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Efficacy of Combined Therapy Compared to Conventional Therapy in the Treatment of Injuries Secondary to Chronic Osteomyelitis

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ABSTRACT

The treatment, using the electric stimulation, with the use of Stimul W[®], in different types of dermal lesions, including those of difficult scarring and the satisfactory results reached with this application, they allowed to investigate about their effectiveness in new pathologies, different to the treated etiology or that they can have certain relationship with them.

A Case Study was carried out to determine the effectiveness of this treatment in lesions secondary to Chronic Osteomyelitis and the positive results achieved led to the subsequent implementation of a Clinical Study to confirm the effectiveness achieved with this treatment and compare the experimental results with those obtained with the use of conventional treatments. The results and conclusions of this Clinical Study are shown in this work.

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Introduction

Acute bone infection resulting from a fracture caused in an accident, the appearance of a dehiscent wound after bone surgery and even the spread of bacteria or other microorganisms through the skin, blood, muscles and tendons, can cause what is called Osteomyelitis. If this infection predominates for several months, it becomes Chronic Osteomyelitis [1].

There are various surgical techniques used in the care of Chronic Osteomyelitis. Curettage, debridement, Toillete and packing with iodofomed gauze mainly stand out. Sometimes other techniques are used such as Masquelet, which is used in the treatment of bone defects of long bones [2,3].

Osteomyelitis tends to occlude local blood vessels and cause bone necrosis and local spread of the infection, which may spread through the cortex of the bone and beneath the periosteum, forming subcutaneous abscesses that may drain spontaneously through the skin. This infection generally generates a fistulous tunnel or an ulcer, considered secondary lesions to osteomyelitis [4].

As reported in the scientific literature, treatments for these ulcers and fistulas can last from a minimum of six weeks to several years [5].

The most common therapies for the care of lesions secondary to chronic osteomyelitis are fundamentally based on the administration of antibiotics, where in many cases, the treatment extends for a very long time [6]. However, according to specialists, chronic

osteomyelitis is long-lasting, making it difficult to eradicate it with antibiotics alone [7,8].

The specific organisms linked to osteomyelitis are frequently bacterial, although they may present some type of fungus or other microorganisms. Among the most common are Staphylococcus Epidermidis, Staphylococcus Aureus, Pseudomonas Aeruginosa, Serratia Marcescens and Escherichia Coli [9].

Conventional treatments are based on the use of antibiotics that are applied for at least 4 to 6 weeks, often intravenously, the outcome of which could be satisfactory. However, for patients with chronic osteomyelitis the prognosis can be poor. Symptoms can come and go for years, even with surgery. Amputation may be required, especially in people with diabetes or poor circulation [9].

The healing times of lesions derived from Chronic Osteomyelitis treated with conventional treatments can be prolonged, taking months and even years, due to complications that can affect healing. Conventional treatments, mainly with the use of antibiotics, do not solve the problem and it is necessary to search for new alternatives or therapies that allow obtaining better results.

Since the 1970s, various works and patents appeared describing the use of electrical stimulation in the treatment of soft tissues, including ulcers, with satisfactory results [10,11]. Since that moment, this technique has been used as an alternative for the prevention and cure of dermal lesions of various etiologies, allowing the acceleration of the healing process [12,13].

In 1997, Combiomed Digital Medical Technology carried out the design and production of the Stimul W® electrical stimulator, for use in healthcare activities in the field of medicine with the aim of preventing and accelerating the healing of different dermal lesions of different etiologies.

The results achieved in the clinical trial and field tests to which the equipment was subjected, allowed the obtaining of the Health Registry, the Invention Patent and the Trademark Registration, achieving its insertion into the Cuban Health System and its use in other countries [14].

In 2023, a Case Study was carried out to verify the effectiveness of the application of combined treatment in lesions secondary to Chronic Osteomyelitis, consisting of the use of conventional therapy in conjunction with electrical stimulation, using the Stimul W® stimulator. The results led to the execution of a Clinical Study to confirm the effectiveness of the proposed treatment and compare the results obtained experimentally with those obtained with the use of conventional treatments.

Problem

The healing times of lesions derived from Chronic Osteomyelitis, treated with conventional treatments, can be prolonged over time, taking months and even years, due to complications that can affect healing. Hospital stays increase over time and hospitalizations for the same reason are even repeated. Conventional treatments, based fundamentally on the use of antibiotics, do not solve the problem and it is necessary to search for new alternatives that contribute to mitigating the situation. The use of electrical stimulation in conjunction with conventional treatments can be an effective alternative.

Materials and Method

Considering that the healing times of a difficult-to-heal wound derived from Chronic Osteomyelitis treated with conventional treatments can be prolonged in time, taking months and even years, due to complications that can affect healing and, based on the experience obtained with the application of the Stimul W® electrical stimulator in the treatment of these types of injuries, the following hypothesis was proposed.

Hypothesis

Therapy with Stimul W® in conjunction with conventional treatment in difficult-to-heal lesions derived from Chronic Osteomyelitis provides a better result than with the application of conventional treatment alone, obtaining healing in less time, with significant bactericidal and bacteriostatic effects, in addition to significantly reducing the hospital stay.

