with the previous studies.

Some studies have shown that Electric Fields (ELF) cause changes in immune system cells through Ca^{2+} signaling [19,20], including upregulated cytokine synthesis and increased cell proliferation [19]. Hypothetically, the 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 ELFs were applied to patients with chronic leg ulcers at a site away from the site of injury. The immediate effects of this treatment on chronic leg ulcers were monitored. Systemic effects are hypothetically explained by the ELF activation of PBMC and its subsequent transport to the site of the ulcer by humoral route. This therapy is effective in selected patients with chronic arterial and venous ulcers.

In a recent study, it has been shown that treatment with radiofrequency (RF), isolated or associated with hydrolyzed collagen, increases and improves neocollagenesis, neoangiogenesis and the thickness of the dermis. These findings confirm that RF treatment has a significant effect on fibroblast proliferation, the amount of hair follicles and epithelial thickness. RF treatment also modulates COX-2 expression, over regulates FGF2 expression and induces neoangiogenesis [21].

With aim to know the effects of capacitive radiofrequency on vascular ulcers, a capacitive radiofrequency treatment was applied to a group of patients with ulcers of more than 3 years of treatment-resistant evolution.

Methodology

We studied 4 patients, who presented ulcers in lower limbs, two men and two women. The study participants were duly informed about the objectives of the study, the possible risks and benefits. All signed the free, prior and informed consent form as soon as they agreed to participate in the study, therefore in accordance with the Declaration of Helsinki.

For the treatment, a C-100 CAPENERGY tech therapy device was used. A total of 10 radiofrequency sessions were applied with a frequency of once a week with a power of 50% and a frequency that is selected among the three delivered by the equipment 0.9, 1 and 1.2 MHz, depending on the absorption and With a power of up to 1,240 Watts, 10 minutes of capacitive electrode treatment was applied first, in the area of the ulcer at a power of 50% of what the equipment delivers. Then it was applied 20 minutes using the C-Boot with active and passive plate, once a week. Using a boot-shaped device that specifically attaches to RF equipment. (C Boot CAPENERGY Figure 1). Designed for these purposes. Finally, 10 minutes of lymphatic drainage were applied by placing the active plaque on the sole of the foot and the passive at the level of the lumbar region.

Figure 1: Boot designed for use with CAPENERGY C-200 to apply the radiofrequency treatment in the diabetic foot.

For the evolution of edema in the region, an ALPINION E CUBE i7 Ultrasound was used, the studies were performed before and after treatment. To assess pain, visual analog scales were used [22]. It is observed how the perception of pain has decreased before starting treatment and at the end.

Results

The presence of edema, observed in all patients in the region of the lower limb, disappeared in the 4 patients. This result was confirmed by ultrasound measurements in which the average edema of the subcutaneous cellular tissue decreased on average 1.73 cm. In the figure 2 the evolution of edema can be observed in the ultrasound study Photo No. 2. The temperature of the area taken before and after the treatment was increased by an average of 1.4 ° C. measured with a thermal imager figure 3.

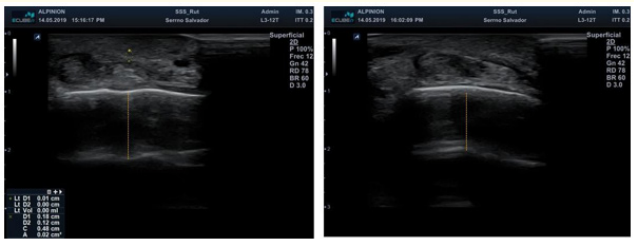

Figure 2: Ultrasound images show the decrease in interstitial fluid thickness.

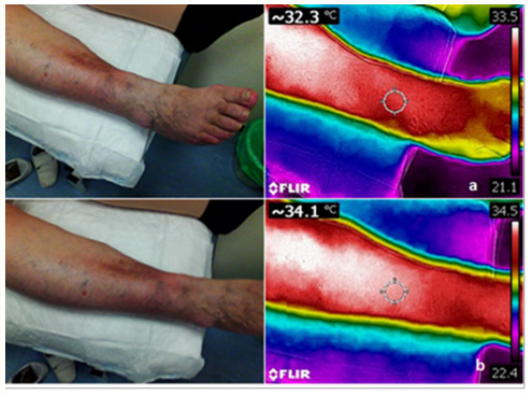

Figure 3: Changes in temperature before and after treatment with thermal imaging camera.

In figure 4 to 7. The clinical evolution of the ulcer of the four patients can be observed after receiving the radiofrequency treatment, observe the evident improvement in the lesions.

