

The use of portable, wearable form of pulsed radio frequency electromagnetic energy device for the healing of recalcitrant ulcers: A case report

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Abstract

Introduction

Pulsed radio frequency energy (PRFE) has successfully been used to treat diabetic and venous stasis ulcers. In this case report, a lightweight wearable form of a PRFE device was evaluated and used to treat 3 diabetic foot ulcers and 1 venous stasis ulcer.

Methods

The ulcers were present on the 4 patients for greater than 3 months and had failed to heal after conventional treatment. A lightweight battery powered, wearable form PRFE device was introduced as a treatment and used 6-8 hrs per day for a period of 6 weeks.

Results

All patients after 1 week of therapy showed improvement and wound size was seen to decrease. Patient 1 had a venous stasis ulcer, and reported significant pain relief after 2 weeks treatment. Patients 2 and 3 achieved complete healing after 3 weeks treatment, and patient 1 and patient 4 had a 95% and 88% reduction in wound size after the 6 week study period. Both these patients continued to complete healing using the PRFE device after the 6 week study period.

Conclusion

PRFE treatment delivered in the form of a wearable lightweight patch appears to offer promise in the treatment of recalcitrant chronic wounds.

Keywords: chronic device healing PRFE wounds

Introduction

Diabetic foot ulcers are the most common chronic wounds in western industrialized countries. Of the millions who have diabetes mellitus, 15 per cent will suffer foot ulceration which often leads to amputation (100,000 per annum in the US alone). The economic burden of treating diabetes as its associated complications is extreme(1) and will likely increase as the rate of diabetes continues to rise. Statistics from the American Diabetes Association show the prevalence of diabetes at 25.8 million children and adults, or 8.3% of the US population. Venous stasis ulcers are a major cause of chronic wounds, and are typically associated with significant pain. Venous stasis ulcers are common in patients who have a history of leg swelling, varicose veins, or a history of blood clots in either the superficial or the deep veins of the legs. Venous ulcers is the most common etiology of lower extremity ulceration, affecting approximately 1 percent of the U.S. population (2).

The healing of diabetic foot ulcers, is necessary for the prevention of amputation and a number of advanced technologies have been introduced to achieve higher success in amputation prevention and limb preservation(3). Electrotherapy in the form of pulsed radio frequency electromagnetic energy (PRFE) has recently received a new focus, with a number of case reports showing promising results in the healing of chronic wounds (4-8). A retrospective study on the Regensis Wound Healing Registry (Regensis Biomedical, Scottsdale, Arizona) has indicated that PRFE therapy holds promise to be an effective treatment for chronic wounds(9). Regensis Biomedical's Provant System is a suitcase sized device that emits non-ionizing, radio frequency energy at 27.12 MHz There is a growing list of clinical studies that have shown the safety and efficacy of PRFE as a therapy, as has been recently reviewed by Guo et al, 2011(10). However, there are still major limitations to PRFE devices, as treatment regimens require 2 x 30 minute treatments per day, making it impractical for most ambulatory patients, restricting it's use to severe chronic wounds.

In this case report we show the application of a wearable battery powered form of PRFE device for the treatment of recalcitrant wounds. The lower energy levels emitted by this form of PRFE device are compensated by extended use times. The PRFE device used in this case study was ActiPatch™ (BioElectronics Corporation, Frederick, MD) which delivers PRFE at a carrier frequency of 27.12 MHz and a pulse rate of 1000Hz.

Materials and Methods

At the Temple University Foot and Ankle Institute, four adult African American diabetic males between the ages of 40 to 75 with ulcers present for longer than three months were admitted into the pilot study. Three patients had diabetic neuropathic ulcers and one had a venous stasis ulcer. All the diabetic ulcer patients had at least one palpable pedal pulse and an ulcer of Wagner Grade II or higher. All ulcers had previously been treated with a variety of methods, without appreciable healing, and are described for each patient. **Patient 1:** was a 72yr with type II diabetes that had a venous stasis ulcer that had undergone multilayer compression therapy for 4 weeks without any appreciable healing. Significant pain was experienced by this patient which was assessed by a 0-10 point visual analogue scale (VAS). **Patient 2:** was 42 yrs old with type II diabetes and an actively working truck driver. Previous

