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Original Research

Pulsed Radiofrequency Electromagnetic Field Therapy: A Potential Novel Treatment of Plantar Fasciitis

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ABSTRACT

Plantar fasciitis is a common cause of heel pain, and although treatments are usually conservative, they can take up to 2 years to achieve resolution. A double-blind, multicenter, randomized, placebo-controlled study was used to evaluate a small, wearable, extended-use pulsed radiofrequency electromagnetic field (PRFE) device as a treatment of plantar fasciitis. A total of 70 subjects diagnosed with plantar fasciitis were enrolled in the present study. The subjects were randomly assigned a placebo or active PRFE device. The subjects were instructed to wear the PRFE device overnight, record their morning and evening pain using a 0- to 10-point visual analog scale (VAS), and log any medication use. The primary outcome measure for the present study was morning pain, a hallmark of plantar fasciitis. The study group using the active PRFE device showed progressive decline in morning pain. The day 7 AM-VAS score was 40% lower than the day 1 AM-VAS score. The control group, in comparison, showed a 7% decline. A significantly different decline was demonstrated between the 2 groups ($p = .03$). The PM-VAS scores declined by 30% in the study group and 19% in the control group, although the difference was not significant. Medication use in the study group also showed a trend downward, but the use in the control group remained consistent with the day 1 levels. PRFE therapy worn on a nightly basis appears to offer a simple, drug-free, noninvasive therapy to reduce the pain associated with plantar fasciitis.

The plantar fascia is a thick fibrous band of connective tissue originating on the bottom surface of the calcaneus (heel bone) and extending along the sole of the foot toward the 5 toes. It acts to support the arch of the foot and aids in resupination of the foot during propulsion (1). The condition "plantar fasciitis" is the most common cause of heel pain, and estimates indicate that 1 million physician visits annually involve the diagnosis and treatment of plantar fasciitis (2). In addition, it is a common complaint in athletes, resulting in approximately 8% of all running-related injuries (3,4).

The pain from plantar fasciitis is usually felt in the heel of the foot and is usually most acute during the first steps in the morning because the fascia tightens up during the night during sleep. As the tissue warms, the pain subsides but can return with activity and long periods of standing. The underlying condition is a degenerative condition, caused by microscopic tears in the collagen of the fascia. The condition has a detrimental effect on the quality of life, and although conservative treatments are often effective, the period to resolution can be up to 2 years. However, most patients experience improvement by 9 months (5). Conservative therapies include rest, nonsteroidal anti-inflammatory medication, night splints, foot orthotics (6), and stretching protocols (7) of the plantar fascia and gastrocnemius/soleus muscle (8). For persistent plantar heel pain, extracorporeal shock wave therapy has been used but with mixed success. Surgery is sometimes used as a last resort but complications can arise, and it is not always successful (9).

Pulsed radiofrequency electromagnetic field (PRFE) therapy or pulsed electromagnetic field therapy has a long history in treating medical conditions. In 1947, the Federal Communications Commission assigned 3 frequencies at the short end of the radiofrequency band for medical use (40.68 MHz, 13.56 MHz, and 27.12 MHz) (10). The frequency of 27.12 MHz is the most widely used in clinical practice. The first PRFE device, the Diapluse (Daipulse, Great Neck, NY) was commercially available in the 1950s and was followed by other commercially available machines. PRFE is a noninvasive therapy that

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delivers electromagnetic energy into soft tissue, generating an electric field that is thought to mediate the therapeutic effects (11). Many studies have shown the clinical efficacy and safety of PRFE therapy recently reviewed by Guo et al (12). For soft tissue injury, these include ankle inversion treatment, in which studies showed a reduction in pain and swelling (13,14). PRFE therapy has shown to be beneficial in the treatment of neck pain (10,15). The treatment of osteoarthritis with PRFE has been reported to improve joint mobility and decrease pain and stiffness (16–18). Recently, there has been a focus on PRFE therapy and its application in controlling postoperative pain and in promoting the healing of chronic wounds. Significant decreases in postoperative pain have been reported after breast augmentation (19,20) and breast reduction surgery (21), with a corresponding decreased need for narcotic pain medication during recovery. Healing of chronic wounds has also been reported in a number of case reports (22–26), and a retrospective study of a wound registry showed that PRFE holds promise to effectively promote the healing of chronic wounds (27). Significantly, studies on animal models of Achilles tendon repair showed increased tensile strength and collagen alignment (28,29) after PRFE treatment. At 3 weeks after transection of the rat Achilles tendon, the tensile strength had increased by 69% compared with the nontreated control rats (29). Also, in a model of Achilles tendonitis, increased collagen alignment, decreased inflammation, and better tissue normality was seen (28). In vitro cuts in primary human tenocyte cultures from supraspinatus and quadriceps tendons exposed to electromagnetic field stimulation showed significantly accelerated cut closure 12 and 24 hours after the injury (30).

