EXTRACORPOREAL SHOCKWAVE THERAPY FOR THE TREATMENT OF INTERDIGITAL NEUROMA: A RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLINDED TRIAL

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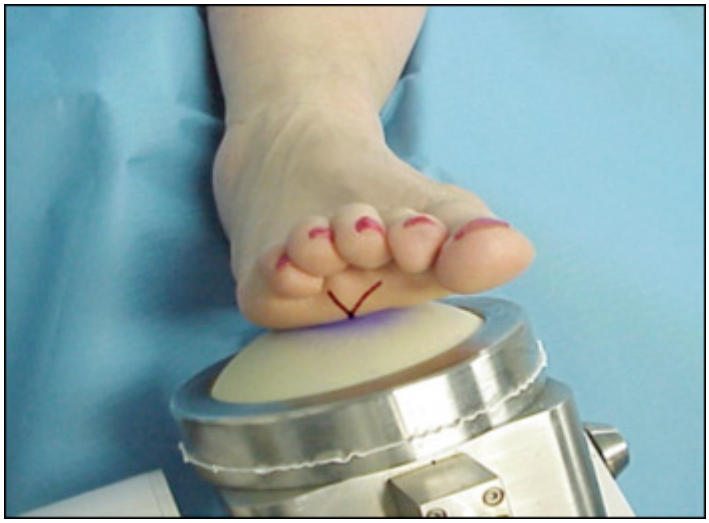
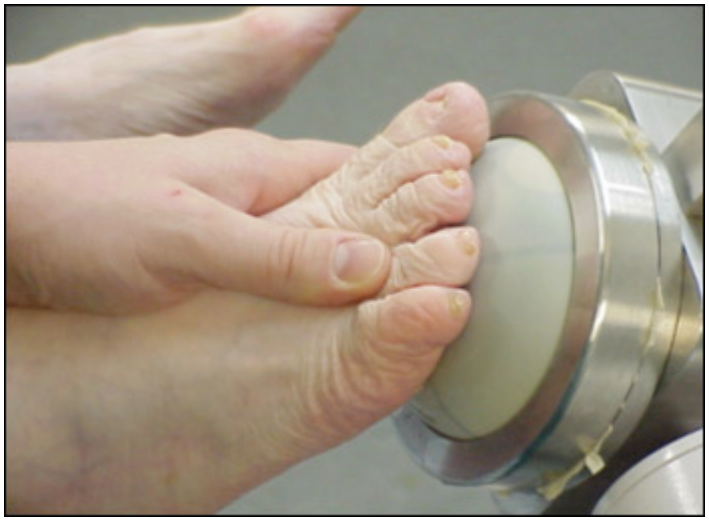
BACKGROUND

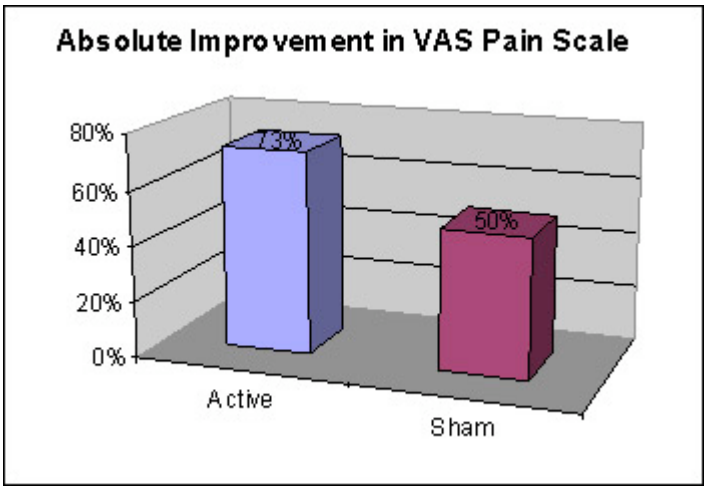
Morton's Neuroma is a common condition, often requiring surgical intervention. The success rate for resolution of symptoms, without complications, is commonly reported to be 85%. Complications can include stump neuroma, adhesive neuritis, and chronic pain syndrome. Endoscopic decompression of the neuroma has been reported but there have been no randomized and blinded studies reported to date. Extracorporeal Shockwave Treatment (ESWT) has a reported complication of nerve injury during treatment for certain musculoskeletal disorders. The purpose of this study is to evaluate the safety and effectiveness of ESWT to destroy a Morton's neuroma as a therapeutic treatment.