failed treatment included wound debridement, use of Promogran matrix, and dry sterile dressing. Once the PRFE device was added to the regimen, Promogran was discontinued. **Patient 3:** 62 year old patient with insulin controlled diabetes that had not responded to debridement and application of triple antibiotic ointment with offloading. Once the PRFE device was added, triple antibiotic was discontinued. **Patient 4:** 74 year old patient with insulin controlled diabetes presented with a right heel decubitus heel ulcer that resulted following hospitalization for prostate surgery. Patient had already had a below knee amputation on the left side. The right heel wound was granular and non-infected. Offloading with a protective boot and wound care consisting of debridement, Promogran matrix, and dry sterile dressings were done prior to the PRFE device use. Once the PRFE device was used, weekly debridement and offloading was maintained. After informed consent, patients adopted a protocol that utilized the PRFE device for six to eight hours per day. The patients with diabetic ulcers, had their wounds covered with moist saline gauze, ActiPatch™, and a dry sterile dressing. When the ActiPatch™ PRFE device was not in use, the ulcer was covered with moist saline gauze and dry sterile dressing. Compression therapy was continued with patient 1 along with the PRFE device for 6-8 hours per day. Patients kept a journal of their PRFE device use and brought the log in during their weekly visits. Weekly visits consisted of sharp debridement and surgical scrub, for the diabetic ulcer patients, followed by measurement and photographic documentation. Wounds were evaluated for any signs of infection and new changes such as increased depth or drainage. The PRFE device was also evaluated for proper functioning at each visit. Patients were educated on their daily wound dressing changes. The wounds were evaluated once weekly for a total of six weeks.

Results

The patients tolerated the PRFE therapy well and reported no negative side effects. Wounds still needed to be sharply debrided on a weekly basis, but patients were pleased with the therapy and its ease of use at home. Table 1 shows the wound measurements at the start of the treatment (week 0) and for the following 6 weeks of treatment. Starting at week 1 all patients were seen to have a decrease in wound size. The ulcers had a steady decrease in side to side closure and in visible peri-wound edema. Patients 2 and patient 3 had complete healing of their diabetic ulcers after 3 weeks of treatment.

Patient 1 had a venous stasis ulcer show in Figure 1, which caused the patient significant pain. After two weeks of PRFE therapy the patient reported significant pain relief. The ulcer of patient 1 decreased in size from 4 x 2.5 cm to 0.7 x 0.5 cm at the end of the 6 week study period, a decrease of approximately 95% of the wound area. The venous stasis continued to complete healing after the study period with continued use of the PRFE therapy device.

Figure 1. The venous stasis ulcer of patient 1 is shown at week 0 , week 2, week, 4 and week 6 of PRFE treatment. Significant pain relief was reported by the patient after 2 weeks treatment. The ulcer had decreased in size from 4.0 x 2.5 cm to 0.7 x 0.5 cm after 6 weeks PRFE treatment. The ulcer continued onto healing using the PRFE therapy.

WEEK 0



WEEK 2



WEEK 4



WEEK 6



Figure 2 shows the left heel ulcer of patient 3. The ulcer improved rapidly with PRFE treatment, recovering 50% of the wound area after 1 week of PRFE treatment. The ulcer progressed to complete healing at 3 weeks. The ulcer is shown at week 0, week 1, week 2 and week 3.

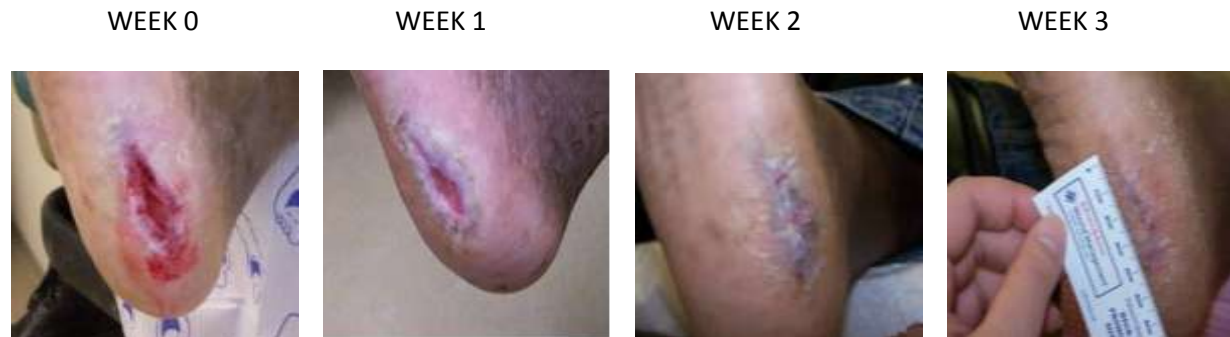


Table 1 Shows the wound size (centimeters) data of each patient at week 0 (start of treatment) and for each week of the 6 week study period.