Classically, most studies of PRFE have used large, fixed main-powered devices, in which therapy is delivered in the clinic. In the present exploratory study for the treatment of plantar fasciitis, we used an innovative, small, wearable PRFE device (ActiPatch, Bio-Electronics, Frederick, MD) that can be used for extended periods. In the present study, it was used as a home-based therapy delivered nightly during sleep.

Patients and Methods

The study was a multicenter, prospective, randomized, double-blind, and placebo- and positive-controlled trial to determine the effects of nightly use of a wearable PRFE device (ActiPatch, Bioelectronics). The North Texas institutional review board at Medical City Dallas approved the study, the study participants provided signed consent forms, and all rights of the enrolled subjects in the present study were protected. The primary outcome measure for the study was morning pain, selected because morning pain is the hallmark of plantar fasciitis. Subjects who had been diagnosed with plantar fasciitis were recruited from the clinical practices of the podiatrist authors. The primary diagnostic criteria was defined as the presence of tenderness at the insertion of the plantar fascia into the heel bone, either plantar medially or plantarly. Radiography was used in all cases to rule out osseous causes of heel pain, including stress fracture or bone tumor. Although patients with fat pad atrophy were not excluded, those with pain directly under the osseous prominence of the calcaneal tuber rather than at the insertion of the plantar fascia, were excluded. Patients in whom neuritis was found to be the primary cause of heel pain as determined by palpation or percussion of the branches of the medial and lateral calcaneal nerves were excluded. Each subject recruited into the study randomly selected a coded PRFE device. The device used in the present study was a pulsed radiofrequency energy device (ActiPatch) that emits a safe form of nonionizing electromagnetic radiation. The carrier frequency is 27.12 MHz, the assigned Federal Communications Commission medical frequency, and it has a pulse rate of 1000 pulses/s and a 100-μs burst width. The peak burst output power of the 12-cm antenna is approximately 0.0098 W and covers a surface area of approximate 103 cm^2. The circuitry consists of low voltage (3 V) digital/analog electronics that control all timing functions to produce the therapeutic radiofrequency field, with the antenna field placed directly above the therapeutic site. This closed loop system of the antenna, low-energy signal generator circuit, and battery power supply transfers the radiofrequency energy to the tissue. The placebo devices did not emit a radiofrequency electromagnetic field but were identical to the active devices, including a light-emitting diode (LED) light showing operation. The energy from the active device is not felt by the user, and the active device cannot be distinguished in any way from the placebo device. Subjects were trained in the use of the PRFE device, which was worn nightly for 7 days with the antenna placed over the heel, the site of pain. The device was kept in place with a wrap and switched off when not in use. No other new treatments were started during the study period.

The subjects were asked to record their pain levels using a 0 to 10 visual analog scale (VAS). The VAS scores were recorded in the morning (AM), assessed on the first steps after awakening, and at night (PM), before bed, for the 7 days of the study. Medication use was also recorded, and medication use was left to the discretion of the patients during the study period.

Statistical Analysis

After completion of the study period and the collection of all available data, the data were analyzed using Excel 2007 (Yuma, AZ) with QI macros (KnowWare International, Denver, CO). Analysis of variance was performed using a generalized linear model, a flexible generalization of ordinary linear regression using SAS software (SAS Institute, Cary, NC). The generalized linear model generalizes linear regression by allowing the linear model to be related to the response variable by way of a link function and by allowing the magnitude of the variance of each measurement to be a function of its predicted value. The slope or rate of decline was compared using repeated measure analysis, which allows for the comparison of the mean variables with time. This analysis allows for a statistical comparison between the rate of decline in the control and study groups. The slope is considered significantly different at the 95% confidence level. Trends in VAS scores were analyzed using the Friedman test for nonparametric repeated measures. The base rates for each group were done relative to the first VAS score taken in the morning of day 1.

