Extracorporeal Shockwave Therapy for Interdigital Neuroma

A Randomized, Placebo-Controlled, Double-Blind Trial

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Background: We sought to evaluate the safety and effectiveness of extracorporeal shockwave therapy as a therapeutic treatment for destroying Morton's neuroma.

Methods: Twenty-five patients (25 feet) were included in the study. Indications for participation were more than 8 months of conservative care with a visual analog scale pain score of 4 or greater. The mean overall pain score on a modified visual analog scale was 6.9 preoperatively.

Results: Thirteen patients were randomized to the active group and 12 to the sham group. Two patients in the sham group were lost to follow-up. Post-treatment evaluations were performed at 1, 6, and 12 weeks by a blinded investigator (L.W.). The end point evaluation parameter was the reduction in visual analog scale score. The treatment group showed a significant difference before and after extracorporeal shockwave therapy ($P < .0001$). The sham group did not have a significant difference after 12 weeks ($P = .1218$).

Conclusions: Extracorporeal shockwave therapy is a possible alternative to surgical excision for Morton's neuroma. (J Am Podiatr Med Assoc 99(3): 191-193, 2009)

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%.[1] Complications can include stump neuroma, adhesive neuritis, and chronic pain syndrome.[2] Endoscopic decompression of the neuroma has been reported, but no randomized and blinded studies have been reported to date.[3, 4] Reported complications of extracorporeal shockwave treatment may include damage to peripheral nerves after sustained exposure.[5] The purpose of this study is to evaluate the safety and effectiveness of extracorporeal shockwave therapy as a therapeutic treatment for destroying Morton's neuroma.

Materials and Methods

Twenty-five patients (25 feet) were recruited and consented to take part in a placebo-controlled, blinded study for evaluation of the efficacy and safety of extracorporeal shockwave therapy to ablate Morton's neuroma that was confirmed clinically and by ultrasound. Indications for participation were more than 8 months of conservative care with a visual analog scale pain score of 4 or greater. The mean time with pain was 41.6 months (range, 10–120 months). The mean overall visual analog scale pain score was 6.9 (range, 4–10). The extracorporeal shockwave therapy procedure was performed under intravenous sedation and local anesthesia using bupivacaine hydrochloride. After intravenous sedation and local anesthesia, patients were randomly assigned to an active or sham treatment group. The active group was treated with an OssaTron (Sanuwave Inc, Alpharetta, Georgia) device using 2,000 pulses at 21 kV directed inferior to the neuroma (Fig. 1). The sham foot received 5 mL of bupivacaine hydrochloride but no extracorporeal shockwave therapy. Given that the patients were under intravenous sedation during the procedure, they were truly blinded to the group to which they were being assigned.

Thirteen patients were randomized to the active group and 12 to the sham group. Two patients in the sham group were lost to follow-up during the study.

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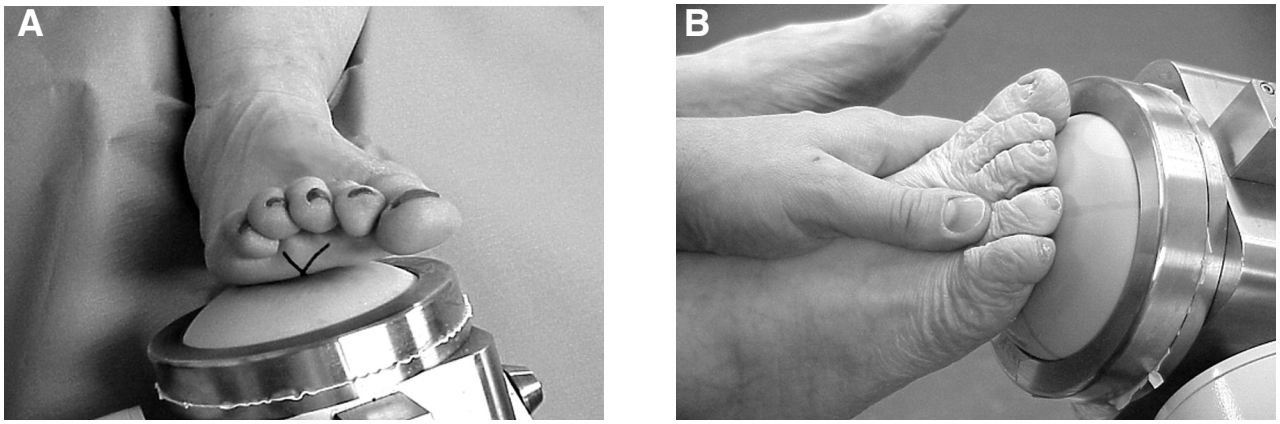

Figure 1. Anteroposterior (A) and lateral (B) views of the correct placement of the foot under the extracorporeal shockwave therapy bellow for treatment of Morton's neuroma.

