

CASE STUDY

Quick Healing of Foot Ulceration Wound Using dermaPACE™ Technology and Rehabilitation



Before



After

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Investigational Device. Not for Sale in the U.S.

Introduction

When a diabetic skin ulcer occurs, the current standard of care includes medical management of the systemic diabetes, offloading pressure points (casts, shoes, etc), debridement of necrotic or non-viable tissue, and wet-to-dry or wet-to-moist wound dressings. When the standard of care does not prove effective, alternative treatments and adjunctive therapies are considered. Pulsed Acoustic Cellular Expression (PACE™) Technology is a novel advanced modality that offers potential promotion of healing. This is a single case study of a patient treated with PACE Technology using the dermaPACE™ wound treatment device.

Method

A 33 year old male patient with a 10 year history of diabetes presented with a recurrent ulcer on the plantar surface of the right foot. The wound had persisted for 24 months despite two debridement treatments, split thickness skin graft, thirty hyperbaric oxygen sessions, and two

partial amputations (1st and 2nd toes). The patient began PACE treatment as part of an Institutional Review Board approved trial. PACE treatments involved a total of six sessions of 500 impulses each over 3 weeks (2 per week) at the E2 setting on the dermaPACE device. A standard of care regimen was continued in addition to the advanced modality treatment.





Week 1



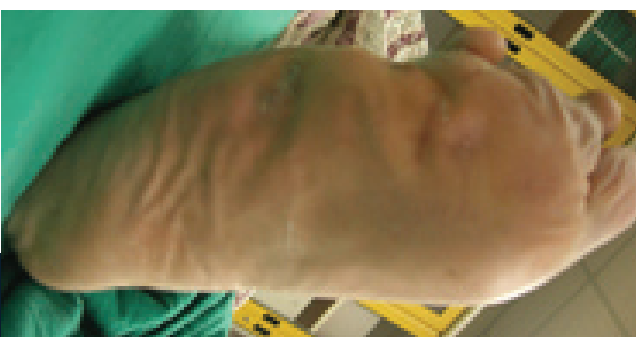
Week 2



Week 3



Week 12



Week 24

Results

The ulcer healed completely in 12 weeks with complete re-epithelialization and no need of a dressing. After 12 months of follow-up, there was no recurrence of the ulcer.

Conclusions & Discussion

PACE Technology is a proprietary form of Extracorporeal Shock Wave Technology (ESWT) utilizing engineering parameters and a treatment protocol specifically designed to optimize healing outcomes. High-energy impulse waves applied by dermaPACE to the wound surface cause microstresses at a cellular level resulting in a biological cellular response which includes the release of growth factors and cytokines (cellular expression) that lead to wound healing. This case study is an example of the remarkable potential this advanced modality treatment has to benefit patients with difficult and persistent wounds.

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