

A Prospective, Randomized, Double-blinded Study with Crossover to Determine the Efficacy of Radio-frequency Nerve Ablation for the Treatment of Heel Pain

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Background: Previous studies have demonstrated that radio-frequency nerve ablation (RFNA) can be an effective treatment for plantar fasciitis. This study provides additional evidence in support of this treatment, with statistically significant data that demonstrate the success of this technique.

Methods: In this multicenter, randomized, prospective, double-blinded study with crossover, 17 patients were divided into two groups, with eight initially receiving RFNA treatment and nine initially receiving sham treatment. If no improvement was observed after 4 weeks, a crossover was offered. Results of the treatment were evaluated by the patient and by a blinded physician using a visual analog pain scale to rate first-step pain, average pain, and peak pain in the heel region.

Results: We observed a statistically significant improvement in the symptoms of plantar fasciitis in patients actively treated with RFNA and no significant improvement in the sham-treated group. More important, those treated with sham subsequently demonstrated statistically significant improvement after subsequent RFNA treatment.

Conclusions: Using a prospective, randomized study with sham treatment and crossover, this study demonstrates the efficacy of RFNA for the treatment of plantar fasciitis. (J Am Podiatr Med Assoc 103(1): 8-15, 2013)

Heel pain has been associated with numerous etiologies, including plantar fasciitis, plantar fascial tears,¹ calcaneal bursitis, nerve entrapments,² fractured bone spurs,³ and stress fractures of the calcaneus. It has also been associated with pes planus and pes cavus deformities. Annually, more than 2 million people are treated for heel pain in the United States alone, and this condition accounts for

11% to 15% of all professional visits related to foot pain.^{4,5} In fact, up to 10% of all Americans will experience heel pain in their lifetime.⁵

Because many physicians view the etiology of heel pain as multifactorial, it has become more accurately described as plantar fasciitis,⁶ or simply heel pain syndrome. This multifactorial view of the condition has led to a multitude of treatments as well. Clinical studies have demonstrated successful treatment using a variety of conservative approaches, including stretching,⁷ physical therapy,⁸ corticosteroid injections,⁹ arch support,¹⁰ anti-inflammatory agents,¹¹ massage,¹² night splints,¹³ and shoe modifications.¹³ Shockwave therapy⁴ and cryotherapy¹⁴ have also been used successfully to treat this condition. Percutaneous, endoscopic, and open partial plantar fascia releases and calcaneal spur resection have also been used to treat this painful condition.⁸ In addition, radio-frequency nerve ablation (RFNA) has been suggested as a viable

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option.¹⁵⁻¹⁷ Regardless of the treatment chosen, one clear message that emerges is that no treatment can provide relief in every case.

Extracorporeal shockwave therapy uses either high- or low-energy shockwaves to treat the interface between the calcaneus and the plantar fascia and has been shown to be beneficial.⁵ Although the actual mechanism by which this therapy relieves pain is unclear, several mechanisms have been proposed. Cavitation, the development of small air spaces in the tissues, is believed to be a result of extracorporeal shockwave therapy, and it has been proposed that this physically separates the plantar fascia from the calcaneus, essentially resulting in a transdermal release.¹⁸ Other researchers have proposed that the relief of pain after extracorporeal shockwave therapy is actually a result of injury to the calcaneal nerve, rendering it either temporarily or permanently unable to conduct signals and resulting in internal numbness.⁵ Regardless of the mechanism of action, extracorporeal shockwave therapy has remained controversial because of the inconsistent nature of the results.⁵ Most users feel that localization of the central cone of the shockwave is a critical step in getting good results with this device and, as such, is highly operator dependent. In addition, the various devices spread the shockwave through the tissues differently, resulting in additional variability in outcome.¹⁸

In the present study, radio-frequency energy is used to ablate sensory nerves, thereby reducing or eliminating the pain associated with plantar fasciosis. Radio-frequency nerve ablation is a technique that has been used primarily by interventional pain physicians for decades to control chronic pain syndromes. This technique has also been used successfully for the treatment of other conditions involving cranial and spinal nerve injury. In these cases, the sensory nerve is identified and destroyed, thereby relieving the pain associated with a particular regional pain syndrome.

