Improving diabetes-related foot ulcers with dermaPACE®

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Background

Extracorporeal shockwave technology (ESWT) was introduced to medical practice in the early 80s for pulverisation of kidney stones (lithotripsy) and has since been used in orthopaedic and other indications once its wound healing effects were discovered. Pulsed Acoustic Cellular Expression (PACE®) Technology has been developed based on scientific and clinical evidence of the beneficial wound healing effects of ESWT. The dermaPACE® uses PACE® technology to deliver high-energy, focused pressure waves to produce compressive (positive) and tensile (negative) stresses on cells and tissue structures. These pressure shock waves result in microcirculatory improvement, including increased perfusion and blood vessel widening (arteriogenesis), the production of angiogenic growth factors, enhanced new blood vessel formation (angiogenesis) and the subsequent regeneration of tissue such as skin, musculoskeletal and vascular structures. PACE® procedures return a chronic condition to an acute condition to help reinitiate the body’s own healing response.

The dermaPACE® system is TGA registered and is indicated for the treatment of acute and chronic defects of the skin and subcutaneous soft tissues, for example diabetes-related foot ulcers.

Materials and Method

During these evaluations, two chronic diabetic foot ulcers were treated with dermaPACE® combined with offloading and the Australian Gold Standard of Care.

After physiological wound cleaning, debridement and wound assessment, wound size measurement took place. The wound size was then programmed into the device. The dermaPACE® probe and machine as depicted in Figure 1 were prepared and a single-use sterile sleeve was slipped over the probe. A sterile gel was applied to the wound bed for transmission of the PACE® pressure waves. Then, a Radio Frequency Identification Device (RFID) card containing pre-programmed parameters such as energy levels and frequency was swiped over a marking on top of the machine. The treatment started when the foot pedal was pressed down. The probe head covered in the sterile plastic sleeve was then gently moved over the surface of the wound.

dermaPACE® treatments were applied according to the standard treatment protocol for diabetic foot wounds as depicted in Figure 2. Four treatments were applied within two weeks with a minimum of two days between treatments. Then, depending on the wound conditions, one further treatment can be applied fortnightly starting at week 4 (procedures at week 4, 6, 8 and 10, if required). Treatments were suspended when a satisfactory wound area reduction and/or wound improvement/closure was achieved.

Case 1 is a 79 year old man with type 2 diabetes (Table 1). Due to his foot deformity the plantar wound fluctuated in size over 9 months, whilst the vascular status remained unchanged. The wound’s dimensions before the first treatment were 0.5cm (l) x 0.6cm (w) x 0.6cm (d) with considerable undermining (2cm x 2cm) as depicted in Figure 3.

A granulating wound bed was observed before the third dermaPACE® procedure. After a total of 5 dermaPACE® treatments, the patient achieved a reduction in wound size as well as a considerable improvement in vascularisation as depicted in Table 2 and Figure 4. The improved vascularisation in the wound bed allowed the patient to undergo minimal incision surgery with a foot and ankle surgeon who previously rejected this intervention due to poor vascularisation.

Results

Case 2 is a 54 year old male with type 2 diabetes, morbid obesity and a foot deformity due to ineffective offloading. The patient was treated with 6 dermaPACE® treatments and achieved a considerable wound area reduction within 12 weeks followed by closure as depicted in Figures 5 to 8. dermaPACE® treatments improved blood supply in the wound area. The patient has now been placed on the orthopaedic surgery waiting list for a correction of his deformity.

Conclusion

This study found that a protocol including dermaPACE® treatments in combination with offloading and standard wound care greatly improves the vascularisation of chronic diabetes-related foot ulcers and facilitates healing. Active dermaPACE® treatments can easily be integrated into current treatment regimens. Both patients responded well to the non-invasive and painless shock wave treatments and no adverse reactions due to the pressure waves were observed. The results suggest that dermaPACE® offers a valuable adjunct treatment option for difficult to treat chronic wounds in the Australian setting.

Conflict of Interest declaration: None