Patient	Age	Location	Week 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
1	66	right leg	4 x 2.5	4 x 2.3	4 x 2	3 x 1.5	2 x 1.5	1 x 0.7	0.7 x 0.5
2	60	right foot	0.5 x 0.5	0.3 x 0.3	0.2 x 0.1	ulcer healed			
3	43	left heel	4 x 1	2 x 0.5	1 x 0.3	ulcer healed			
4	74	right heel	2.5 x 1.75	2 X 2	2 X 1.5	1.7 X 0.7	1 X 1	1 X 0.5	1 X 0.5

The diabetic ulcer of patient 4 had a wound size at the beginning of treatment of 2.5 x 1.75 cm, by week 4 this had decreased to 1 x 1 cm, approximately a 73% reduction in size and by week 6 the wound area decreased to 1 x 0.5 cm, a reduction of 88% in size. Wound area reduction at week 1 and week 4 is a strong indicator of complete healing(10). Patient d 4 had significant reduction in wound size at 6 weeks and continued on to healing after the study period utilizing the PRFE treatment.

Figure 3. Patient 2 had a 0.5 x 0.5 cm diabetic ulcer at the beginning of PFRE treatment, which healed after 3 weeks PRFE therapy. The ulcer at week 0, week 1 and week 3 is shown.



Discussion

The mechanism by which PRFE promotes the healing of chronic wounds is not fully understood. But studies on cells and animals have given insight into the effects of PRFE therapy. Up-regulation of gene families involved in tissue repair in co-cultures of human dermal fibroblasts and epidermal keratinocytes treated with PRFE has been shown(Moffett, Griffin et al. 2010) . These included metalloproteinase and tissue inhibitor of metalloproteinase, and interleukin -related genes, interferon-related genes, and tumor necrosis factor-related genes. Cell studies have demonstrated up-regulation of FGF-2 after PRFE exposure, an important molecule in wound healing for promoting endothelial cell proliferation, angiogenesis and granulation tissue formation. PRFE therapy given to animal wound models of diabetes have reported to an up-regulation of FGF-2(12), increased wound healing, and wound tensile strength compared to sham control animals(13,14).

A portable wearable PRFE device was first used in 1982 for the treatment of postoperative wounds following blepharoplasty(15). A study by Stiller et al 1993, using a wearable form of PFRE device evaluated it's clinical efficacy and safety in a placebo controlled multicenter trial. Significant decreases in wound depth and pain intensity favoring the active group were seen, wounds after 8 weeks treatment in the active group had a 47.7% decrease in wound surface area vs. a 42.3% increase for placebo(16)(Stiller, Pak et al. 1992). The device used in this study weighed 505 grams and was used 3 hrs per day. More recently clinical trials on the postoperative recovery after breast augmentation surgery(Heden and Pilla 2008) , and breast reduction surgery(18) have clearly demonstrated the control of postoperative pain with newer versions of wearable, portable PRFE devices.

In this pilot study presented here, a light weight wearable form of PRFE was used to facilitate the wound healing process in both diabetic and venous stasis lower extremity ulcers. The PRFE device used in this case study was a in the form a patch and was easy to use from both the physician's and patient's standpoint. Since the completion of this study ActiPatch has been refined and updated, and now consists of a small control module and a 12 cm, or 8 cm antenna and weighs approximately 8 grams. The reconfigured device is now used as a 24 hr continuous PRFE therapy with the same carrier frequency of 27.12 MHz and 1000Hz pulse rate. Figure 4 shows the application of the PRFE device on a patient with a venous stasis ulcer, prior to PRFE therapy this patient was considered for amputation, however, the ulcer healed within 8 weeks and the patient avoided amputation (unpublished data).

The results from this pilot study suggest that lightweight wearable PRFE devices maybe an effective adjunct therapy for recalcitrant wounds promoting healing and reducing pain. The ease of use, low cost and compatibility with current conventional therapy also suggest this form of wearable PRFE device could be widely applied as a first choice therapy, though further studies are required to determine their true value.



Figure 4. A version of PRFE device is shown in use on a patient with a venous stasis ulcer

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