Radio-frequency nerve ablation involves a multi-step process in which the sensory nerve is first identified and differentiated from adjacent motor nerves. The nerve is then ablated and sealed at its surface using low-temperature radio-frequency energy. Once transected, the nerve is rendered nonfunctional distal to the site of ablation. By selecting the sensory nerve, the patient is left with a small pain-free region. Although internal numbness may occur, it was previously reported that most patients do not notice this because the cutaneous sensory nerves are not impacted.¹⁵

In a previous study, RFNA was used to treat 31 heels of 21 patients.¹⁵ This retrospective study showed a 92% success rate, as defined by a decrease of approximately 5 points on a 10-point visual analog pain scale more than 1 month after treatment. Based on this early success with RFNA, a prospective, randomized study was designed and implemented to explore the efficacy of RFNA for the treatment of plantar fasciosis.

The present study was designed to address some of the shortcomings of the previous study. Specifically, in the present study, a sham treatment was introduced to evaluate the possibility of a placebo effect. This design will also help determine whether the act of inserting a needle into the painful area and causing focal acute trauma may actually play a role in the perceived improvement. Second, this study was expanded to a multicenter study (four sites) to diminish the risk of creating bias caused by physician technique. Third, study participants and the treating investigators were blinded, and subjective outcomes were evaluated by the study patient and an independent (nontreating) physician. Finally, the present study was prospective, with a crossover offered to all of the participants, so that, ultimately, each patient can serve as his or her own control, thereby strengthening the power of the study.

In this study, we prospectively examined the outcomes from treatment of plantar fasciosis with RFNA in 17 patients. All of the participants had heel pain for at least 3 months that was recalcitrant to conservative measures. It was hypothesized that plantar fasciosis can be successfully treated with an RFNA device (NT250; NeuroTherm, Wilmington, Massachusetts).

Methods

This was a crossover study in which initially approximately half of the participants received actual treatment and approximately half received sham treatment. To qualify for the study, participants had to meet all of the inclusion criteria and none of the exclusion criteria, including the presence of heel pain for at least 3 months and failure of at least three conservative measures. The inclusion and exclusion criteria, including a list of acceptable conservative preenrollment measures, are given in Table 1.

Patients who met the inclusion and exclusion criteria were offered the opportunity to participate in this study. Each participant understood that this was a crossover study and that approximately half of them would receive sham treatment initially.

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria

A patient must meet all of the following inclusion criteria to be enrolled in the study:

1. Heel pain located at the plantar medial aspect of the heel
2. Pain present in the heel for ≥ 3 months and rated at least 6 at its peak (with palpation) and 5 on average on the day of screening as measured on the 10-point visual analog scale
3. Patient has undergone ≥ 3 of the following treatments, with no significant or lasting relief:
 - Physical therapy
 - Custom-molded or over-the-counter arch supports
 - Shoe modifications or heel lifts
 - Corticosteroid injection
 - Night splints
 - Strapping or taping
 - Stretching on a regular basis
 - Oral nonsteroidal anti-inflammatory drugs or oral corticosteroids (ie, methylprednisolone [Medrol] dose pack)
4. Willingness to sign the informed consent form and to comply with the study regimen
5. Age 18 years or older

Exclusion Criteria

Patients were excluded if they met any of the following criteria at the time of randomization:

1. Previous surgery for plantar heel pain syndrome or any type of heel pain
 2. Evidence of fracture to the calcaneus (new or old) confirmed by radiography in the past year
 3. Allergies to local anesthesia
 4. Severe fat pad atrophy, calcaneal bursitis, scarring, or other skin abnormalities around the study heel
 5. History of a more proximal nerve injury that may be responsible for heel pain (ie, spinal injury, tarsal tunnel, or sciatica)
 6. Peripheral nerve neuropathy being treated with gabapentin (Neurontin), pregabalin (Lyrica), Cymetra, or other agents specifically used for the treatment of nerve pain or the inability to feel a Semmes-Weinstein monofilament 5.07 in the area of the treatment heel
 7. Fibromyalgia
 8. Currently undergoing treatment for alcoholism or drug abuse
 9. History of reflex sympathetic dystrophy
 10. Pregnancy
 11. Inability to tolerate acetaminophen (Tylenol) or similar pain medications
 12. Neither dorsalis pedis nor posterior tibial pulses are palpable on the study foot
 13. Long-term treatment with oral prednisone, such as with arthritic conditions
 14. History of nerve ablation treatments, including radiotherapy and sclerosing injections
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Study patients indicated that they could comply with the schedule of assessments and were given the opportunity to enroll in this study once they signed the informed consent form approved by Western Institutional Review Board (Olympia, Washington).

Statistical analysis involved two cohorts, the Student *t* test to compare outcomes based on quantitative data gathered from a visual analog pain scale from the patient, and the physician's assessment of the patient's condition. Covariates such as sex, body mass index, age, and the patient's assessment of activity level were also considered. Statistical significance was present at $P \leq .05$. In

each case, the pretreatment level of discomfort was compared with the post-treatment levels.

Once the patients consented, they were randomly assigned to receive either the actual treatment or sham treatment at the start of the study. A centralized randomization scheme was used. Sham treatment involved all aspects of actual treatment, including insertion of the needle probe and administration of the anesthesia. All of the steps were identical except for turning on the nerve ablation device after insertion (Fig. 1). Study patients were blinded by erecting a barrier so that they could not see the procedure being conducted. The device timer was turned on so that the sounds were



Figure 1. A, The NT250 radio-frequency device (NeuroTherm, Wilmington, Massachusetts). B, The probe being inserted into the heel.

identical in the treatment and sham groups as well. Because a local anesthetic agent is injected before nerve ablation, neither treatment group nor sham group participants could feel the nerve ablation process.

All of the participants were asked to rate their level of pain before enrollment in the study and at each visit regarding the first step in the morning, overall maximum (peak) pain, and the average pain level. Evaluations were performed on a 10-point visual analog scale. Pain evaluation was performed by the patient and also by a clinician who was not the treating physician to maintain a double-blinded status.

Four weeks after the initial treatment, patients who did not achieve an improvement of at least 3 points for either peak pain or average pain on a 10-point visual analog scale were offered the opportunity to cross over and receive either active or sham treatment, the opposite of whatever they received initially. In this way, each patient served as his or her own control. Patients who originally had RFNA treatment were still offered the opportunity to cross over to sham treatment to control for the fact that it is possible that the insertion of needles and the administration of local anesthesia may somehow stimulate the healing process. However, none of the patients who received RFNA initially elected to cross over to receive sham treatment.

Patients were clinically evaluated immediately before treatment and weekly for up to 16 weeks after treatment. In the event that a patient had this condition bilaterally, he or she was permitted to undergo randomization for each foot, and each foot was considered and evaluated individually.

The radio-frequency grounding pad was applied to the study patient's lower calf and was plugged

into the NT250 Radio Frequency Generator. A small bolus of anesthetic agent was placed along the medial aspect of the heel with 1 mL of 2% plain lidocaine. This was done superficially to diminish the risk of masking deep pain, which would otherwise reduce the investigator's ability to localize the source of pain. A sterile hypodermic needle (cannula) with a stylet was inserted through the anesthetized area of skin and was advanced to the anterior medial aspect of the calcaneus in the area of pain. The stylet was withdrawn, and the electrode was placed through the cannula to the area of pain. Using the nerve ablation device, sensory stimulation was performed by gradually increasing impedance from 0 until the patient begins to feel some tingling stimulation. Patient feedback was essential for this step to be accomplished properly, and the investigator could not proceed until there was a clear indication that the study patient could feel the stimulus. Proper placement of the probe was accomplished when stimulation was felt with less than 1 V of impedance. Ideal placement of the probe occurred when the patient could feel an impedance of less than 0.5 V.