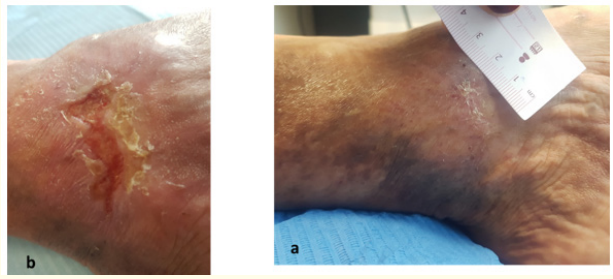

Figure 4: Notice the improvement of the lesion after radiofrequency treatment.

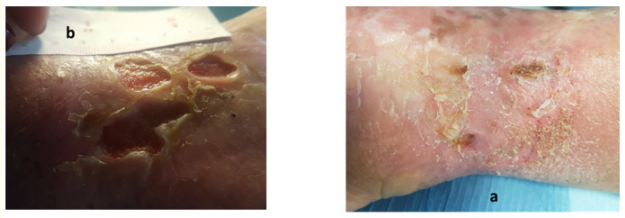

Figure 5: You can see the changes in the improvement of the lesion after treatment.

Figure 6: The ulcer closure of this patient can be observed. The dark color is due to the presence of an angioma.

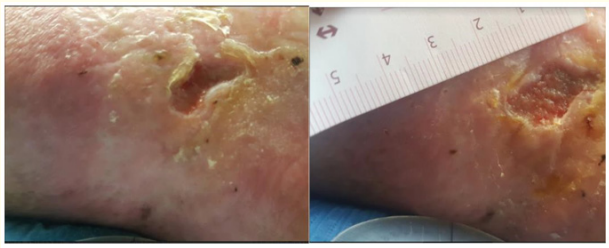

Figure 7: Shows the improvement of the ulcerative lesion. This patient was not very consistent with treatment.

Discussion

Several factors, such as the stage of the wound, the age of the wound and the age of the patient, can affect the results of wound healing, impediments often associated with chronic diseases and / or advanced stages of the wound, as well as for wounds that occur in elderly patients. Our patients came spontaneously to the Clinic and were treated without considering anything other than their ulcer.

The body always responds to an injury with a predictable inflammatory response, as the first step towards healing. Redness, heat, swelling and pain are associated with this first stage. Redness and heat are caused by increased blood flow. Swelling is the result of the increased movement of fluid and white blood cells into the injured area. The release of chemicals and the compression of nerves in the area of injury cause pain. The pain and swelling can keep the patient from using the injured part, serving to protect it from further injury. However, often times, the body's response is excessive. Managing edema after trauma or injury is a primary concern for health care professionals, as it is theorized that delaying the removal of edema will increase secondary injury and result in a longer recovery period. The inflammatory process generates a series of events, starting with bleeding and ultimately leading to fluid accumulation in intercellular spaces and the formation of edema [23]. Once edema is formed, the lymphatic system plays a tremendous role in removing excess interstitial fluid and returning the fluid to the circulatory system [23]. This explains the importance of performing lymphatic drainage at the end of RF treatment.

RF produces effects on bacteria. This effect may be directed at the bacteria themselves or the immune system that, through thermal shock proteins, develop immunological events.

Most pathogenic bacteria are mesophilic and thrive at temperatures between 33 and 41° C. Elevated temperatures inhibit bacterial proliferation and mobility, which in turn, can increase autolysis and cell wall damage [24]. Recent studies showed that elevated temperatures alter staphylococcal biofilms to have a lower elastic modulus, and reducing the stiffness of the biofilm could benefit the physical techniques used for biofilm removal (debridement) (Richardson 2016).

In response to external EMF, producing the mobilization of cellular Ca2+ signals or the interference of an EMF with Ca regulatory processes is considered an important target of EMF action. For lymphocytes, Ca mobilization is among the earliest detectable events triggered upon binding of a ligand (e.g., antigen, receptor antibody, mitogenic lectin) to an appropriate receptor structure exposed on the outer cell surface. The cascade of cellular reactions in lymphoid cells subsequent to ligand-receptor interaction is best understood for T cells [25].

Extracellular cell stress proteins are highly conserved phylogenetically and have been shown to act as powerful signalling agonists and receptors for selected ligands in several different settings. They also act as immunostimulatory 'danger signals' for the innate and adaptive immune systems. Other studies have shown that cell stress proteins and the induction of immune reactivity to self-cell stress proteins can attenuate disease processes. Some proteins (e.g. Hsp60, Hsp70, gp96) exhibit both inflammatory and anti-

inflammatory properties, depending on the context in which they encounter responding immune cells [26].

