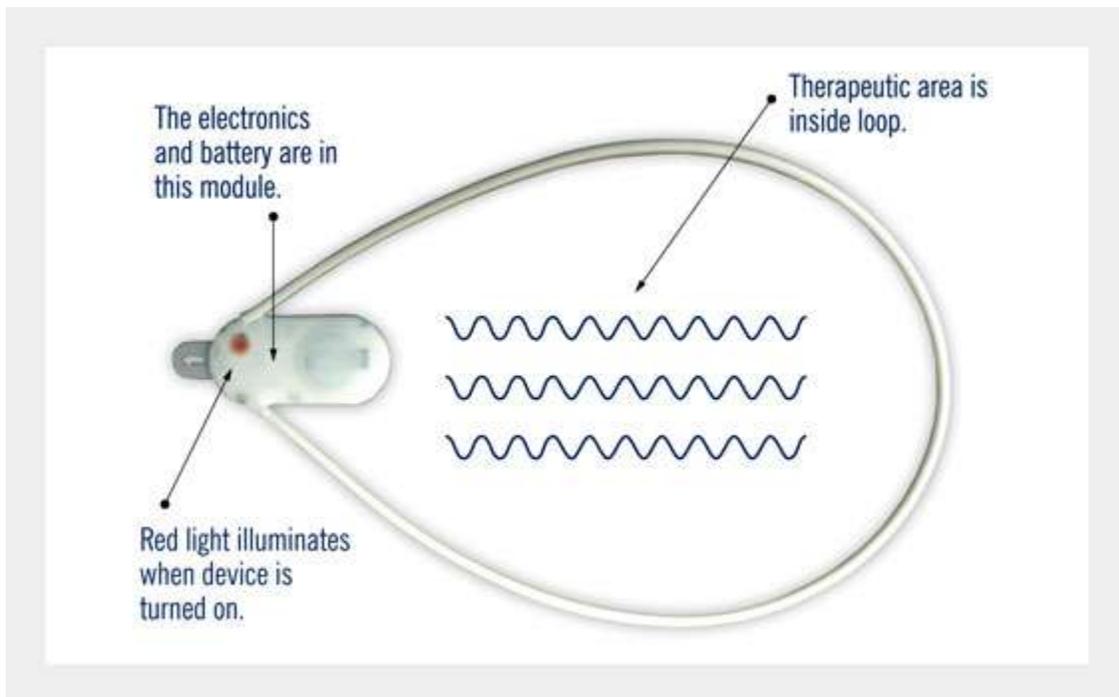


# BioElectronics Chronic Wound Case Series

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## Pulsed Radiofrequency Electromagnetic Field Therapy:

### An Adjunct Pain and Wound Healing Therapy



## Introduction

Bioelectronics Corporation makes an innovative medical device, designed to replace larger clinic-based devices that treat chronic wounds, pain and edema with pulsed radiofrequency electromagnetic field energy. All therapeutic pulsed radiofrequency electromagnetic field devices emit a safe form of non-ionizing electromagnetic radiation. BioElectronics medical devices, as do many larger clinic based devices, use a frequency of 27.12 MHz, an assigned FCC medical frequency. The unique device design by BioElectronics has refined the technology into an 8gram wearable miniature form, which delivers the radiofrequency electromagnetic field at a pulse rate of 1000 pulses per second and at 100 microsecond burst widths. Peak burst output power of the 12 cm antenna is approximately 0.0098 watts covering a surface area of approximate 100 cm<sup>2</sup>. The circuitry consists of low voltage (3 V) digital/analog electronics that control all timing functions to produce the therapeutic RF field, where the antenna field is placed directly above the therapeutic site.