Once the probe was placed, it had to be confirmed that the nerve being stimulated was a sensory, and not a motor, nerve. This confirmation was accomplished by reducing the sensory nerve impedance setting to 0 V and increasing the motor stimulation setting. If the probe was making contact with a motor nerve, an involuntary contraction of the foot or toes was observed. In the absence of involuntary contractions, it was determined that the targeted nerve is a sensory, and not a motor, nerve.

With care being taken not to allow any movement of the cannula, the electrode was withdrawn and 1 mL of 0.5% plain bupivacaine hydrochloride was

injected into the cannula. The electrode was reinserted and locked into place. Once the local anesthesia set in, nerve ablation was performed at 90°C for 60 sec. In the sham group, the start button was not pressed.

After treatment was completed, the cannula was directed proximally to an area without numbness, and the entire nerve location, stimulation, anesthesia administration, and nerve ablation procedure was repeated adjacent to the first area. The cannula was withdrawn, and an adhesive bandage was placed over the injection site. The study patient was permitted to immediately resume normal activities to tolerance.

Results

Seventeen patients were enrolled in this study, with nine randomly assigned to the sham group and eight to the active treatment group initially (Fig. 2). Of those assigned to the active treatment group, seven patients (87.5%) were observed for 16 weeks and one discontinued the study after 4 weeks with no improvement in pain. This patient declined the opportunity to cross over (to the sham group). The seven patients who remained in the study were not eligible for crossover because they improved dramatically.

All nine patients initially assigned to the sham group qualified to cross over to the active treatment group owing to a lack of improvement in symptoms. Eight of these patients chose to cross over (88.9%), and one opted to discontinue the study after 4 weeks.

Each patient was asked to describe his or her symptoms by using a visual analog pain scale. The data for the two groups demonstrate that their pretreatment level of pain in each category was comparable between the groups. The location of their pain was overwhelmingly in the vicinity of the anterior medial plantar aspect of the heel, in the location typically associated with plantar fasciitis. A summary of the symptoms in each group of patients appears in Table 2.

When examining the outcomes after active treatment, we observed a dramatic change in relative pain after the first step of the day (ie, poststatic dyskinesia), average pain, and peak pain, as recorded by the physician and the study participant (Fig. 2).

Changes in pain levels were found to be statistically significant ($P < .05$) in all of the categories after active treatment and statistically nonsignificant in all of the categories where sham treatment

