



Extracorporeal Shockwave Therapy (ESWT) - PACE® Technology: Micro-Vascular Stimulation Post-Amputation applied to Incision Lines Promotes Healing and Reduce Edema - Avoiding Extended Wound Care or the need for further Surgical Intervention.

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Introduction

Recent studies have shown that extracorporeal shockwave therapy **PACE®/(ESWT)** can accelerate the healing of diabetic foot ulcers. We hypothesized that this improved healing time may be due to the effects of **PACE®/(ESWT)** shockwave therapy on the microvasculature, neovascularization and reduction of endothelial inflammation and this phenomenon's overall effect on improving perfusion. The aim of the study is to observe the effect of large target area **PACE®/(ESWT)** has on the speed of healing incision lines of the primary closed diabetic foot surgeries as well as the reduction of postoperative edema.

Methods

Patients selected for this study were identified from our operative list requiring surgery to correct either a foot deformity, a nonhealing wound as a result of the deformity or diabetic peripheral ischemia and associated distal gangrene. All operative sites were closed primarily. Patients selected, were between the ages of 55 and 69, had type 2 diabetes in variable states of control, with A1c's ranging from 7.6 -11.2, had lengthy histories of chronic foot wounds or peripheral gangrene that required definitive surgery. All test subjects had peripheral arterial disease as measured by pulse volume recordings (Sensilase; Vasamed) and 14 of the 21 patients had at least one attempt to revascularize, either endovascularly or surgically.

Surgery was performed in an outpatient center under regional block and immediately thereafter a 1000 shock counts with **PACE®/(ESWT)** to the incision line was administered and the periwound area. This process was repeated on 2 successive occasions, one week apart, for total of 3-treatments. The periwound was assessed visually for edema and the incision line for tissue annealing.

Results

In this observational study we were able to realize how the outcome of **PACE®/(ESWT)** effects the healing of primarily closed wound sites. The operations included digit amputations, ray resections and forefoot amputations. Our assessments included rate at which the incision line came together and the amount of edema postoperatively. We observed that the edema reduced quickly from between 3-4+ perioperatively to negligible amounts after the third **PACE®/(ESWT)** shockwave treatment. This contrasts with our previous experience with similar operations in which edema and incision line healing dehiscence were intimately linked postoperatively and tended to slow the overall healing after these surgeries. The introduction of **PACE®/(ESWT)** shockwave therapy to the protocol, appears to hasten the overall healing affect and allowed the patient is to return normal weightbearing activities sooner.

Of the 21 patients enrolled in the study, 15 went on to complete healing within the 3-treatment protocol. Of the 6 remaining patients who did not go on to heal after the 3-treatment protocol, 3 of them healed after 2 subsequent visits and application of **PACE®/(ESWT)**, noting that their edema reduction was like those that healed after 3 treatments. The remaining 3 had postoperative complications with wound dehiscence unrelated to the shockwave treatment, 1 of those individuals passed away.

Discussion

The use of **PACE®/(ESWT)** in the treatment of diabetic wounds has been shown to be effective in accelerating the healing process. Recently, work efforts in other countries overseas, has focused on large-area **PACE®/(ESWT)** to improve the microvascular bed patients with diabetic, distal ischemia. We believe the positive outcome is due to the reduction of endothelial inflammation. Our hypothesis that this microvascular effect may also be effective in speeding up the annealing of incision lines and as well, the reduction of postoperative edema in primarily closed diabetic foot surgeries appears to be supported by our findings in this small cohort of 21 patients. We saw a demonstrable reduction in postoperative edema and an increase in durably healed incision lines after 3 **PACE®/(ESWT)** treatments postoperatively. The mechanism how effects this event is still unclear. We have strong rationalizations that stimulation of neovascularization as well as the reduction of microvascular endothelial inflammation have a role in this phenomenon. It is worthwhile that more objective work be done in this regard. Investigators are encouraged to extrapolate on the findings of the previous studies/work examining **PACE®/(ESWT)** and its effect on accelerating the closure of diabetic wounds and use the data to expand the scope of this promising and exciting new technology.

CASE 1 April 4 2019

68 yrs. with history of CAD and PAD with multiple peripheral revascularization surgeries as well as CABG, chronic left fourth metatarsal head ulcer as a result of a transfer wound after a long fifth ray amputation previously. A 4th and fifth ray amputation was performed, with appropriate contouring and resumption of normal ambulation

**Procedure date
April 4th
Healed May 9th
Total healing
time = 5 weeks**



April 4 2019



April 11 2019



April 25 2019



May 7 2019

Case 2

64-year-old diabetic with history of endovascular revascularization of the right lower leg, but not the foot. Developed revascularization distal gangrene and underwent a successful forefoot amputation with subsequent resumption of normal ambulation after casting for custom orthotics and shoes.

**Procedure date
April 4th
Healed May 3th
Total healing
time= 6 weeks
Pitting edema:**



April 4 2019



April 11 2019



April 24 2019



May 11 2019

CASE 36

9-year-old diabetic with history of chronic left fifth metatarsal head wound, and associated PAD corrected endovascularly. 1/5 ray amputation was performed with durable resolution of the chronic wound and a return to normal ambulation in appropriately selective footwear. R

**Procedure date
April 4th
Healed May 7th
Total healing
time= 5 weeks
Pitting edema:**



April 4 2019



April 11 2019



April 25 2019



May 7 2019