From the Histology Laboratory to the Wound Care Clinic: Pain Shield™ MD Diathermy

Jonathan Rosenblum DPM [1], Leon T. Gilead MD PhD [2], Constantin Reinus MD PhD [3]

[1]Director, Diabetic Foot Service Shaarei Zedek Medical Center Jerusalem Israel, [2]Head, Hard to Heal Wound Service, Department of Dermatology Haddasah University Medical Center Jerusalem Israel, [3] Director, Department of Pathology Shaarei Zedek Medical Center Jerusalem Israel

PURPOSE

We evaluate a novel technology: Pain Shield MD Diathermy (NanoVibronix Inc. NY), which has been proven in a laboratory setting to have a positive affect on epidermal growth and its precursors in the dermal-epidermal junction, on Wound Healing in Diabetic Foot Ulcers in a clinical setting.

Surface Acoustic Waves (SAW) have been used in a variety of commercial settings. Until recently they have not been utilized in a biological or clinical setting. SAW functions similar to low intensity ultrasound, which has been shown to have a positive effect on collagen synthesis as well as increased topical drug uptake. The downfall of low intensity ultrasound and therefore its almost non-usage in the clinical realm is the inconvenience of the device. A properly set LIUS is a massive device which is operator dependent and therefore not realistic for clinical application. SAW and the fractionated acoustic waves generated by the Pain Shield MD Diathermy are generated by a driver that can fit in a patient's pocket (Figure 1) and can be applied by the patient. Also, because of the extremely safe level of energy produced and delivered by the unit, it can be applied for extended treatment periods (Figure 2).

METHODS

A series of patients with chronic ulcers of the lower extremity were given therapy with a Pain Shield MD Diathermy device for a period of one week in addition to standard wound care therapy. The ulcers treated were of a neuroischemic mix, and one ulcer was an Ulcus Cruris and had all been present for at least 6 months and stalled in their healing for at least 60 days. The device was incorporated into their primarybandage and was cycled on and off for 30 minutes for at least eight hours a day. The Pain Shield MD Diathermy patch was placed with its wide edge just proximal to the wound. Patients were reevaluated at the end of one week.

RESULTS

Therapy with Pain Shield MD Diathermy showed significant changes in the wound. Necrotic/ Fibrotic tissue was less adhesive to the wound bed after a 30 minute initial treatment with the device placed over a hydrocolloid dressing immediately over the wound. After the treatment patch was moved to its fixed position proximal to the wound and applied for the week, purulent drainage and other signs of infections were reduced by a factor of 4+. Necrotic tissue was moved distally away from the wound and decreased in size (Figures 3 and 4). In another patient wound size was significantly reduced and there was a covering of epithelium over the wound bed (Figures 5 and 6). Patients related a significant decrease in their wound pain.

CONCLUSIONS

Pain Shield MD is a good adjunctive therapy to the wound care regimen. There is a direct result on epithelial growth attributable to SAW as well as a direct affect on surface as well as wound bed bacteriology. More research needs to be conducted to evaluate how Acoustic Waves affect the wound and periwound tissue. A large scale study is currently being started to examine these issues on a gross, clinical, microbiological and histological scale. SAW has all the benefits of Low Intensity US without any of its drawbacks, as well as providing almost all of its energy in the dermal epidermal range and over an area of approximately 20 square centimeters (Figures 7 and 8).

Figure 1: The PainShield Device; Driver and Actuator Patch

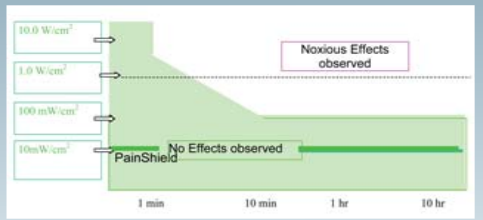

Figure 2: American Institute of Ultrasound in Medicine guidelines; ultrasound energy below 100 mW/cm2 shows no adverse bioeffects, continuously up to 10 hours.

Figure 3: Application of PainShield patch.

Figure 4: Note the Granulation Tissue at the base of the 3rd toe where 1 week previously there was only necrosis.

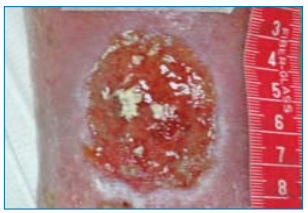

Figure 5: Fibrosis before application of the Pain Shield patch. Note the fibrosis especially at the center of the wound.

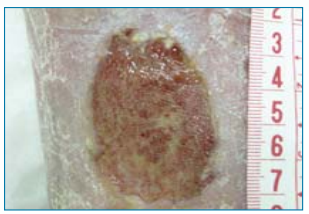

Figure 6: Same patient after treatment with PainShield. Note the soft epithelialization over almost the entirety of the wound as well as the overepithelializtion at the proximal edge.

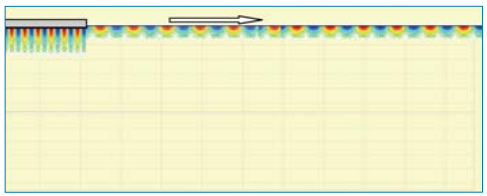

Figure 7: Acoustic Surface Waves travel up to 20cm along the surface which allows for more efficient treatment of a surface, both in respect to its depth and surface area.

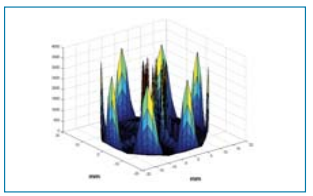

Figure 8: Surface Acoustic Waves create fractionated ultrasound with a maximal acoustic intensity of approximately 1-3 W/cm2, and a depth of energy penetration of only about 2 cm, decreasing when distancing from the actuator.