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Case report

Use of pulsed radio frequency energy in the effective treatment of recalcitrant plantar fasciitis: Six case histories

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ABSTRACT

Plantar fasciitis (or Heel Pain Syndrome) is a common foot disorder. Whereas most patients with this condition have satisfactory outcomes with conventional treatment, the condition can become recalcitrant. For these patients, the use of Pulsed Radio Frequency Energy (PRFE) appears to be a safe, noninvasive, and effective treatment option. While PRFE has been used to provide pain relief for other clinical conditions, little clinical information is available regarding its effectiveness for the treatment of plantar fasciitis. Reported here are outcomes for six cases of recalcitrant plantar fasciitis (duration 6 months or longer) that were unresponsive to conventional treatment alone, for which complete or near complete pain relief was achieved following adjunctive PRFE therapy.

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1. Introduction

1.1. Short literature review

1.1.1. Plantar fasciitis—pathology and histology

Plantar fasciitis (or heel pain syndrome) is a common foot disorder encountered in the outpatient clinic [10]. In the US, it is estimated that plantar fasciitis occurs in about 10% of the general population [28], and represents 11–15% of foot problems related to pain requiring professional care [28,40]. The typical presentation is sharp pain localized along the middle to posterior aspect of the sole of the foot [7]. Plantar fasciitis is associated with plantar fascial thickening [26,31,50], and often, but not always, with a heel spur (exostosis) [10,26,40]. While most patients with this condition have satisfactory outcomes with conventional nonsurgical treatment [10], there are still many patients who require advanced therapies [23].

Historically, the term plantar fasciitis is used in recognition of the symptoms that occur along the plantar fascia. More recently however, the term plantar fasciosis has gained popularity, as it more closely describes the degenerative nature of the condition without implying inflammation [40], since biopsy specimen show degenerative changes with or without inflammatory changes. Histological findings indicate that microtears and chronic collagen degeneration in the plantar fascia from stress overload may contribute [14]. The prominent pathological abnormality is located near the origin of the plantar fascia at the medial tuberosity of the calcaneus [28].

Risk factors include reduced dorsiflexion of the ankle, obesity, and prolonged weight bearing, though in approximately 85% of the cases, the specific cause is unknown [40]. The symptoms of this condition, however, are well known and diagnosis is straightforward [10,40,46,52].

1.2. Conservative treatment

A common but unproven belief is that initiating conservative treatment within six weeks after the onset of symptoms may speed resolution. There is strong evidence to support the use of orthotic devices as the intervention most likely to provide short-term reduction in pain and improvement in function [28]. Limited evidence suggests that casting may be beneficial [10]. Conventional

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treatment further involves exercises to stretch the plantar fascia and gastrocnemius-soleus muscles, massage, application of ice (to reduce pain and inflammation), reduction of activity, and the use of analgesics (NSAIDS), as well as corticosteroid injections [10,40,45,52].

1.3. Advanced therapies

There are an increasing number of potential advanced therapy alternatives with plantar fasciitis. Recent studies on the efficacy of extracorporeal shock wave therapy (ESWT) are conflicting. Successful resolution of pain with ESWT is attributed to neovascularization, and while found effective in some groups of patients, the treatment has been shown to be ineffective in a number of randomized control trials [8,10,18,21,32,33,39,40,44]. Other emerging treatments may include botulinum toxin type A injection, injections with platelet-rich plasma or sclerotic agents, and cryosurgery [4,5,14]. In severe or chronic cases, surgical resection may be indicated to release the plantar fascia from its bony attachment at the calcaneus [7,10]. Surgery may be considered for a small subgroup of carefully selected patients who have persistent, severe symptoms for at least 6–12 months despite other treatments. Surgical procedures are varied but include open or closed, partial or complete plantar fascia release [7,10,40], with a reduction in time to return to full activity and lower occurrence of serious postoperative complication rates reported as advantages of endoscopic fasciotomy compared to traditional plantar fasciotomy [21,49]. Calcaneal spur resection, excision of abnormal tissue, and nerve decompression may also be beneficial [9,40].

