Pressure ulcers, also called decubitus ulcers, are a common challenge of humanity and are exceptionally difficult to heal. They are wounds that are initiated by relatively short periods of pressure on the skin that blocks blood circulation causing the skin and underlying tissues to die, leading to an open wound. Pressure release can prevent further tissue degeneration, and some ulcers heal and disappear by themselves. However, many pressure ulcers never heal and continue to grow in diameter and depth. By one year, such unhealing ulcers are referred to as chronic ulcers. Chronic ulcers frequently jeopardize the life of the patient due to infections that become increasingly deep until they invade bones and the circulatory system. We report on a patient with a chronic pressure ulcer at his coccyx prominence. Fourteen months after the ulcer had appeared, a surface pulse electromagnetic force (PEMF) stimulator was applied over T7 - T8, 45 cm cephalic to the ulcer, as part of a nerve stimulation study. Although the ulcer had continued to grow both in diameter and depth for 14 months and showed no signs of healing, within 6 days of applying the PEMF stimulator, the ulcer began to heal and was fully eliminated after 3 months. We concluded that the electrical stimulation induced the healing of the pressure ulcer. The ulcer elimination is quite surprising due to the exceptionally low electric field-force being generated by the stimulator at a distance of 45 cm.

Key words: Pressure ulcers, Ulcer elimination, Wound healing.
(25, 26), hormone replacement therapy (HRT) (27, 28), near-infrared low-level laser therapy (LLLT) under temperature-controlled conditions (29), light therapy (30), radiant heat (31, 32), polarized light (33), dietary supplements (34), techniques that induce angiogenesis (35), maggots for debridement of wounds and diabetic ulcers (36-39), antibiotics (40), prostaglandin E (41-43); honey (44-54), inhibiting metalloproteases (55-59), and hypobaric oxygen treatment (23, 60-62).

One of the most promising is the use of bio-electrical stimulation therapy (BEST) (63, 64), and pulsed electromagnetic force stimulation (PEMF), also called interrupted direct current (IDC), (65-68). One concept on which electrical stimulation is based is that the human body has an endogenous bioelectric system that enhances healing of bone fractures and soft-tissue wounds (63). Another is that the stimulation induces bone to release a host of wound and bone healing factors (69), and that the stimulation of bone leads the bone to release these factors (25, 63, 69-71).

Other research has found that electrical stimulation failed to induce ulcer elimination (72). The differing results may have been due to the great differences in the methodologies of electrical stimulation, and differences in electrical field forces used, from weak to high-voltage pulsed galvanic stimulation (73, 74), and the relatively small numbers of participants in the studies. Therefore, further work is required to determine the validity of electrical stimulation as a means of eliminating pressure ulcers and the optimal stimulation parameters.

Materials and Methods

A pulse electromagnetic force (PEMF) stimulator coil was centered over the T6-T8 vertebral region where we had performed a spinal cord repair operation. The electrical stimulation was part of an IRB-approved clinical study on the effects of electrical stimulation on axon regeneration. The patient was requested to apply the stimulator for a total of 8-10 hours per day every day, although it was not required that the hours be continuous. Thus, the use of the stimulator was left to the decision of the patient, but it was generally used for about 8 hours per day.

Results

An 18-year-old male presented with a gunshot-induced complete spinal cord transection from T-7 to T8. According to an IRB-approved protocol, and using IRB-approved patient consent and HIPAA documents, we exposed the damaged region of the spinal cord and refreshed the damaged ends of the spinal cord.

Fourteen months post surgery, in accordance with an IRB-approved protocol, we invited the patient to participate in our clinical study to examine the potential influences of electrical stimulation on axon regeneration following his spinal cord injury. The study involved placing a PEMF stimulator over the region of the spinal cord injury, T7-T8, with the unit held in place with Velcro straps.

Within two weeks of his spinal cord injury, the patient developed a pressure ulcer in the region of the coccyx prominence. From the beginning of the appearance of the pressure ulcer, the patient rigorously followed the recommended treatment for pressure ulcers by cleaning it several times per day. However, the ulcer did not heal and continued to grow in depth and diameter. When the patient began to use the PEMF stimulator, he had had the ulcer for 14 months, at which time, because it would not heal, the ulcer was defined as chronic. The distance from the caudal end of the PEMF stimulator and the center of the ulcer was 45 cm.

Within 6 days of initiating the PEMF stimulation, the tissue within the ulcer changed from white to rosy, and the ulcer began to diminish in depth and diameter. After 3 months, the ulcer was completely healed, at which time the patient stopped using the PEMF stimulator. Throughout the time the ulcer was healing, the PEMF was always positioned over the upper region of the vertebral column, 45 cm from the center of the ulcer.