Although not typically used, to show the group trends in medication use during the 7-day study period, the following method was used. Medications were converted to 1 pill doses using a base dose for each medication used by the study participants. One pill was recoded as 200 mg ibuprofen, 250 mg acetaminophen, 250 mg naproxen, or 100 mg celecoxib. The use of a diclofenac topical patch was recorded as 1 dose.

Results

The planned enrollment for the study was 140 patients, and 70 active- and 70 placebo-coded devices were mixed in boxes. The patients randomly chose a device, and the device code was recorded. The planned enrollment was not met owing to time constraints, and only 70 patients were enrolled in the study (42 active and 28 placebo). Given the shortness of the study period and the simplicity of the treatment, no patients were lost to follow-up and no data were missing. Although this was a multicenter study, an intersite analysis was not performed because subject site recruitment data were not recorded by the study coordinator.

The demographic data indicated the randomization was successful (Table 1). No significant difference was found in age, height, weight, or plantar fasciitis duration between the 2 groups. The percentage of females in the 2 groups was 75% in the control group and 73.8% in the study group.

The PRFE therapy devices were well tolerated by all the patients, and no adverse effects were noted. Data were obtained from all 70 enrolled patients and were available for statistical analysis. The mean AM-VAS scores and the standard deviation for the 7 days of the study are presented in Table 2.

The day 1 VAS scores were not significantly different between the study and control groups. The VAS pain scores for the 7 days of the study showed a consistency in the control group with a day 1 to day 7 difference of 0.26 VAS points. In contrast, the AM-VAS score in the study group showed a steady decline. The day 1 to day 7 VAS score difference was 1.74 VAS points, for a 7.5-fold greater reduction in pain than in the control group (Fig. 1). Regression analysis of the

Table 1
Demographic data (N = 70 patients)

Variable	Control Group (n = 28 patients)	Study Group (n = 42 patients)	*p* Value
Age (y)	49.7 ± 15.2	53.2 ± 14.7	.35
Height (in.)	64.3 ± 2.9	65.5 ± 3.0	.09
Weight (lb)	196.4 ± 58.6	176.0 ± 28.8	.14
Plantar fasciitis duration (mo)	13.1 ± 8.7	11.9 ± 8.1	.60

Data presented as mean ± standard deviation, with no significant difference ($p \leq .05$) detected between the 2 groups.

Table 2
Mean morning visual analog scale scores (N = 70 patients)

Day	AM-VAS Score	
	Control Group (n = 28 patients)	Study Group (n = 42 patients)
1	3.67 ± 2.01	4.38 ± 2.39
2	3.75 ± 2.30	3.64 ± 2.15
3	3.28 ± 2.40	3.45 ± 2.11
4	3.13 ± 2.37	3.26 ± 1.91
5	3.54 ± 2.86	2.87 ± 2.16
6	3.30 ± 2.59	3.01 ± 2.13
7	3.41 ± 2.80	2.64 ± 1.88

Abbreviation: AM-VAS, morning visual analog scale.
Data presented as mean ± standard deviations.
Friedman test for nonparametric repeated measures showed significant difference ($p = .036$) between mean values for control and study groups.

study group showed an R^2 of 0.887 ($p = .002$, slope = −0.252; i.e., y = 4.33 − 0.252 × day). For the control group, the R^2 was 0.239 ($p = .265$, slope = −0.051; i.e., y = 3.643 − 0.051 × day). The regression analysis showed a significant downward slope of 0.25 VAS points/day in the study group. A standard repeated measure analysis using the SAS generalized linear model routine showed significantly different rates of improvement in morning pain between the 2 groups ($p = .03$). An F test was also performed using Excel 2007 QI macros and showed the group means to be significantly different ($p = .036$).

The AM-VAS scores from day 2 through day 7 were compared with the day 1 AM-VAS scores using the Student's *t* test (Table 3). The AM-VAS scores from day 2 to day 7 in the control group show no significant differences compared with the day 1 scores. In contrast, the steady decline in pain scores in the study group had become significantly different at day 4 ($p = .021$) compared with the day 1 score. The decline in pain continued to be significant through day 7.

The mean PM-VAS score with standard deviation is listed in Table 4. The control and study groups showed declines compared with the day 1 VAS scores.

