

ESWT - PACE® Technology Utilizes High-Energy Acoustic Pressure Shockwaves to Produce Compressive and Tensile Stresses on Cells/Tissue Structures with Ultimate Goal of Regenerating Healthy Tissue In Chronic Foot Ulcers in a Community Clinical Setting



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Background and Aims:

Studies indicate that Extracorporeal Shockwave Therapy (ESWT) is effective in treating chronic ulcers. The aim of this study was to evaluate the outcomes of ESWT in chronic foot ulcers in a Community Clinical Setting. The optimal adjunctive therapy for wounds that have not healed despite best practice wound care has not been verified. Clinical evidence suggests improved healing in wounds treated with Extracorporeal Shockwave Therapy (ESWT). This study was conducted to assess the impact of adjunctive ESWT on the healing of wounds that did not progress to healing with conventional wound care alone.

Methods:

Subjects for the study were selected from the existing practice population at the Newmarket Foot Centre in Newmarket, Ontario

The total number of participants was 9 that presented with at least one chronic foot ulcer that was more than 3 months in duration to qualify for inclusion. Those subjects who were diagnosed with active osteomyelitis and those with abnormal ABI (Ankle Brachial Index) were not considered. Eligible participants were aged 18 years or older, had a non-healing wound, and received ESWT of the wound and periwound at least 2 times per week during the study period. Non-healing wounds were those that had failed to progress to at least 15% closure in the prior 12 weeks of best practice therapy.

All the participants had type 2 diabetes with a well controlled A1c between 5.5 and 6.2. As is often the case in chronic wound care, comorbid medical conditions were the rule rather than the exception. By far, the most common comorbid condition was cardiovascular or vascular disorder (91% of participants)

Wound sizes varied from 2cm dia with depth probing to bone to 1cm dia with 5 mm depth.

Visit 1 of the trial: Target wounds were measured; data and pictures were recorded. Debridement was performed where necessary. Treatment with ESWT was performed and best practice wound dressings were applied. Visit 2 and subsequent weekly visits until the end of the study or the wound closed; Target wounds were measured; data and pictures were recorded.

The participants were all compliant with the treatment schedule which started on Sept 11 2018 and completed in March 2019

Results

Wound area reduction was evident within the first two treatments. The significance of the ESWT treatment was well tolerated and patients were relatively compliant. Of the 9 patients 7 had complete closure of wounds by the end of the study and marked improvement in the remaining 2.

Several changes in wound tissue characteristics and drainage suggested a clinical benefit of ESWT. First, the proportion of participants with greater than 75% healthy granulation tissue rose significantly, from 20% before ESWT to 55% after ESWT ($P<.0001$). Second, the proportion of skin around the wound rated as normal increased from 20% before ESWT to greater than 75% after ($P<.0001$). Third, the amount of exudate was reduced significantly. Most of the wounds (88%) had either moderate or slight drainage at the start of ESWT, whereas by the end of treatment, most of the wounds (77%) were classified as having no drainage ($P=.0002$). The type of exudate (primarily serous) did not change substantially during the study period. Pre-treatment eschar was present only in 2 wounds and was not present after the course of treatment with ESWT. Undermining, tunneling, odor, and maceration were uncommon, although any amount present before ESWT treatment was eliminated after the course of treatment

Discussion

One of the 2 remaining had an elevated A1c of 14 causing impairment of wound healing. The second of the 2 had an orthopedic issue that required surgery to offload the lesion on the plantar surface. 5 of the wounds had been open for over 12 months prior to treatment and after (ESWT) treatment had resolved to viable tissue.

Conclusions

The Participating patients made note of the fact that they had a variety of other modalities utilized on their wounds in the past and there had been no improvement and Extracorporeal Shockwave therapy was the only treatment that resolved their wounds. Results indicated that ESWT -PACE technology for regenerating healthy tissue may be suitable to increase the healing rate of chronic wounds and ulcers. The device was easy to apply by clinicians in a Community Clinical setting. During the ESWT treatment there was no treatment-related toxicity, infection, or deterioration of any kind.

CASE 1 September 11 2018

62-year-old male IIDM X 15 YEARS with a plantar pressure ulcer over 2nd and 3rd metatarsal heads measuring 6mm x 5 mm x 5 mm depth probing to metatarsal head



Sept 11 2018
1st visit



Dec 6 2018
Ulcer had reduced size to 1mm x 1mm x 1mm depth



Jan 9 2019
Complete closure of wound with intact Epidermis

CASE 2

72 year old male IIDM X 20 YRS with chronic pressure ulceration of Right 1st interphalangeal joint plantar aspect Present for 14 months measuring 11 mm x 10 mm x 6 mm depth



Sept 11 2018



Oct 11 2018
Ulcer had reduced to 7mm x 4 mm x 3 mm depth



Mar 7 2019
Ulcer had resolved with intact Epidermis

Case 3 Sept 11 2018

56 year old male IIDM X 15 YEARS Chronic ulcer present 9 months 6mm x 3mm x 3mm depth



Sept 11 2018



Oct 23 2018
Has resolved 50% by volume



Dec 6 2018
Ulcer has resolved with Intact epidermis and slight Hyperkeratosis

CASE 4 SEPT 11 2018

62 year old female IIDM X 14 YEARS Pressure ulcer over left 1st metatarsal phalangeal joint Present for 4 months



Sept 11 2018
1st visit



DEC 3RD, 2018
L/ 1st MPJ closed ulcer with Underlying extravasation