Bioelectronics Medical Devices enable:

- ✓ Continuous 24 hr. therapy
- ✓ Direct focus onto the wound
- ✓ Convenience – home-based
- ✓ Small, light and portable
- ✓ Easy to use
- ✓ Improved patient compliance
- ✓ Dramatically lower cost of therapy
- ✓ Safety and Elimination/Reduction of Drugs

*Figure 1. A traditional Diapulse delivering 30min x 2 daily required treatments,  
And the BioElectronics RecoveryRX PEMF device incorporated into the wound dressing giving continuous 24hr home based therapy*



## Pulsed Radio frequency Electromagnetic field as a Chronic wound therapy

The use of pulsed radiofrequency electromagnetic field (PEMF), also termed (PRFE) therapy has shown notable success in healing of chronic wounds. PEMF is a non-ionizing energy at the shortwave radiofrequency band of the electromagnetic spectrum, commonly at a frequency of

27.12MHz. Since the introduction of PEMF in the 1950s, clinical studies on healing of chronic wounds(1-6) and surgical recovery(7, 8), as well orthopedic studies(9-12) have documented PEMF as a successful clinical therapy. A series of case reports (13-17) and a retrospective study on a wound registry(18) have re-introduced PEMF therapy as an adjunct wound healing therapy, as newer more portable PEMF devices have been introduced.

## **Known Downstream Biological Effects of PEMF**

While the exact mechanism by which PEMF interacts with cells to initiate the therapeutic effects is not fully understood, cell studies have given valuable insight into the downstream biological effects of PEMF therapy. Human fibroblasts exposed to PEMF signal show p42/44 MAP kinase activation(19), and increased cell proliferation. The MAP kinase family of intracellular signaling proteins is activated by a range of stimuli and the activated MAP kinase translocate to the nucleus and transactivate transcription factors, changing gene expression to promote growth, differentiation or proliferation. Co-cultures of human epidermal keratinocytes and human dermal fibroblasts which were studied by gene array demonstrated an up-regulation of gene families associated with all phases of the wound healing cycle(20, 21). These included many genes involved in the inflammatory stage of wound repair and expression of genes involved in angiogenesis and tissue remodeling. Cell studies on human vascular endothelial cells confirm angiogenesis effects of PEMF fields(22), as well as up-regulation of FGF-2(23), a growth factor that promotes angiogenesis. Nitric oxide is up-regulated by PEMF, nitric oxide is a vasodilator and also promotes angiogenesis(24).

In a mouse models of diabetes, wound healing rates were increased when exposed to PEMF, compared to animals that were sham PEMF treated(25). And notably increased proliferation of dermal fibroblasts was determined, measured by the cell proliferation marker Ki67, a protein that accumulates in the cell nucleus of cells progressing through the cell cycle.

## **PEMF Delivery**

PEMF therapy is none invasive and is delivered through the wound dressing, and to date has shown no unwanted side effects. With positive reports in the literature documenting PEMF as an effective therapy, its wider adoption as an adjunct therapy seems warranted. However, limitations exist, that have restricted its adoption as a widely employed wound

healing therapy. Current treatment regimens require 2 x 30 minute treatments per day and are delivered by clinic-based, mains powered devices (figure1).

Considering that in many patients, chronic wounds can take many weeks to heal, making clinic based therapies that are require twice daily treatments impractical for most patients. The potential answer to this inherent limitation is portable lightweight wearable PEMF technology, which ideally could become be an integral part of the wound dressing as shown in Figure 1. Stiller et al 1992 (26), published a randomized control trial, in which a portable, wearable device to deliver the PEMF therapy was used. The portable device allowed for a home based treatment; in this case it was used for predominantly venous leg ulcers. The PEMF delivery device that was used, weighed 508g with treatment protocol consisting of 3 hrs per day. Significant decreases in wound area, wound depth, healthy granulation tissue and decreased pain intensity favoring the active group were seen. This study suggests that wearable, portable forms of PEMF could be an effective adjunct wounding healing therapy. Nicole and Bentall 1982 (27) were the first to publish a study using wearable battery powered extended use time PEMF device in which edema and bruising were reportedly decreased following blepharoplasty. Bental, also published a paper documenting that extended use time wearable PEMF, reduced the healing time of experimental human skin wounds(28). Healing was shown to be 52 days in the untreated group compared to 39 days in the PEMF treated group. Histological analysis also showed advanced wound architecture, including near normal epidermal thickness in the treated wounds compared to a thin epidermis in the untreated wounds. More recent studies, have demonstrated the effectiveness of small wearable extended use time PEMF devices. A significant reduction in postoperative pain in randomized, double blind placebo controlled studies has been reported (29-31). Plantar fasciitis, a recalcitrant heel pain has also been shown to be treated with portable, wearable extended use PEMF therapy(32). Given that postoperative pain is significantly controlled by wearable PEMF it seems probable that chronic wounds can also be treated with these devices. Below is a series of case studies that have utilized RecoveryRx to induce wound healing in chronic wounds of various etiologies.

