



Recovery Rx[®]

Chronic Wounds Recovery Therapy

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Introduction

Chronic wounds, also known as ulcers, are those that do not progress through the regular stages of healing and can persist beyond the expected healing period of eight weeks. About 6 out of 10 patients with chronic wounds also report significant pain associated with their wound/ulcer. Diabetic foot ulcers, venous leg ulcers and pressure ulcers are all examples of chronic wounds/ulcers and affect up to 4.5 million people in the United States. Of the millions who have diabetes mellitus, 15% are expected to suffer foot ulceration, which often leads to amputation (100, 000 per annum in the US alone). 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 are the most common etiology of lower extremity ulceration, affecting approximately 3 million Americans. The healing of diabetic foot ulcers and other difficult to heal wounds, is necessary for the prevention of limb amputation. Existing management techniques and technologies provide only limited effectiveness. There is a need for an inexpensive modality that can effectively reduce pain and improve the healing rate of with chronic wounds.

RecoveryRx® Medical Device for Chronic Wounds

The RecoveryRx is a wearable, drug-free medical device that is designed to reduce pain and improve the healing rate of chronic wounds. This product is already FDA-cleared (as Pulsed Shortwave Therapy or PSWT) for the treatment of edema following blepharoplasty and musculoskeletal pain associated with knee osteoarthritis & plantar fasciitis. The device emits a safe, low-power electromagnetic field that pulses 1000 times a second and cannot be felt by the user during use. Additionally, the device can be used 24/7 and works even through bandaging. As a result, it can be conveniently placed on top of bandaged wounds.

Mechanism of Action

The Recovery Rx technology works by regulating the activity of afferent nerves in the body, a process known as neuromodulation. The pulsed field of 27 MHz penetrates deeply into the body tissues, creating low level electrical fields which, in combination with electrical "noise" in the tissues, can significantly influence nerve activity. This mechanism is known as stochastic resonance, since the interaction occurs in a stochastic (random) fashion. Neuromodulation is known to decrease pain, reduce inflammation and improve healing due to three factors: 1) Activation of the natural inflammatory reflex, which is known to inhibit inflammation. 2) Activation of the motor reflex arc, which serves to activate muscles in the area and “pump” interstitial fluid away from the site of the wound, reducing inflammation. 3) Regulation of afferent nerve activity is known to reduce pain, by mitigating irregular “afferent noise”. Irregular afferent noise is known to activate pain receptors, leading to hyperalgesia and/or allodynia.

Summary

- Chronic wounds affect up to 5 million people
- Existing wound management practices are very expensive, but only marginally effective
- RecoveryRx® is a wearable medical device that regulates nerve activity (neuromodulation)
 - The device is drug-free, can be used 24/7 and has no harmful side effects
 - The device can be used over existing wound bandaging
 - The device is inexpensive, at 4 cents/hour of therapy
- Case studies using the RecoveryRx device indicate efficacy (**Appendix**)

Appendix

Case Studies

The following case studies document patients who had long standing chronic wounds of various etiologies, and were treated with the RecoveryRx device. The case studies are for patients treated in clinics based in USA, Belgium and Holland. Each patient had previously been treated with a variety of existing wound care therapies, without success in healing their wound. Persistent wound pain was also present in many cases. The RecoveryRx devices were introduced in the treatment regimen of each patient, without changing any other treatment parameters. Wound size and wound pain were evaluated for each patient, both before and after introduction of RecoveryRx therapy.

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 PSWT 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 PSWT device; and C shows the wound after 3 weeks of RecoveryRx PSWT 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 PSWT 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 PSWT 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 PSWT 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 PSWT therapy.

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



A.



