First experimental Results of an Observational study on the application of Electrical Stimulation in Diabetic Foot Ulcers

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Abstract

Aims: According to the World Health Organization, between 1980 and 2014 the total number of people with diabetes in the world increased from 108 million to 422 million and by the end of 2020, the total number was approximately 463 million. The most frequent complication in this type of patient is diabetic foot ulcer, where conventional treatments generally fail to solve the problem and in many cases the condition ends with amputation.

In 1998, an electrical stimulator was developed, called Stimul W, whose application in the healing of pressure and venous ulcers has yielded satisfactory results, allowing not only to obtain the Medical Registry by health entities in Cuba and other countries and even patent the mentioned equipment, but it has been achieved, in more than two decades of work, the healing of 1,191 ulcers of both types, with 94.5% effectiveness, a healing time that ranges between 21 and 42 days, according to the characteristics of the ulcer and without recurrence in any case treated.

Starting in 2015, the application of this technique began in diabetic foot ulcers with the objectives of measuring the effectiveness and achieving an alternative treatment for this type of injury. In the present work a brief compilation of the results achieved in the treatment of diabetic foot ulcer using electrical stimulation is shown.

Statistical Model: 31 diabetic patients, over 40 years old, with a total of 38 diabetic foot ulcers (some patients had more than one lesion) were treated, with times with the ulcer ranging between 1 and 6 months. The treatment consisted of a daily application for 30 minutes, using the Stimul W electrical stimulator, through the use of self-adhesive electrodes, conveniently placed around the affected area and on healthy skin, with current values corresponding to scale 8 of the stimulator, approximately 1.5 mA and using the two stimulation channels.

Results: In 27 of the 31 patients treated, the ulcer was healed with an effectiveness of 87%. In relation to ulcers, 33 ulcers healed in total, for 86.8% effectiveness. Average healing times were between 30 and 42 days, considering a daily session.

Conclusion: Acceleration of healing was achieved with respect to conventional treatments, reducing healing times, and not producing adverse events during and after the application of the treatment.

Keywords: diabetic foot ulcer; electrical stimulation; healing; recurrence.

Introduction:

Since the 70s of the last century, experimental tests have been increasing to verify the effectiveness of electrical stimulation in the treatment of different types of ulcers [1].

In the same way, randomized and controlled clinical trials have been carried out to compare the results of this type of treatment with respect to those used in a conventional way, [2,3] demonstrating that the use of electrical stimulation increases the healing rate of ulcers, higher to that obtained with the standard treatment and at the same time, acceleration of healing is achieved, reducing treatment times. [4,5]

The search for new effective treatments for the healing of different types of ulcers has been a permanent task for researchers, [6,3] with emphasis on the injuries typical of diabetic patients, precisely called diabetic foot ulcers, due to the annual increase in people with this disease in the world. In April 2016, according to WHO was found that, “422 million adults worldwide had diabetes in 2014, up from 108 million in 1980. Global prevalence (normalized by age) of diabetes has almost doubled since that year, since it has gone from 4.7% to 8.5% in the adult population” [7]

One of the techniques applied in the treatment of diabetic foot ulcers is the application of electrical stimulation, where the researchers report the satisfactory results achieved with its use. [8]

For more than two decades, the electrical stimulator called Stimul W was developed at the Central Institute for Digital Research, currently Combimed Digital Medical Technology, intended to accelerate the
healing of ulcers, with satisfactory results in the treatment of pressure ulcers and venous, which was registered by the health institutions of the Republic of Cuba and other countries and patented. [9-11]

The aforementioned medical team has also been used in the treatment of diabetic foot ulcers, to verify its effectiveness in this type of injury and to propose its use as an alternative to traditional methods, which sometimes fail to solve the problem. The aim of the present study was shows the first results achieved with the application of electrical stimulation, using the electrical stimulator Stimul W, in the treatment of diabetic foot ulcers.

**Materials and methods:**

In Cuba, for several years, all patients with diabetic foot ulcers have been treated, through a national system of care for diabetics, with the use of a Cuban drug called Heberprot-P with very positive results. However, not all patients suffering from this pathology are included to receive it, in some cases for medical reasons such as kidney dysfunction (among other causes), which make them not eligible and in other cases, although the treatment, do not achieve definitive healing of the injury.

As neither, in many cases, conventional treatments achieve the expected result [12], it was decided to use electrical stimulation, as an alternative to solve the problem.

To verify the effectiveness of this technique, the health entities were requested authorization to apply electrical stimulation to a group of patients who were not included in the treatment with Heberprot-P patients. In this way, 31 diabetic patients, older than 40 years, were selected, with a total of 38 diabetic foot ulcers (some had more than one lesion), with permanence times with the lesion that ranged between 1 and 6 months.

A proposed treatment consisted of a daily application for 30 minutes, using the Stimul W electrical stimulator, through the use of self-adhesive electrodes, conveniently placed around the affected area and on healthy skin, applying current values corresponding to scale 8 of the stimulator, approximately 1.5 mA and using the two stimulation channels.

During the treatment application stage, no type of medication or treatment other than the one designed was used.

**Results and Discussion:**

In 27 of the 31 patients treated, the ulcer was healed, so 87% managed to resolve their problem. In relation to the ulcers, 33 healed, representing 86.8% of the total. The average healing times were between 20 and 42 days, considering a daily session (table 1)

![Image 1](image1.png)

**Table 1:** Results of the application of electrical stimulation in patients with diabetic foot ulcers.

| Treated Patients | Healed Patient | % Treated Patients | Treated Ulcers | Healed Ulcers | % Treated Ulcers |
|-----------------|---------------|--------------------|----------------|---------------|-----------------|
| 31              | 27            | 87,0               | 38             | 33            | 86,8            |

During the time of application of the treatment and between one treatment and the next, no adverse events were manifested and at the end of the healing of the lesion, there were no recurrences, even in times after the treatment, controlled by the specialists.

Some of the results achieved are shown in Figures 1, 2 and 3, where the dates included define the start and end of the treatment applied with electrical stimulation.

Figure 1 shows the results of the application of treatment with electrical stimulation in a 59-year-old, white, male patient with hypertension and type II diabetes mellitus, who presented a diabetic foot ulcer with approximate dimensions. 115 mm² of surface area, generated six months ago. Healing occurred after 25 treatment sessions.

![Image 2](image2.png)

**Figure 1:** Ulcer healed after 25 treatment sessions.

The results of the application of the aforementioned treatment in a more complicated diabetic foot ulcer are shown in Figure 2, where a 50-year-old black male patient with hypertension and type II diabetes mellitus was treated, who, for four months, had a diabetic foot ulcer with a surface area of approximately 280 mm², which healed after 35 treatment sessions.

![Image 3](image3.png)
Treatment with electrical stimulation was also applied to a diabetic foot ulcer in a 47-year-old, white patient (figure 3) with comorbidities of Type II diabetes mellitus, HTN and Chronic Renal Insufficiency, who presented a lesion of approximately 132 mm², of surface area. The ulcer healed after 19 treatment sessions.

**Conclusion:**
Acceleration of healing was achieved with respect to conventional treatments, reducing healing times, and not producing adverse events during and after the application of the treatment.

**Conflicts of Interest**
The authors declare that there are no financial interests or any type of conflict of interest.

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