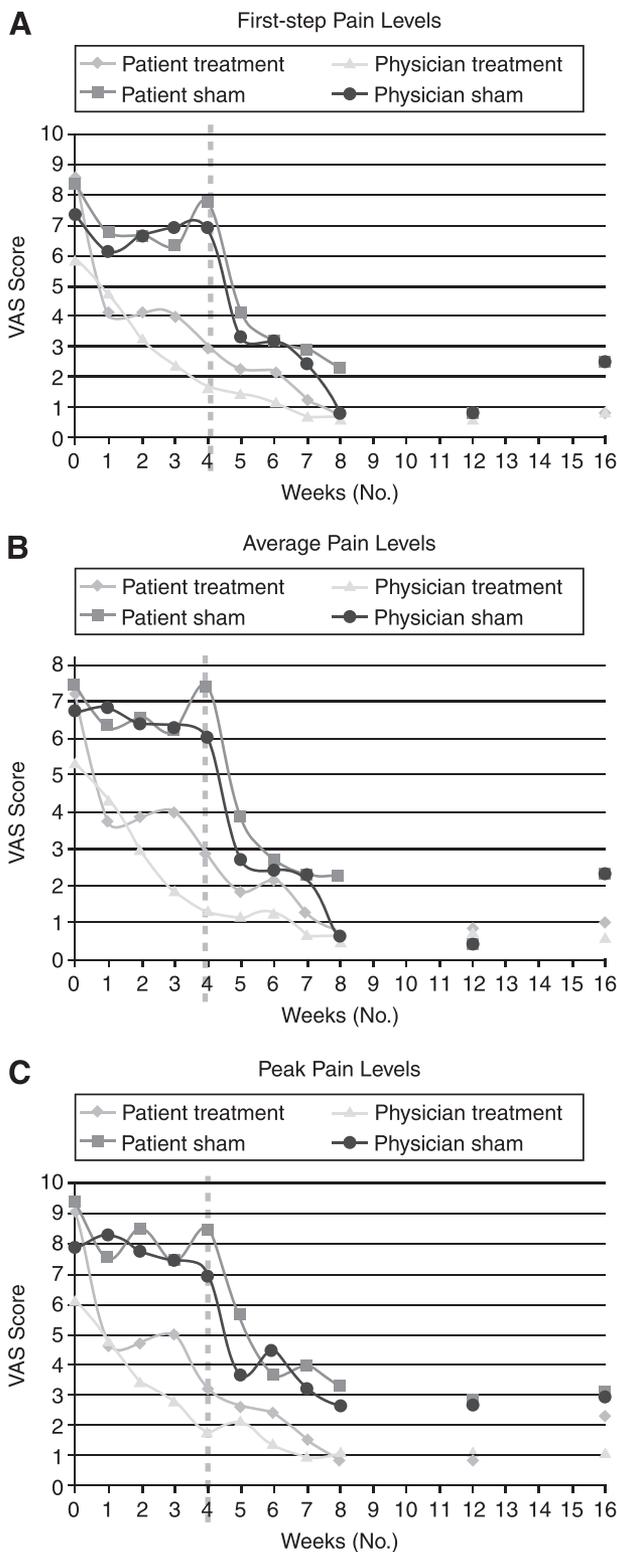


Figure 2. Patient and blinded physician perceptions of pain associated with the first step in the morning (poststatic dyskinesia) (A), the average pain level (B), and the peak pain level (C). Crossover occurred at week 4. VAS indicates visual analog scale.

Table 2. Baseline Symptoms in Each Group as Measured by the Physician and the Patient

Group	VAS Score (Mean ± SD)		
	First-step Pain	Initial Average Pain	Initial Peak Pain
Physician measure			
Active treatment	5.88 ± 2.70	5.38 ± 2.97	6.25 ± 2.32
Sham treatment	7.33 ± 1.70	6.78 ± 2.54	7.89 ± 1.90
<i>P</i> value	.199	.310	.151
Patient measure			
Active treatment	8.63 ± 2.00	7.25 ± 1.28	9.10 ± 1.60
Sham treatment	8.33 ± 1.23	7.44 ± 2.19	9.40 ± 1.00
<i>P</i> value	.718	.310	.600

Abbreviation: VAS, visual analog scale.

was administered. A summary of these findings is given in Table 3. Based on the clinical data, it was demonstrated that the success rate after a single treatment with the RFNA device resulted in reduced pain levels. The data also indicate that patients given sham treatment experienced essentially no change in pain levels compared with their pretreatment condition.

Discussion

Previous case series have shown that there is a significant level of pain reduction associated with nerve ablation in patients with heel pain.¹⁵⁻¹⁷ However, no other reports of randomized, prospective, double-blinded, placebo-controlled studies with crossover to assess the efficacy of RFNA were found for the treatment of heel pain.

Numerous previous studies have demonstrated that heel pain will respond to conservative management consisting of biomechanical control or anti-inflammatory drug therapy in many cases. When these measures are unsuccessful, then more invasive procedures, such as surgery, are frequently considered. Although placebo-controlled studies are not available, surgical measures involving partial or complete release of one or more fascial bands and resection of the calcaneal spur have demonstrated a high level of success, approaching more than 70% success in some studies.^{19,20} However, partial or complete plantar fascial release is not without problems. Historically, a small percentage of these surgical releases have been linked to cuboid compression syndrome, iatrogenic pes planus, and calcaneal nerve injuries.^{5,21} In addition, surgical site complications such as hematoma, infection, dehiscence, and postoperative calcaneal fractures have been observed.