# Bioelectronics RecoveryRx - Case Studies

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## **Pain Therapy**

## **Healing therapy**

### Introduction

The following case studies document patients who had long standing chronic wounds of various etiologies that were treated with BioElectronics RecoveryRX PEMF device. The patients were treated from three different clinics, in the USA, Belgium and Holland. Each patient had previously been treated with a variety of therapies which had failed to heal their chronic wounds. Persistent wound pain was also present in a number of cases. Bioelectronics RecoveryRX PEMF patented devices were introduced to the treatment protocol of each patient, at this time no other treatment parameters were changed. Wound size and wound pain, were evaluated for each patient, prior to introduction of RecoveryRX PEMF therapy, and after subsequent RecoveryRx treatment.

## Case Study 1 Exposed Vascular Prosthetic Vein

A left leg ulcer with exposed vascular prosthetic vein. Treatment consisted of debridement and 2 weeks of negative pressure wound therapy. After which the PEMF device RecoveryRx was introduced with Polymem dressing. The leg ulcer reduced in size and was 50% reduced by 3 weeks of pulsed radiofrequency and Polymem dressing treatment. Wound went onto complete closure.

A shows the patient's venous stasis leg ulcer; B, the wound dressing incorporating a RecoveryRx PEMF device; and C shows the wound after 3 weeks of RecoveryRx PEMF therapy. Patient went to complete healing.



## Case Study 2 Necrotic Toe Amputation

Patient 2 had an ischemic right foot with rapid evolution to a necrotic toe. An urgent amputation was performed. The patient needed surgical debridement of necrotic wound edges after which negative pressure vacuum therapy was started and continued for 1 month. Split skin graft was used but an open wound was still left. RecoveryRx PEMF therapy in combination with antiseptic Polymem silver was introduced. The split skin graft was then successful and the remaining open wound healed with the combination of RecoveryRx and Polymem silver dressing.

A. shows the split skin graft, and B. Polymem dressing with Recovery RX and C. 17 days after treatment.



### Case Study 3 – Venous Stasis Ulcer

A 72 yr patient with type II diabetes had a venous stasis ulcer that had undergone multilayer compression therapy for 4 weeks without any appreciable healing and was accompanied by significant pain. The venous stasis ulcer of patient 1 is shown at A. week 0 , B. week 2, C. week, 4 and D. week 6 of RecoveryRx PEMF treatment.

Noteworthy pain relief was reported by the patient after 2 weeks of treatment. The ulcer had decreased in size from 4.0 x 2.5 cm to 0.7 x 0.5 cm after 6 weeks RecoveryRx treatment. The ulcer continued onto complete healing using the RecoveryRx therapy.



## Case Study 4 - Diabetic ulcer

A 62 year old patient with insulin controlled diabetes with a ulcer on his heel that had not responded to debridement and application of triple antibiotic ointment with offloading. Once the RecoveryRx device was added, triple antibiotic was discontinued. The ulcer improved rapidly with RecoveryRx treatment; 50% of the wound area was healed after 1 week of RecoveryRx PEMF treatment. The ulcer progressed to complete healing at 3 weeks.

The ulcer is shown at A. week 0, B. week 1, C. week 2 and D. week 3.



## Case Study 5 – Diabetic Ulcer

A 42 yr old truck driver with type II diabetes had a 5 x 0.5 cm diabetic ulcer. Previous failed treatments included wound debridement, use of Promogran matrix, and dry sterile dressing. Once the RecoveryRx device was added to the regimen, Promogran was discontinued. The diabetic ulcer healed after 3 weeks RecoveryRx PEMF therapy.