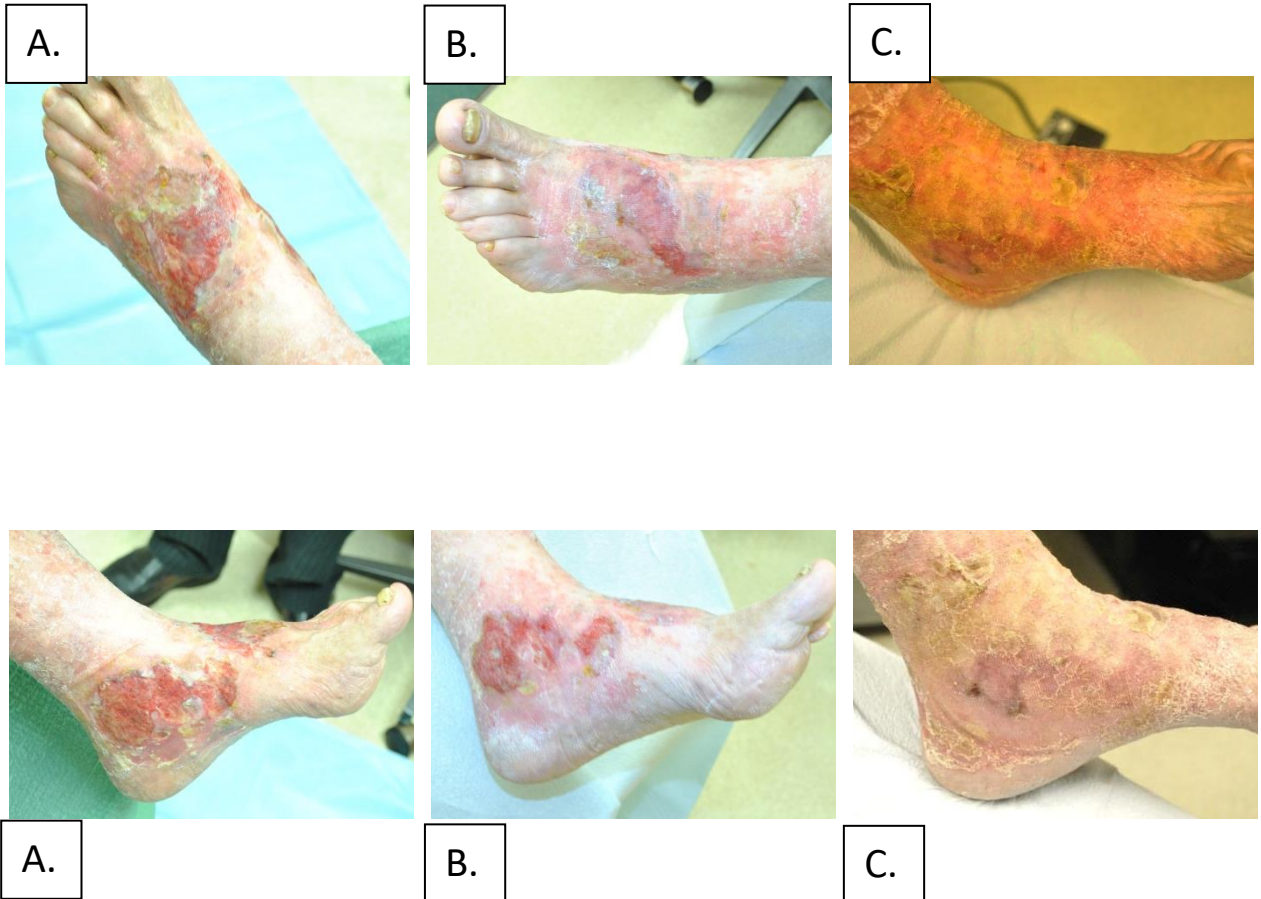
B.



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.

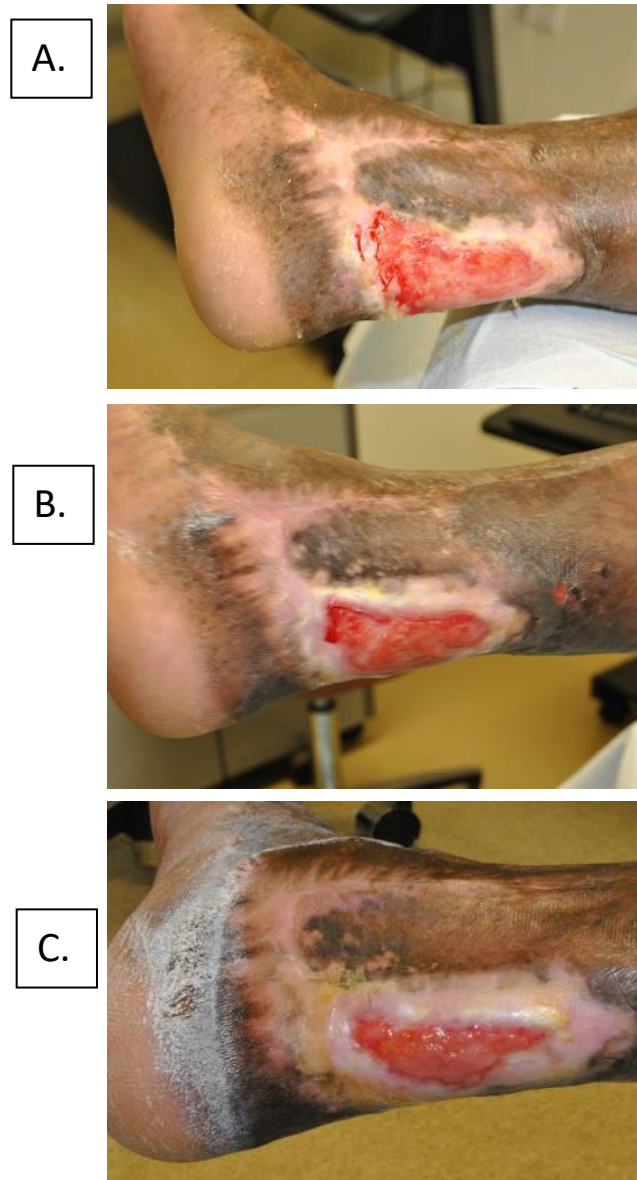


Pain was rapidly resolved and the 2 yr old ulcers moved into the healing phase after addition of RecoveryRx. The ulcers at A. week 0, B. week 2 and at C. week 11 are shown.

Case Study 7- Pyoderma Ulcer

Pyoderma ulcer was present on the left ankle of the patient for 3 year. Before addition of RecoveryRx PSWT 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.

A.



B.



C.



Case Study 10 – diabetic Ulcer

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



Case Studies Summary

The introduction of the RecoveryRx device had a significant and positive effect on all the chronic wounds in this case study series. 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 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 PSWT 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.