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Research Article

Granulation Acceleration with the Combined Use of Electrical Stimulation and Ozone in the Treatment of Diabetic Foot Ulcers

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Abstract

The use of electrical stimulation and the results achieved in accelerating the healing of diabetic foot ulcers (DFU) have allowed this technique to be established as an alternative for the treatment of this type of injury. One stage of the ulcer healing process is called Proliferation, an action related to the regeneration of damaged tissue, which is essential to achieve complete healing of the lesion. However, this procedure, as with other types of treatment, is affected by the presence of infections characteristic of DFUs.

The search for solutions to this situation originated the use of ozone as an effective element to combat the different types of pathogens that affect them, in order to achieve tissue granulation in a short time. In the present work, the first results of the application of ozone in combination with electrical stimulation are shown, to achieve the elimination of the infection and the accelerated obtaining of the granulation tissue in the ulcer.

Keywords: Diabetic Foot Ulcers; Electrical Stimulation; Granulation Tissue; Ozone

Introduction

Diabetic foot ulcer is a significant complication of Diabetes Mellitus (DM), with an annual incidence of 2% with respect to the total number of patients who suffer from it, which increases in a range between 5.0% and 7.5% in those cases. that also present with peripheral neuropathy [1]. It is estimated that 15% of patients with DM develop DFU at some point during their lives, and between 10% and 30% of them progress to amputation of the affected lower limb.

The normal ulcer healing process is divided into four phases: hemostasis, inflammation, proliferation, and remodeling. The therapeutic management of a patient with DFU, depending on the degree of ulceration, is based on: metabolic control, surgical debridement, healing and bandaging of the lesion to protect it from moisture, antimicrobial treatment of infections and procedures for revascularization.

The etiology of diabetic foot includes gram-positive or gram-negative pathogens with aerobic or anaerobic metabolism, such as Enterococcus Faecium, Staphylococcus aureus, and, less frequently, some nonfermenting gram-negative organisms such as Stenotrophomonas Maltophilia, Pseudomonas SPP, and Acinetobacter SPP13 [2]. Precisely, the presence of bacteria and germs that cause infec-

tions in the PDUs threaten ulcer healing, so disinfecting it before using the established treatment is a process that can be considered essential.

The present work shows the results of a preliminary study carried out in four patients who presented a difficult-to-heal UPD, to whom the combined treatment of ozone was applied to combat different types of infections present in the UPD and electrical stimulation, using the STIMUL W® stimulator, to accelerate the granulation process.

Materials and Methods

For more than 20 years, in Cuba, electrical stimulation has been applied in different health institutions, with the use of STIMUL W® medical equipment, in the treatment of different types of ulcers, such as pressure ulcers, ankle ulcers and leg ulcers varicose [3-5].

As of 2015, this treatment began to be applied to diabetic foot ulcers with positive results, making the method an alternative for specialists. Achieving granulation in a short time and subsequently epithelialization are the fundamental objectives of the use of electrical stimulation. However, during the studies carried out, it was observed that the presence of various types of infectious agents delayed the healing process, so it was decided to use some medication or disinfectant that could, in combination with electrical stimulation, contribute to the healing process.

Ozone (O_3) was selected, since this gas is characterized by having a great oxidizing power, which makes it a highly effective and safe solution for disinfection. Its use contributes to the elimination of pathogens through the oxidation of the cover of viruses, bacteria and fungi and a wide spectrum of microorganisms, which are deactivated [6]. Once this has happened, ozone decomposes in the same way that occurs naturally in the atmosphere and returns to oxygen, so it does not leave any type of chemical residue.

The exclusion criteria were established based on the presence in the patient of chronic decompensated diseases (such as Diabetes Mellitus, arterial hypertension, among others), presenting oncological diseases of the skin (such as basal cell carcinoma and cutaneous melanoma), a history or suspicion of any type of neoplasm, psychiatric illness or mental disability, pregnancy or lactation period and who is participating in another clinical trial at the time of selection.

The main variables included in this study were based on the healing of the ulcer, through the reduction of the surface, determined by the weekly measurements made to each of the lesions and the healing time related between the start and end dates, when healing of the lesion is achieved. However, depending on the objective of the work presented, we will refer only to the granulation process.

The secondary variables focused on the granulation process of the ulcer, based on the yes/no dichotomy, the result of the visual effect identification of the presence of granulation tissue, which allows determining, a priori, the area covered by this type of tissue weekly and reference it as a percentage of the surface area and, at the time of granulation, referred to the date of initiation of treatment and the date on which granulation of the entire area of the ulcer is reached.