Discussion

Although some pressures heal by themselves, others that do not can become chronic, defined as not healing for more than 1 year. A number of techniques increase the healing rate of pressure ulcers. While many techniques improve ulcer healing times only slightly, some techniques induce more rapid healing. The most effective techniques for eliminating pressure ulcers include the direct application of neurotrophic factors, neurotrophic factors and wound healing factors released from platelets within platelet-rich fibrin placed in the ulcer (2-16), electrical stimulation (25, 63, 64, 69, 70), metalloprotease inhibitors (55-59, 75), and hypobaric oxygen therapy (23, 24, 60-62, 76).

Other research found that electrical stimulation failed to induce ulcer elimination (72). However, the different studies had great differences in the methodologies of electrical stimulation, and differences in electrical field forces used, from weak
to high-voltage pulsed galvanic stimulation (73, 74), and involved relatively small numbers of participants. For example, for electrical stimulation, there are great differences in the electrical pulse strength used (63, 64, 66-69). In the case of inhibiting metalloproteases, which is quite effective in animal models, it cannot be used clinically because there is no such FDA-approved material. Thus, more extensive studies are required to determine which technique, singly or in combination with other techniques, provides the most reliable and optimal rate of ulcer healing.

Our patient had a chronic pressure ulcer and showed no signs of healing for 14 months, in spite of the application of a daily regular cleaning regime. However, the ulcer began to heal within 6 days of initiating PEMF stimulation, and the healing continued with the continued use of the electrical stimulation until the ulcer was completely eliminated. The positive correlation between the initiation of PEMF stimulation and ulcer healing suggests that the healing resulted from the electrical stimulation. This is consistent with data from other groups (66-68).

This study differs significantly from those of other groups in that the electrical stimulator was always placed directly over the pressure ulcer (66-68), whereas in our patient, the center of the pressure ulcer was 45 cm from the caudal end of the PEMF coil. At this distance, the expected field force generated by the PEMF stimulator would be close to or zero.

The distance of the electrical stimulator from the ulcer, and the exceptionally weak force thus applied to the ulcer raises the question of what electro-magnetic force is required to induce wound healing. It also raises the question of whether the electrical stimulation acted directly on the ulcer to induce its healing.

Little is known about the field force required to reverse the growth of ulcers and induce their healing. Thus, although we concluded that electrical stimulation induced the ulcer elimination, its mechanism of action and the optimal electrical field force used in inducing ulcer elimination must still be examined. It is also possible that the electrical stimulation did not induce healing directly, but by another mechanism, such as stimulating spinal nerves innervating the ulcer region, or via a broad based mechanism that induced angiogenesis within the ulcerous tissue.

The present results have led to our initiating a clinical study to examine the efficacy of PEMF stimulation when the stimulator is placed directly over ulcers, as well as testing various electrical field strengths on ulcer elimination. Finally, the study will examine the effectiveness of combining several established ulcer eliminating techniques when used simultaneously.

**Resumen**

Ulceras de presión, también llamadas “decubitus ulcer”, son un reto común para la humanidad y son excepcionalmente difíciles de sanar. Son heridas iniciadas por periodos relativamente cortos de presión en la piel que bloquean la circulación sanguínea causando la muerte de la piel y el tejido cercano, conduciendo a una herida abierta. La liberación de la presión puede prevenir la degeneración de tejido adicional, y algunas úlceras sanan y desaparecen sin solas. Sin embargo, muchas úlceras de presión nunca lo hacen y continúan creciendo en diámetro y profundidad. Después de un año, esas úlceras no sanadas son llamadas úlceras crónicas. Las úlceras crónicas frecuentemente ponen en peligro la vida del paciente debido a que las infecciones se vuelven increíblemente profundas e invaden los huesos y el sistema circulatorio. Presentamos un paciente con una úlcera crónica en su eminencia cocígea. Comenzando 14 meses luego de su aparición, una estimulación de fuerza electromagnética superficial de pulso (PEMF) fue colocada sobre el T7-T8, a 4 cm cefálicos a la úlcera, como parte de un estudio de estimulación nerviosa. Aunque la úlcera había continuado su crecimiento tanto en diámetro como en profundidad por 14 meses, y no mostraba señales de recuperación, en 6 días de aplicar el estimulador PEMF la úlcera comenzó a sanar, y fue completamente eliminada luego de un mes. Concluimos que la estimulación eléctrica induce la recuperación de las úlceras de presión. La eliminación de la úlcera es sorprendente debido a la gran distancia entre el estimulador y la úlcera, en la que la fuerza del campo eléctrico hubiera sido excepcionalmente baja.

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This study was conducted in compliance with all ethical regulations concerning patient trials, using only FDA-approved materials, and only after receiving written informed patient consent on IRB-approved patient consent and HIPAA forms. There were no conflicts of interests in the clinical study, and no economic or other incentives provided by any entity.

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