The arrival of blood to the area of the ulcer is an event of great importance for the healing of it there is evidence for a novel mechanism of EF-mediated regulation of endothelial cell angiogenic responses via frequency-sensitive vascular endothelial growth factor, VEGFR2-independent, activation of the mitogen-activated protein kinase/extracellular signal-regulated kinase (MAPK/ERK) signalling pathway. *In vivo*, this mechanism translates into VEGF accumulation in the wound, which may result in increased wound vascularization and improved healing [27]. RF causes the activation of mononuclear blood cells and their subsequent transfer to the site of the ulcer by humoral route. This therapy is effective in patients with chronic arterial and venous ulcers [28].

The results presented show, the benefits of the use of radiofrequency in the treatment of ulcers. 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 quality of life of these patients. It is important to note that the results reported in this article are similar to other studies that have demonstrated effective wound healing, Using similar therapy type as in the current study, [29] reported a mean percent wound closure of 64% after 4 weeks of therapy versus 8% for sham-treated wounds in an randomized clinical trials study of pressure ulcers (Stage III – IV) in patients with Spinal Cord Injury.

The treatment of 30 minutes 10 minutes using the manual mode with a capacitive electrode at a frequency that is selected depending on the absorption of energy by the patient, over the area of the ulcer, followed by 20 minutes with the use of c-Boot. The magnetic characteristics of the blood in the arteries are of great hemodynamic interest with possible clinical implications. Previous research *in vivo* that demonstrated the beneficial effects of an external magnetic field in blood flow hemodynamics [30]. One study showed that a static magnetic field induces some small but significant changes in microcirculation and skin temperature in anesthetized animals [31], which may explain the great improvement of these patients, together with the mobilization of Ca^{2++}, vascular and epithelial growth factors, which have an important role in the healing of diabetic foot.

Future Perspectes

The use of Electromagnetic Fields (EMF) in regenerative medicine opens a new way for the treatment of various diseases. Due to its non-ionizing and non-invasive nature, the use of EMF has obvious advantages compared to current chemical, biological and physical methods of tissue regeneration and wound healing. The electrical and magnetic components of EMF could be used separately or in combination for different therapeutic purposes. Both components have demonstrated an ability to stimulate cell proliferation and differentiation.

EMF has great potential to be used for the treatment of wounds in combination with metal nanoparticles of noble metals Tang., *et al* [32]. Gold and silver have been credited with antimicrobial properties for many centuries. Modern technology allows the manufacture of stable gold and silver nanoparticles with the desired size and shape [32,33,34]. The particle size may provide the possibility of enlarging the contact area, which leads to an increase in antibacterial activity and accelerates wound healing processes [35,36]. Noble nanoparticles could be incorporated into wound dressings made of various types of materials, such as polymer films, hydrogels, compounds and alginates. EMF can be applied externally and non-invasively to wound dressings that contain noble nanoparticles to improve their antimicrobial action. This approach could serve as the basis for developing a completely new type of wound dressing.

Conclusion

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

The faster healing of the wound presented can be explained by the anti-inflammatory effect caused by changes in coagulation and anticoagulation systems, the improvement of microcirculation and hormonal excretion. Together, they contribute to increased 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 antiedematous, analgesic and anti-inflammatory effects, which is one of the reasons for their wide application in surgery.

Bibliography

1. Mustoe TA., *et al.* "International clinical recommendations on scar management". *Plastic and Reconstructive Surgery* 110 (2002): 560-571.

2. Levenson SM., *et al.* "The healing of rat skin wounds". *Annals of Surgery* 161 (1965): 293-308.

3. Roten SV., *et al.* "Elastic fibers in scar tissue". *Journal of Cutaneous Pathology* 23 (1996): 37-42.

4. Mani R., *et al.* "Chronic wound healing. Clinical measurement and basic science". New York: WB Saunders (1999).

5. Bollinger A., *et al.* "Microvascular changes in venous disease: an update". *Angiology* 48 (1997): 27-32.

6. Browse NL and Burnard KG. "The cause of venous ulceration". *Lancet* (1982): 243-245.

7. Cheatle TR., *et al.* "The pathogenesis of skin damage in venous disease: a review". *European Journal of Vascular and Endovascular Surgery* 5 (1991):115-123.

8. Coleridge Smith PD., *et al.* "Causes of venous ulceration: a new hypothesis". *British Medical Journal* 296 (1988): 1726-1727.

9. Coleridge Smith PD. "The microcirculation in venous hypertension". *Cardiovascular Research* 32 (1996): 789-795.

10. Falanga V and Eaglstein WH. "The trap hypothesis of venous ulceration". *Lancet* 341 (1993): 1006-1008.

11. Second European Consensus Document on Chronic Critical Leg Ischemia. *Circulation* 84.4 (1991):1-25.

12. Mathur RK., *et al.* "Low-level laser therapy as an adjunct to conventional therapy in the treatment of diabetic foot ulcers". *Lasers in Medical Science* 32.2 (2017): 275-282.