The decline in the control group was 1.05 VAS points or 19%, and the decline in the study group was 1.49 VAS points or 30%. The SAS analysis of variance and F test showed no significant difference between the 2 groups. However, the decline in the control group from day 1 to day 2 was 0.64 VAS point and an additional 0.36 VAS point from day 2 to day 3. From day 3 to day 7, no additional decline occurred in the mean VAS score (4.46 and 4.41 points, respectively). In contrast, the VAS score decline was more evenly spread in the study group, with a day 1 to day 2 decline of 0.33 VAS point and a day 2 to day 3 decline of 0.39 point. The VAS point decline from day 3 to day 7 was 0.77 VAS point in the study group. Fig. 2*A* shows the mean decline in the PM-VAS score for both groups during the 7-day study period, and Fig. 2*B* shows the day 3 to 7 mean decline.

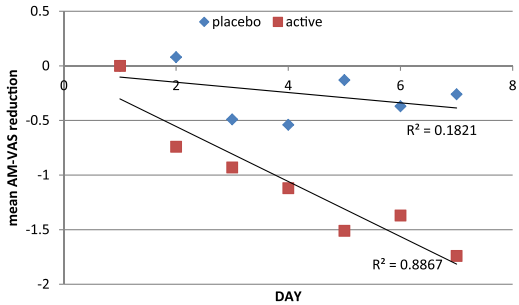

Fig. 1. Effect of overnight use of ActiPatch device on morning pain. Data presented as mean reduction in morning visual analog scale (AM-VAS) score for pain from day 1 to day 7. As can be clearly seen, the level of pain decrease in the treated group was greater than that of the control group by a factor of 7.5.

Table 3
AM-VAS scores on day 2 through day 7 compared with day 1 score using Student's *t* test (N = 70 patients)

Day	*p* Value	
	Control Group (n = 28 patients)	Study Group (n = 42 patients)
2	.90	.15
3	.52	.06
4	.36	.021*
5	.83	.0035*
6	.61	.0076*
7	.69	.00045*

Abbreviation: AM-VAS, morning visual analog scale.
* Statistically significant difference.

The results of the PM-VAS analysis were similar to those of AM-VAS analysis, when comparing the scores of day 2 through day 7 with the day 1 scores using the Student's *t* test. Significance was shown for days 4 through 7 in the study group, with no significant decrease seen in the control group (Table 5).

Medication

The medication used by each group is shown in Table 6. Although the randomization of the study was successful as shown by the demographic data (Table 1), a greater percentage of patients were taking medication in the control group (9/28, 32.1%) compared with the study group (10/42, 23.8%) on day 1. However, of those patients in the 2 study groups taking medication, the average pill use on day 1 was very similar (control group, 2.55; study group, 2.44 pills per subject; Table 7). This was also shown by the total pill use, which was similar at day 1 (study group, 22; control group, 23). The daily total pill use and average patient pill use in the control group showed day to day variability but showed no decline overall. In contrast, in the study group, the total pill and patient average use showed a downward trend (Table 7 and Fig. 3). By day 7, the pill use in the control group was 28 and in the study group was 11, and the average pill use was 2.8 pills per patient in the control group and 1.57 pills per patient in the study group. The number of patients taking pills in the control group was 10 (35.7%) of 28 and in the study group was 7 (16.6%) of 42 at day 7. However, no significant difference was found between the 2 groups.

Discussion

In the present study, we have presented the results from a prospective study using a small, lightweight wearable PRFE device as a treatment for plantar fasciitis. The subjects were instructed to wear the device overnight and the pain experienced in the morning and evening was recorded for 7 days. The results showed that overnight wear of the PRFE device was effective at significantly reducing morning pain, a hallmark of plantar fasciitis. The significant decline in

Table 4
Mean daily PM-VAS scores

Day	Control Group		Study Group	
	Mean Score	Day to Day Decline	Mean Score	Day to Day Decline
1	5.46 ± 2.7	—	4.97 ± 2.5	—
2	4.82 ± 2.9	−0.64	4.64 ± 2.5	−0.33
3	4.46 ± 2.9	−0.36	4.25 ± 2.7	−0.39
4	4.59 ± 3.1	+0.13	3.74 ± 2.2	−0.51
5	4.45 ± 3.0	−0.14	3.81 ± 2.4	+0.06
6	4.14 ± 2.8	−0.31	3.79 ± 2.5	−0.02
7	4.41 ± 2.9	+0.33	3.48 ± 2.4	−0.31
Total	—	−1.05	—	−1.49

Abbreviation: PM-VAS, evening visual analog scale.
Data presented as mean ± standard deviation.