Objectives

General Objective

To check the effectiveness and safety of treatment with Stimul W® in conjunction with conventional treatments in difficult-to-heal lesions derived from Chronic Osteomyelitis.

Specifics Objective

- Evaluate the bactericidal and bacteriostatic effect of the treatment.
- Evaluate the hospital stay of the study cases in relation to the control cases.

Sample Selection

12 patients were selected (eight study cases and four control cases) at the “Fructuoso Rodríguez” Teaching Orthopedic Hospital in the period between June and August 2024. All patients treated in the study had lesions that were difficult to heal secondary to Chronic Osteomyelitis, located in the Osteomuscular System (SOMA in Spanish).

Proposed Treatments

Clinical Study Period

It was established that the patients belonging to the Study Cases would receive at least a total of approximately 21 sessions of the combined therapy and would be compared with the Control Cases, who would only receive conventional therapy in the same number of sessions. For all patients, each session consisted of the daily application of the therapy, according to the group to which they belonged.

About Patients

- They signed the Informed Consent.
- A culture and an antibiogram were performed before the start of the Clinical Study and at the end of it.
- The surface area of the lesion was measured weekly and the variation in its depth was observed [15].
- A Data Collection Notebook was prepared which included the patient's Initial Data, History of the current Illness, Treatments (according to the group to which they belonged), Microbiological Studies, Graphic Evidence, Records of admissions and hospital stays and the Results.

Control Group

They receive daily treatment consisting of the application of conventional therapy (dry cures in the room, cures in the operating room and timely antibiotic therapy).

Study Group

They receive daily treatment consisting of the application of conventional therapy and subsequently therapy using the Stimul W® electrical stimulator (a one-hour session of electrical stimulation, using Self-Adhesive, Superficial Electrodes, with currents that reached 50 mA, depending on the electrical resistance of the patient's skin).

Analysis and Discussion

Control Cases

- **Patient HODFR-GC1:** A 46-year-old female patient who suffers from chronic osteomyelitis as a result of an accident that occurred in 2016. She was part of the case study where she presented a vesicocutaneous fistula with signs of infection, which by applying joint therapy was able to heal after 27 days of daily treatment. Subsequently, he presented a new fistulous tract in a different location than the previous admission and the same affected limb, but conventional therapy did not achieve the expected result. Treatment Period: June 1 to 24, 2024.
- **Patient HODFR-GC2:** Despite the decrease in the surface area of both lesions, this was a patient with a prolonged hospital stay, exceeding three months. Conventional treatments and the application of sessions in the Hyperbaric Chamber led to little clinical improvement and an unsatisfactory microbiological result. Treatment Period: June 1 to 24, 2024.
- **Patient HODFR-GC3:** With a hospital stay of 46 days, his evolution was not considered satisfactory, resulting in little

clinical improvement and an unfavorable microbiological result. Treatment Period: June 1 to 21, 2024.

- **Patient HODFR-GC4:** With a hospital stay of 18 days, from a clinical point of view he had a favorable evolution, reducing the initial surface area of the lesion by almost half. However, from a microbiological point of view it was not favorable, where both at the beginning and at the end of the study a growth of countless colonies of *Staphylococcus Aureus* was obtained. Treatment Period: July 25 to August 7, 2024.

Study Cases

- Patient HODFR-GP1: Had a notable improvement from a clinical and microbiological point of view. The granulation tissue and healing of the lesion occurred in a much shorter time when compared to similar episodes in previous admissions, achieving closure of the fistulous tract with almost total healing of the epithelial tissue. Treatment Period: May 24 to June 17, 2024.
- Patient HODFR-GP2: Clinically favorable evolution with total granulation of the lesion. A wound without discharge or odor was achieved, with useful granulation tissue. It did not evolve microbiologically because it did not have a therapeutic arsenal (antibiotics) that would allow for combined therapy to eliminate *Acinetobacter*. Treatment Period: June 1 to 27, 2024.
- Patient HODFR-GP3: A practically epithelialized lesion was achieved and with a microbiological result that, despite showing a slight bacterial growth, did not give clinical translations, since the wound had useful granulation tissue, without stench or secretions. Treatment Period: June 10 to 30, 2024.
- Patient HODFR-GP4: Favorable clinical evolution. The effectiveness of the combined therapy meant that there was no need to remove the femoral head despite the fact that it showed radiological signs of avascular necrosis, making it possible in the near future that, in the event of another septic or painful episode, it would have to be removed. Treatment Period: June 14 to July 12, 2024.
- Patient HODFR-GP5: The patient had three fistulous tracts at the level of the lower third of the right tibia and it was decided to perform a fistulectomy of the three tracts, achieving a bloody area without the fistulous tunnels. A significant rapidity in granulation of the tissue until its epithelialization was subsequently observed in a period of approximately 45 days, despite being a lesion in which a septic process underlies. Treatment Period: June 25 to July 26, 2024.
- Patient HODFR-GP6: The patient obtained a satisfactory result from a clinical and microbiological point of view, since closure of the fistulous tract and a considerable decrease in colony-forming units (CFU) of *Staphylococcus Aureus* was achieved. Treatment Period: May 24 to June 17, 2024.
- Patient HODFR-GP7: Although microbiologically the result was positive, clinically, despite the decrease in the surface area value, useful granulation tissue was not achieved that would allow a skin graft to be performed. Treatment Period: June 25 to July 25, 2024.
- Patient HODFR-GP8: From the microbiological and clinical

point of view the result was positive. The sepsis did not progress, so there was no need to remove the prosthesis. Treatment Period: July 13 to 29, 2024.