Although RFNA is a relatively new modality to treat heel pain, the technology itself is not new. Radio-frequency ablation has been used in the operating room for years, in various forms, as a bovie used to coagulate blood vessels and cut tissues. Finney et al²² presented data that demonstrated that this was an effective way to treat Morton's neuroma. Catanese¹⁶ also presented a technique paper that demonstrated that RFNA can be used to treat plantar fasciitis. In addition, interventional pain management physicians have performed many thousands of spinal and peripheral nerve ablations with this type of device for patients with chronic pain as well. What distinguishes the current nerve ablation device from the bovie used in surgery is the ability to control temperature and to

Table 3. Summary of Short- and Long-term Results with Treatment

Symptom	Group	VAS Score (Mean ± SD)	<i>P</i> Value
Change in first-step pain from baseline			
4 weeks after treatment	Treatment	5.00 (3.90)	.300
	Sham	1.33 (2.30)	
16 weeks after active treatment	Treatment	7.71 (2.00)	.041
Change in average pain from baseline			
4 weeks after treatment	Treatment	4.06 (2.10)	.047
	Sham	0.8 (1.81)	
16 weeks after active treatment	Treatment	6.57 (1.33)	.001
Change in peak pain from baseline			
4 weeks after treatment	Treatment	5.33 (4.31)	.048
	Sham	1.80 (2.08)	
16 weeks after active treatment	Treatment	8.29 (1.52)	.002

Abbreviation: VAS, visual analog scale.

stimulate and identify a nerve before it is severed. This aspect greatly increases the accuracy and specificity of the procedure while reducing the potential for complications.

The method of RFNA in previous studies¹⁵ was reviewed, and these have also pointed out that the successful treatment of plantar fasciosis with this technique was highly dependent on placement of the electrode relative to the nerve. In this study, two of the clinical sites were highly experienced with this procedure, one had moderate previous experience (<20 previous cases) and one was a new user, having been through the training program only and having performed one procedure before enrollment of his or her first patient in this study. Statistically, there was no difference in the outcomes associated with these four practitioners. This finding indicates that the technique can be easily performed with appropriate training. Nonetheless, it is important to note that the operator must be trained in needle placement.

Safety is always a concern with any new treatment modality. Although the technology used in the NeuroTherm NT250 device has been tested over several decades, there are several safety mechanisms incorporated into the device to provide additional protection. Discriminatory sensory and motor nerve stimulators make it virtually impossible to injure a motor nerve while attempting to ablate a sensory nerve. Similarly, the regulation of temperature at the treatment site greatly reduces the risk of thermal injury to the surrounding tissues. The only adverse events observed in this study were associated with injections. Specifically, ecchymosis at the injection site and, in some cases, a little dizziness and vasovagal response associated with fear of injections. Some pain associated with localization of the nerve was also reported, and this was deemed comparable with standard heel injections.

Conclusions

In the present study, it was demonstrated that this technique reduced or eliminated pain in the heel. The results presented herein are consistent with those presented previously by Liden et al,¹⁵ Catanese,¹⁶ and Sollitto et al,¹⁷ who also found that they were able to achieve complete resolution of heel pain in 92% of their patients (n = 39) after treatment with RFNA.

The study data show statistically significant improvement in all of the categories after actual treatment and no significant improvement in the

sham-treated group. It is a straightforward procedure that can be performed in the office setting. Furthermore, the added features of the NeuroTherm NT250 device helped the investigators localize the appropriate nerve and reduced the risk of damage to adjacent tissues. Based on these data, RFNA was shown to be an excellent option compared with extracorporeal shockwave therapy and percutaneous and open surgery and is recommended for patients with plantar fasciosis who have failed other conservative measures.

Outcomes longevity and recidivism are also considerations with any new treatment modality. In the present study, patients were observed for 16 weeks, with minimal recurrence of symptoms. Hopefully, a follow-up report with a much longer follow-up will be presented in the future. It is worth noting that a previous study had follow-up of just less than 1 year, with a nonsignificant level of recidivism noted.¹⁵

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Conflict of Interest: Dr. Landsman is a paid consultant for NeuroTherm.

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