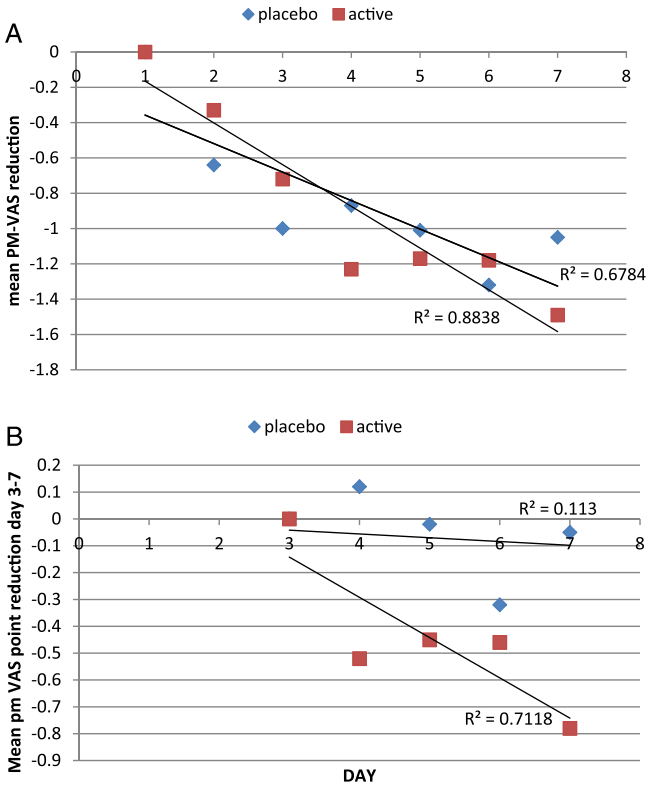

Fig. 2. (*A*) Mean evening visual analog scale (PM-VAS) point reduction after overnight use of Actipatch device. Data are presented as mean reduction in evening visual analog scale pain from day 1 to day 7, with no significant difference between the 2 groups. The study group decreased 1.49 visual analog scale points compared with 1.05 visual analog scale points in the control group. (*B*) Mean evening visual analog scale score reduction from days 3 to 7. Data show that the control group mean evening visual analog scale score remained essentially unchanged from day 3 through day 7 but study group mean evening visual analog scale score showed a continued decline.

morning pain in the study group wearing the active PRFE device was 40% compared with the 7.9% in the control group during the 7-day study period. The analysis of the nighttime pain showed no significant difference between the 2 groups. The pain declined 30% in the study group and 19% in the control group. The control group had a day 1 to day 3 decline of 1.00 VAS point in the evening, although very little decline (0.05 VAS points) was seen for the following 3 to 7 days. This suggests that there was a strong initial placebo effect for the first few days of the study. The decline in the study group was more consistent, indicating a longer study period would have resulted in a significance difference between the 2 groups. Medication use in the study group showed a downward trend during the 7-day study but remained more consistent in the control group, although the results were not significantly different. The consistent decreases in morning pain seen in the study group would be expected to lead to decreased medication use, which occurred.

Table 5
PM-VAS scores on day 2 through day 7 compared with day 1 score using Student's *t* test (n = 70 patients)

Day	*p* Value	
	Control Group (n = 28 patients)	Study Group (n = 42 patients)
2	.41	.55
3	.20	.21
4	.28	.02*
5	.20	.03*
6	.08	.03*
7	.17	.007*

Abbreviation: PM-VAS, evening visual analog scale.
* Statistically significant.

Table 6
Group medication use (N = 70 patients)

Medication	Control Group (n)	Study Group (n)
Acetaminophen 250 mg	3	24
Ibuprofen 200 mg	85	46
Naproxen 250 mg	38	22
Celebrex	28	0
Flector patch (diclofenac)	0	7
Loratab	0	2
Total	154	101

Control group used 154 pain medication pills compared with 101 pain medication pills in the study group. (1 pill counted as 200 mg ibuprofen, 250 mg acetaminophen, 250 mg naproxen, 100 mg celebrex, or 1 Flector patch).

The PRFE device used in the present study is based on work pioneered by Bentall (31) in the 1980s who first showed that reducing the power and size but extending the use time produced equivalent results to larger, more powerful devices. A study by Nicolle and Bentall (32) on surgical recovery showed that extended-use PRFE devices were able to control edema after blephoraplasty. There has been a new focus on small, extended-use PRFE devices, and a number of studies on postoperative recovery and wound healing have been published (19–21,26).