13. Morishita K., *et al.* "Effects of therapeutic ultrasound on intramuscular blood circulation and oxygen dynamics". *Journal of the Japanese Physical Therapy Association* 17 (2014): 1-7.

14. Yokota Y., *et al.* "Effect of Capacitive and Resistive Electric Transfer on Tissue Temperature, Muscle Flexibility, and Blood Circulation". *Journal of Novel Physiotherapies* 7 (2017): 325.

15. Karasuno H., *et al.* "Change in intramuscular blood volume induced by continuous shortwave diathermy". *The Journal of Physical Therapy Science* 17 (2005): 71-79.

16. Crockford GW., *et al.* "Thermal vasomotor responses in human skin mediated by local mechanisms". *The Journal of Physiology* 161 (1962): 10-20.

17. Kellogg DL Jr., *et al.* "Role of nitric oxide in the vascular effects of local warming of the skin in humans". *Journal of Applied Physiology* 86 (1999): 1185-1190.

18. Okada K., *et al.* "The influence of hot pack therapy on the blood flow in masseter muscles". *Journal of Oral Rehabilitation* 32 (2005): 480-486.

19. Cossarizza A., *et al.* "Exposure to low frequency pulsed electromagnetic fields increases interleukin-1 and interleukin-6 production by human peripheral blood mononuclear cells". *Experimental Cell Research* 204 (1993): 385-387.

20. Matos MA and Cicerone MT. "Alternating current electric field effects on neural stem cell viability and differentiation". *Biotechnology Progress* 26 (2010): 664-670.

21. Meyer PF., *et al.* "Radiofrequency treatment induces fibroblast growth factor 2 expression and subsequently promotes neocollagenesis and neoangiogenesis in the skin tissue". *Lasers in Medical Science* 32.8 (2017):1727-1736.

22. Reips U and Funke F. "Interval level measurement with visual analogue scales in Internet-based research: VAS Generator". *Behavior Research Methods* 40 (2008): 699-704.

23. Villeco JP. "Edema: a silent but important factor". *Journal of Hand Therapy* 25 (2012): 153-161.

24. Tsuchido T., *et al.* "Destruction of the outer membrane permeability barrier of Escherichia coli by heat treatment". *Applied and Environmental Microbiology* 50 (1985): 298-303.

25. Walleczek J. "Electromagnetic field effects on cells of the immune system: the role of calcium signalling". *The FASEB Journal* 6 (1992): 3177-3185.

26. Pockley AG and Henderson B. "Extracellular cell stress (heat shock) proteins-immune responses and disease: an overview". *Philosophical Transactions of the Royal Society B* 373.1738 (2018): 20160522.

27. Galiano RD., *et al.* "Topical vascular endothelial growth factor accelerates diabetic wound healing through increased angiogenesis and by mobilizing and recruiting bone marrow-derived cells". *The American Journal of Pathology* 164 (2004): 1935-1947.

28. Cañedo-Dorantes L., *et al.* "Healing of chronic arterial and venous leg ulcers through systemic effects of electromagnetic fields [corrected]". *Archives of Medical Research* 33.3 (2002):281-289.

29. Kloth LC., *et al.* "Effect of pulsed radio frequency stimulation on wound healing: a double-blind pilot study". In: Bersani F, ed. Electricity and Magnetism in Biology and Medicine. New York: Academic/Plenum (1999): 875-878.

30. Haik YV and Pai CJ. "Chen Apparent viscosity of human blood in a high static magnetic field". *Journal of Magnetism and Magnetic Materials* 225 (2001): 180-186.

31. Ichioka S., *et al.* "Ueno High intensity static magnetic fields modulate skin microcirculation and temperature in vivo". *Bioelectromagnetics* 21 (2000): 183-188.

32. Tang CL., *et al.* "Green and facile fabrication of silver nanoparticles loaded activated carbon fibers with long-lasting antibacterial activity". RSC Adv 4 (2014): 523-530.

33. Kim JS., *et al.* "Anti-microbial effects of silver nanoparticles". *Nanomedicine* 3 (2007): 95-101.

34. Shin KS., *et al.* "Novel fabrication and catalytic application of poly(ethylenimine)-stabilized gold-silver alloy nanoparticles". *Journal of Nanoparticle Research* 14 (2012): 3.

35. Hebeish A., *et al.* "El-Naggar ME Antimicrobial wound dressing and anti-inflammatory efficacy of silver nanoparticles". *International Journal of Biological Macromolecules* 65 (2014): 509-515.

36. Mackowiak PA. "Direct effects of hyperthermia on pathogenic microorganisms: teleologic implications with regard to fever". *Reviews of Infectious Diseases* 3 (1981): 508-520.