Some Graphic Example

Patient Control Group HODFR-GC-1



Start of Treatment

End of Treatment

Patient Study Group HODFR-GP-1



Start of Treatment

End of Treatment

Results

Microbiological Studies

- No favorable results were obtained in any of the four cases belonging to the Control Group.
- In the cases of the patients in the Study Group there were six favorable results where the decrease in CFU was observed and only two unfavorable ones. Of these two unsatisfactory cases, one of them was due to not having timely and combined antibiotic therapy (deficiency of antibiotics in the hospital) that would allow better treatment and thus better evolution.
- Microbiologically, more satisfactory results were observed in cases that combined conventional therapy with electrical stimulation than in those that only used conventional therapy, because a decrease in CFU was achieved in the majority of patients.
- of the Study Group, two were discharged without bacterial growth. This result of the joint treatment is highly significant, since patients who normally receive conventional treatment are discharged with a microbiological culture and generally show bacterial growth to a lesser extent in relation to admission. These patients improve clinically, but are unable to express a positive result from a microbiological point of view, which is only achieved in some cases, after several months of indicated treatment and monitored through outpatient consultations.

Average Hospital Stay Compared to the Last Admission

- The stay of the last admission was compared with the average of previous admissions in each case, whenever possible, since some had only one admission, which was not useful for such a comparison.
- Considering all patients, regardless of the group to which

they belonged, a reduction of 370 days of hospital stay was obtained, considered a positive result, since it contributes to the economy of the institution and to the psychological well-being for the patient who spends less time in conditions of institutional stress. Remember that this type of patient generally has long stays, sometimes lasting several months of admission.

- In the Control Group, the decrease was 74 days, while in the Study Group it was decreased by 289 days, showing that the combined treatment provides better results from an economic point of view, mainly in the costs of admission (significant reduction in hospital stay), medications used and with positive consequences for patients.

Conclusions

Conventional therapy associated with electrical stimulation, as a combined treatment, had a satisfactory result compared to conventional therapy from the clinical, microbiological and psychological point of view for the Study Cases, as well as a reduction in hospital stay, with the consequent decrease in the cost for this concept per patient as each of them spent a shorter time in the institution.

We consider that the main objective of the Clinical Study related to the evaluation of the efficacy and safety of treatment with Stimul W® in conjunction with conventional treatment in difficult-to-heal lesions derived from Chronic Osteomyelitis was met.

The main achievements achieved in the present study were:

- It was possible to verify the possibility that the combined therapy produced a bacteriostatic effect by achieving (according to microbiological analyses) a higher concentration of Colony-Forming Units (CFU) and a lower appearance of the amounts of CFU
- The bacteriological effect is verified, with the total elimination of bacteria upon discharge of two patients (not common events and detected for the first time).
- The hospital stays in patients who received combined therapy decreased significantly, compared to patients who received only conventional treatment, contributing economically to savings in the institution due to admission time and use of medications and to improving the quality of life of patients, positively verifying the proposed hypothesis.

Conflict of Interest

The authors declare that there is no conflict of interest

Authors' Contribution

Dr. C. Juan Enrique Suen Díaz

- Main author of the Stimul W® electrical stimulator used in the case study.
- Prepared the Clinical Study proposal, the Case Collection Notebook and the Informed Consent proposal.
- Participated in the application of the treatment and the control of the daily information obtained.
- Performed all digital information processing and statistical analysis.
- Participated in the writing and revision of this article.

Dr. Joel Chirino Abreu

- Main specialist doctor in the Clinical Study.
- Provided the medical information of each patient to be included in the Case Collection Notebook, as well as participated in the signing of the Informed Consent of each

patient, as the main specialist.

- Directed and participated in the daily application of the treatment.
- Participated in the writing and revision of this article.

M. Sc. Niria Castro Sánchez

- Performed all microbiological studies (cultures and antibiograms) performed on the patients' lesions.
- Processed all the information obtained in the microbiological studies.
- Participated in the review of this article.

Dr. Antonio Raunel Hernández Rodríguez

- As Director of the hospital institution, he participated, facilitated and supervised all the logistics necessary for the development of the case study and compliance with the application of the proposal.
- Participated in the review of this article.

M. Sc. Yadel Forneiro Martín-Viaña Ing. Barnel Quintero Navarro

Ing. Dennis Legrá Lugo

- Participated in the processing of all the information obtained.
- Participated in the writing and revision of this article.

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