The current treatment for most plantar fasciitis cases results in positive resolution with conservative modalities (6,33–36). Conservative forms of treatment, including nonsteroidal anti-inflammatory drugs, heel pads or orthotics, physical therapy, stretching of the gastrocnemius-soleus, and corticosteroid injections, provide substantial relief for about 80% of patients. However, along with the long interval to resolution, these treatments have additional drawbacks. Injection of corticosteroids for the treatment of plantar fasciitis is almost always painful and can cause both local and systemic side effects (37). Long-term use of nonsteroidal anti-inflammatory drugs can have significant side effects such as gastrointestinal complications and an increased risk of serious cardiovascular events (38). Although custom orthotics are often prescribed, they may only show a short-term benefit in reducing the pain associated with plantar fasciitis (39).

After failure of conservative therapy, treatments such as extracorporeal shock wave therapy and surgery, are used. Extracorporeal shock wave therapy has been reported to be effective in some studies after conservative treatment has failed. Metzner et al (40) reported good results with extracorporeal shockwave therapy. In their study, success was defined as a 30% VAS reduction, which was seen in 81% of patients at 6-week follow-up. However, other studies have reported conflicting results, with the treatment seeming no better than sham therapy (41–43). Although surgery to treat plantar fasciitis is used as a last resort, it has had a variable (70–90%) success rate, and recovery from surgery can vary from several weeks to a few months. Potential complications include transient swelling of the heel, heel hypoesthesia, rupture of plantar fascia, flattening of the longitudinal arch, and calcaneal fracture (9).

Table 7
Medication use (N = 70 patients)

Variable	Day						
	1	2	3	4	5	6	7
Control group (n = 28 patients)							
Subjects using medication	9	8	10	8	9	8	10
Total medication use	23	21	24	19	20	19	28
Average pill use	2.55	2.65	2.4	2.37	2.22	2.37	2.80
Study group (n = 42 patients)							
Subjects using medication	9	7	7	5	7	8	7
Total medication use	22	16	12	7	17	16	11
Average pill use	2.44	2.28	1.71	1.4	2.42	2.0	1.57

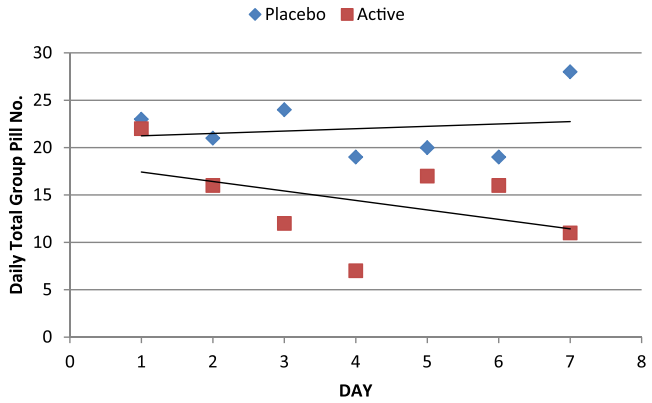

Fig. 3. Mean daily pill use for study and control groups showing decline in pill use in the study group from 22 pills on day 1 to 11 pills on day 7. In contrast, no decline in pill use was seen in the control group (23 pills on day 1 and 28 pills on day 7).

This is the first study to show that PRFE therapy used in this format can potentially treat plantar fasciitis. PRFE therapy for plantar fasciitis appears to offer a therapy that is easy to use, noninvasive, and drug free, with no reported side effects. The results from the present initial study indicate that PRFE therapy results in a relatively rapid decline of pain, given the usually protracted nature of the condition. However, the present study had a number of limitations, including the length of time that data was collected (7 days), the lack of long-term follow-up, and the lack of intercenter analysis. Also, no power analysis was performed to calculate the study size, owing to the lack of data on the effects of this form of therapy on plantar fasciitis heel pain. The sample size was determined by the amount of time the podiatric authors could allot to do the study, which resulted in lower than anticipated recruitment goals. However, the study results suggest that PRFE therapy in this form holds promise as a new treatment of plantar fasciitis.

This is the first study using this form of therapy for plantar fasciitis heel pain. The results from our study indicate that additional studies are warranted to confirm these initial findings.

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