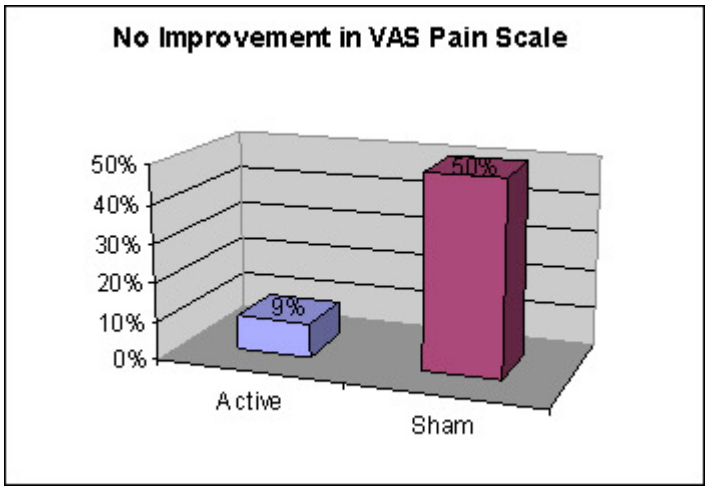
MATERIALS AND METHODS

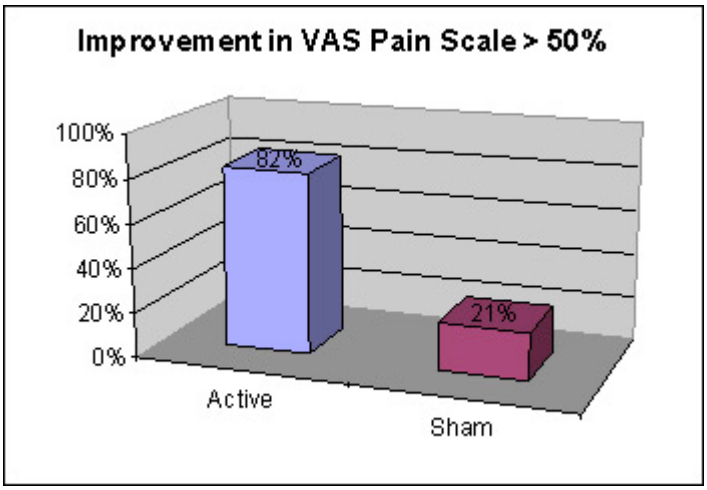
25 patients (25 feet) were recruited and consented to take part in a placebo-controlled and blinded study for evaluation of the efficacy and safety of ESWT to ablate a Morton's neuroma which was confirmed clinically and via ultrasound. Indications for participation were >8 months of conservative care with a visual analog pain score (VAS) of > 6. The mean time with pain was 41.6 months (range 10-120 months). The mean overall pain VAS was 7.5 (6-10). The ESWT procedure was performed under intravenous sedation (IVS) and local anesthetic (LA) using Marcaine 0.5%. Following IVS and LA, subjects were randomly assigned to an active or sham treatment group. The active group was treated with an Ossatron® (Healthtronics) device using 2000 pulses @ 21 Kv directed inferior to the neuroma. The sham foot received no treatment. 14 subjects were randomized to the active group and 11 to the sham group. Post treatment evaluations were carried out at 1, 6, and 12 weeks by a blinded investigator. End point evaluation parameters were reduction in VAS and Roles-Maudsley quality of life assessment.

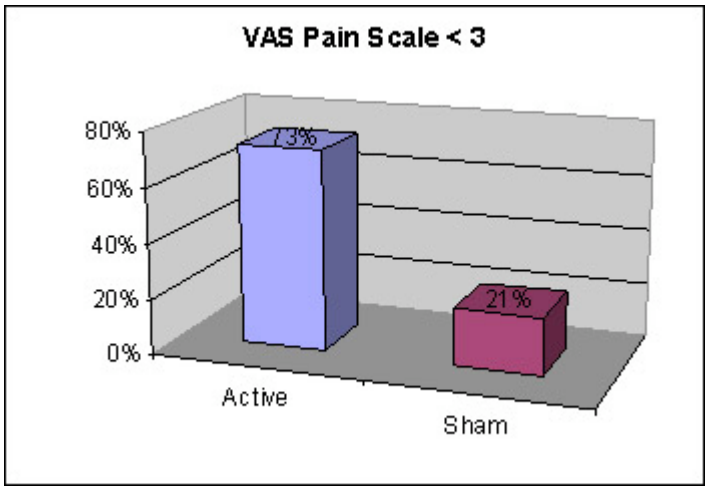












RESULTS

64% of the active group (n=9) reported improvement of > 50%, as compared with only 27% of the sham group (n=3). At 12 weeks post treatment, 57% of the active group (n=8) attained a VAS of <3, while only 27% of the sham group (n=3) achieved a similar reduction. 7% of the active group (n=1) had no improvement,

while 64% of the sham group (n=7) had no improvement. There were no complications in either group.

DISCUSSION AND CONCLUSION

ESWT has been shown to be clinically effective in treating numerous musculoskeletal problems, including lateral epicondylitis, calcific tendonitis of the shoulder, and plantar fasciitis. Delius (5) reported that the most common side effects of high-dose ESWT are local soft tissue damage and hemorrhage, which have an incidence of less than 1%. Nerve damage has been reported if the shockwave focal point is within the path of a nerve. Given that the eventual treatment for Morton's neuroma is surgical excision, one of us (LWJ) postulated that focused shockwave may damage the nerve irreparably, and obviate the need for open surgery. A pilot study testing this theory was conducted at the Weil Foot and Ankle Institute, and consisted of 30 patients with Morton's neuroma unresponsive to conservative care. In this study, an Orbasone® (Orthometrix) device was used and all patients were consented and received ESWT. A success rate of 90% was achieved within the pilot study. In this trial there was an identifiable difference between the active and sham groups at 12 weeks (p=.0014). Additionally, the active group had a majority of subjects (57%) that attained a VAS of <3. Likewise, only 8% of the treated patients had no significant improvement after ESWT, while 50% of the sham group felt no difference before or after treatment. Conclusions as a result of this trial are limited due to the small number of subjects and the difficulty of stratifying subjective pain results. Four of the active subjects went on to have surgical excision. Microscopic evaluations of the "failed active subject's" excised nerves revealed "traumatic neuroma" in two cases. The other two cases had the typical report as seen in most neuroma pathology reports. In our opinion, animal studies would prove to be very valuable to evaluate, in a blinded fashion, the nerve damage produced by ESWT. Due of our success with this procedure, no complications in any case, and no post treat disability, we continue to offer ESWT as an alternative to surgical excision for Morton's neuroma.

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