The treatment consisted of placing the UPD, for 30 minutes, once a day, in an ozone environment, using nylon bags that covered the lesion, within which the gas was found, and then electrical stimulation was applied for 30 minutes. Minutes Initially, a photograph of the state of the UPD was obtained and its surface area was measured. A week after starting treatment, a graphic image of the ulcer was obtained again, the surface area was measured and the presence of granulation tissue was observed, compared with the initial data. Surface area measurements were performed using the public domain ImageJ program for digital image processing [7], programmed in Java and developed at the National Institutes of Health.

Results and Discussion

For the preliminary study, four patients with difficult-to-heal DFUs were selected, whose surface areas of the lesions were between 34 cm2 and 160 cm2 approximately. Previously, the patients had received other types of treatment, but they had not given any positive results and there was the possibility of applying the surgical procedure of amputation, but it was decided to use the option presented in this work.

The following table shows the data of the patients who received the proposed treatment

Note that, in all cases, the surface area decreased in relation to its initial value, evidencing the effectiveness of the treatment. All

Patient	Age (years)	Sex	Race	Start Date	Superficial Area (cm^2)	
					Start	1st. Week
1	55	M	W	4 January	34,49	28,41
2	59	M	W	6 January	28,21	22,97
3	52	M	W	6 January	158,91	50,30
4	64	F	W	24 January	38,83	30,05

Table 1: Data of the patients included in the study.

patients had a medical history of Type 2 Diabetes Mellitus, admitted to the Diabetic Angiopathy service with Diagnosis of Neuroinfectious Diabetic Foot (abscess).

The graphic combination of figure 1 shows the result of the application of the treatment in the treated cases.

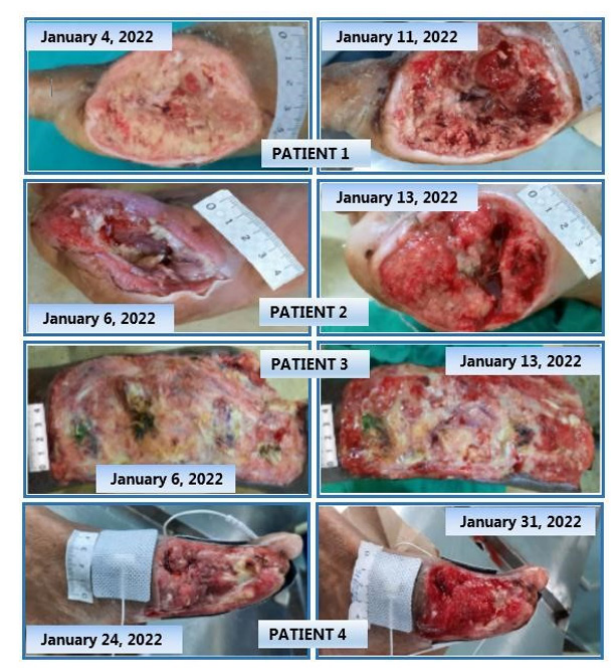

Figure 1: Photos of the ulcers of the patients at the beginning and after one week of treatment.

A systematic decrease in the surface area of the ulcer and the rapid formation of granulation tissue are observed, which shows that the combination used in the treatment turns out to be effective. In all cases, total granulation was reached in an average of 22 days.

It was not possible to obtain quantitative data on the depth of the ulcer, because we did not have the necessary resources. However, qualitatively, the characteristic behavior of healing is observed when applying the combination of both products: a significant decrease in depth, with respect to the variation of the surface area, corroborating what was stated in previous publications [4]; that is, the healing process begins first from the bottom of the ulcer towards the surface and then from the edges of the surface to the center of the lesion.

In addition, an increase in granulation is observed, a process that occurs as part of the decrease in depth and the significant decrease in infection in the ulcers, presented at the beginning of treatment.

It is important to point out that, with conventional treatments, granulation, in this type of difficult-to-heal ulcer, takes longer than what is obtained and, in some cases, it is not possible to achieve a positive result.

In the work that we present are the first results of a larger study that we are executing, so we consider that it is very premature to give other conclusions than those that we have obtained from the practical application of this treatment.

Conclusion

The combined application of electrical stimulation and ozone in the treatment of diabetic foot ulcers made it possible to eliminate the initial infection, characteristic of this type of injury, and

achieve acceleration of granulation, from the decrease in surface area and the depth of the ulcer, allowing this type of treatment to be considered as a viable alternative that contributes to reducing its prevalence.

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Conflict of Interest

I declare that there are no conflicts of interest or economic interest.

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