The ulcer at A. week 0, B. week 1 and C. week 3 is shown.



A.



B.



C.

## Case Study 6- Pyoderma Ulcer

Pyoderma gangrenosum: Patient had a history of ulcerations and had two lesions: one on the left dorsal midfoot and the other on medial heel/ankle that had been present for 2 years. Therapy prior to RecoveryRx addition consisted of compression, curettage, hydrofera blue, and silvadene treatments. The left dorsal midfoot wound base was 80% red and 20% yellow with a moderate serosanguinous exudate. His pain was 10 out of 10 on the Visual Analogue Scale. Medial heel ankle wound ulcer base was 80% red and 20% yellow with moderate serosanguinous drainage and a pain of 9 out of 10 on the Visual Analogue Scale. Vicodin was used for pain medication.



Pain was rapidly resolved and the 2 yr old ulcers moved into the healing phase after addition of RecoveryRx. The ulcers at A. week 0, B. week 2 and at C. week 11 are shown.

## Case Study 7- Pyoderma Ulcer

Pyoderma ulcer was present on the left ankle of the patient for 3 year. Before addition of RecoveryRx PEMF therapy the wound measured 6.7cm length x 4.0cm width x .2 cm depth. He had a moderate exudate with serous drainage. The wound base was 90% red and 10% yellow. The wound care protocol consisted of silvercel antimicrobial dressing application and triple layer compression, pain was 5 on the VAS scale.

Pain levels rapidly resolved to 0 with RecoveryRx treatment, and the wound has reduced in size by 50%, with a 100% red wound bed and reduced wound drainage.



## Case Study 8 – Pyoderma Ulcer

Pyoderma ulcer was present on the dorsal and distal side of the foot. The ulcers had been present for 2 years and failed systemic corticosteroid and immunosuppressant therapy. Recovery Rx was added to his wound care regimen of Bionect on the wound and desoximetasone .05% applied to the periwound area. The wound base was 50% red and 50% yellow with moderate serous exudate and a pain level of 4 out of 10 on the Visual Analogue Scale.

Wound Pain reduced from 4 to 0 on introduction of RecoveryRx and wound bed formed a 100% red base with reduced wound drainage. Pain has been controlled over 1 year.



## Case Study 9 – Venous Stasis Ulcer

Venous stasis ulcer received after fall in 2009, amputation was considered before treatment began with Recovery Rx. The wound improved rapidly and the patient was removed from the amputation list. The wound healed in 12 weeks.



## Case Study 10 – diabetic Ulcer

105 yr old with a diabetic ulcer present for 2 yrs. Treated with RecoveryRx PEMF therapy. The ulcer began to heal after 2 weeks treatment and closed after 12 weeks of PRFE therapy



## Conclusion

The introduction of RecoveryRx PEMF therapy had a significant and positive effect on all the chronic wounds under study. Chronic recalcitrant wounds that had been present for up to 2 years, showed improvements, and in most cases complete healing after the addition of RecoveryRx therapy. A second significant finding was that persistent wound pain was also markedly reduced, usually within two weeks of the beginning of RecoveryRx therapy. Wound healing is a series of complex events that include inflammation, proliferation and maturation. Chronic wounds are stalled in the inflammatory phase of wound healing. The RF energy from RecoveryRx, unlike most wound therapies, works at a cellular level, rapidly resolving edema and breaking the cycle of chronic inflammation. The cells re-establish cell to cell contact and a healthy wound environment forms which allows for cell proliferation and wound repair to progress.

Each of the wounds in the case studies had failed to heal with previous therapies and addition of RecoveryRx PEMF therapy was the only change in the wound treatment protocol. These findings are therefore notable in that the wounds moved into a healing phase and strongly indicate that RecoveryRx is a significant addition to the available wound healing therapies. The ease of use of RecoveryRx, its low cost and compatibility with current conventional therapies and wound dressings demonstrate that RecoveryRx can be widely applied as a first choice wound healing therapy.

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