Post-treatment evaluations were performed at 1, 6, and 12 weeks by a blinded investigator (L.W.). End point evaluation parameters were reduction in visual analog scale scores.

Results

A *t* test calculator using GraphPad software (GraphPad Software Inc, La Jolla, California) was used to analyze the data (Table 1). The treatment group (n = 13) showed a significant difference before and after extracorporeal shockwave therapy at a 95% confidence interval ($P < .0001$). The sham group (n = 10) did not have a significant difference after 12 weeks ($P = .1218$). Sixty-nine percent of the active group (n = 9) reported improvement of greater than 50% compared with 40% of the sham group (n = 4). Twelve weeks after treatment, 69% of the active group (n = 9) attained a visual analog scale score of 3 or less, whereas only 40% of the sham group (n = 4) achieved a similar reduction. Eight percent of the active group (n = 1) had no improvement, and 30% of the sham group (n = 3) had no improvement or an increase in visual analog scale scores. There were no complications in either group.

Discussion

Extracorporeal shockwave therapy has been shown to be clinically effective in treating numerous musculoskeletal problems, including lateral epicondylitis, calcific tendonitis of the shoulder, and plantar fasciitis. Delius[6] reported that the most common adverse effects of high-dose extracorporeal shockwave therapy

Table 1. Data Group and Statistical Analysis for the Treatment and Sham Groups

	VAS Pain Score	
Patient No.	Baseline	After 12 wk
ESWT group		
1	9	1
2	7	0
3	9	0
4	6	5
5	6	4
6	9	3
7	7	1
8	5	0
9	8	8
10	8	1
11	7	6
12	7	3
13	6	0
Sham group		
1	9	1
2	4	7
3	4	0
4	7	0
5	7	6
6	5	0
7	6	10
8	7	5
9	8	8
10	7	6

Abbreviations: ESWT, extracorporeal shockwave therapy; VAS, visual analog scale.

Note: The mean (SD) [SEM] VAS scores were 7.23 (1.3) [0.36] and 2.46 (2.63) [0.73] for the ESWT group at baseline and after 12 weeks, respectively, and 6.4 (1.65) [0.52] and 4.3 (3.74) [1.18] for the sham group at baseline and after 12 weeks, respectively.

are local soft-tissue damage and hemorrhage, which have an incidence of less than 1%.

Premature epiphyseal union is a concern, and, therefore, extracorporeal shockwave therapy is not indicated in patients with open epiphyseal plates.[5] Nerve damage has been reported if the shockwave focal point is within the path of a nerve.[5] Given that the eventual treatment for Morton's neuroma is surgical excision, the senior author (L.W.) postulated that a focused, high-powered shockwave may irreparably damage the nerve and obviate the need for open surgery. An unpublished pilot study testing this theory was conducted at Weil Foot and Ankle Institute (Des Plaines, IL) prior to this randomized controlled trial and consisted of 30 patients with Morton's neuroma unresponsive to conservative care.

In this pilot study, an Orbasone (Orthometrix Inc, Naples, Florida) device was used. All of the patients gave informed consent and received extracorporeal shockwave therapy. A successful outcome was qualified by a reduction in visual analog scale scores by half and a Roles-Maudsley assessment of excellent or good. At 12 weeks, 90% of patients deemed the procedure outcome to be excellent or good and had a visual analog scale score reduction of 50%.

The promising data from the pilot study led to the development of this clinical trial. In the present study, there was a statistically significant difference between the active and sham groups at 12 weeks. In addition, only one treated patient had no significant improvement after extracorporeal shockwave therapy, and three patients in the sham group felt no difference or increased pain at 12 weeks. Conclusions as a result of this trial are limited owing to the small number of participants and the difficulty in stratifying subjective pain results. Four of the active patients went on to have surgical excision. Microscopic evaluations of the "failed active patients'" excised nerves revealed "traumatic neuroma" in two cases. The other two cases had the typical description as seen in most neuroma pathology reports. In our opinion, animal studies would prove to be very valuable to evaluate, in a blinded manner, the nerve damage produced by extracorporeal shockwave therapy. Owing to the success with this procedure (no complications and no post-treatment disability), we continue to offer extracorporeal shockwave therapy as an alternative to surgical excision for Morton's neuroma.

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Conflict of Interest: None reported.

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