Although there are many approaches used for plantar fasciitis, few quality studies exist to support the use of one over another [48]. Decisions regarding the management strategy should be determined in light of the self-limiting nature of the condition [9,10].

1.4. Pulsed radio frequency energy

Pulsed radio frequency energy (PRFE) is a noninvasive, noncontact adjunctive therapy that involves delivery of pulsed radio frequency energy to a target tissue without direct electrode contact to the body [15,30]. PRFE uses a carrier frequency of 27.12 MHz, and energy is delivered in a pulsate fashion to allow for dissipation of heat between pulses, thus providing therapeutic effects in a nonthermal manner [15,30]. It is currently indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue [2]. Positive clinical outcomes have been reported for its use in pain relief both postoperatively as well as for nonpostoperative pain, including pain associated with heel neuroma, foot and ankle injuries and sprains, posttraumatic algoneurodystrophy, as well as neck pain and whiplash [15,17,30,38,42]. In general, PRFE therapy is not associated with adverse health effects when used as directed, though it is contraindicated in patients with implanted metallic leads, implanted cardiac rhythm devices, metallic implants in the area of application, children, patients who are pregnant, with the precaution that its effects on people with cancer in the site of treatment are not known [15]. Unlike bipolar radiofrequency microtenotomy [37], PRFE therapy is noninvasive, and not intended for use in tissue ablation [15,30].

The underlying mechanism of action of PRFE is not well understood, however evidence suggests that PRFE-mediated pain relief may be due to induction of the body's endogenous response to soft tissue injury [29]. *In vitro*, PRFE is mitogenic (i.e. cell-cycle stimulating) [13], and has been shown to modulate transcript levels of a large number of gene products involved in soft tissue repair, including numerous cytokines as well as matrix metalloproteases (MMPs) and their inhibitors (TIMPs) [29]. The effect of PRFE on inflammatory cytokine levels was the subject of a recent clinical study evaluating the use of PRFE for postoperative pain relief, which revealed reduced IL-1β levels in wound exudates from PRFE-treated patients relative to control patients, an effect accompanied by a reduction in pain in the PRFE-treated patient group [38]. Thus, multiple changes at the molecular level likely contribute to PRFE-mediated pain relief observed in the clinical setting [30].

1.5. Statement of the problem

The podiatrists at the Fayetteville Veterans Administration Medical Center are very familiar with the PRFE wound therapy technology as it is used in the treatment of chronic foot ulcers [12,22,36,47]. Given its indication for the treatment of pain and edema, and previous reports of successful use in foot and ankle injuries and reconstructive surgery [20,34,41,42,51], the therapy might also have a role in the treatment of plantar fasciitis, a condition that is seen frequently in our institution. The decision was made to use the technology in a small group of patients with recalcitrant plantar fasciitis.

2. Case reports

2.1. Patient demographics

Table 1 provides a summary of patients described in this case histories report.

The patients reported here ranged in age from 44 to 67. Typical of the VA patient population, the majority of patients were male (five males, one female). Four patients had unilateral plantar fasciitis, and two had bilateral plantar fasciitis. Patients had a variety of systemic, articular, and podiatric comorbidities and conditions. All patients that received PRFE therapy presented to the Podiatry Clinic with plantar fasciitis that proved to be severe, recalcitrant, and interfered with their qualities of life. Each of the patients described in this report had the condition for a minimum of six months before treatment with the PRFE device.

Each patient received standard therapy for plantar fasciitis as described in Table 1. This included physical therapy and prescription insoles or orthoses, as well as corticosteroid injections or NSAID therapy for a subset of the patients. In addition, a few of the patients received night splints. PRFE therapy (Provant® Therapy System, Regenesis Biomedical, Inc., Scottsdale, AZ) was prescribed after the therapies described for each patient (Table 1) failed to provide relief, although patients may have continued to use them.

Patients were instructed in how to use the device at home. Treatments were administered twice daily for 30 min 8–12 h apart as described in the FDA-approved device manual [2]. Treatments involved placement of the device applicator over the treatment area and application of therapy as indicated in the manual [2]. In the case of the two patients with bilateral plantar fasciitis, PRFE was prescribed for use on both feet (one device).

Treatment outcomes were assessed using the patient's description of pain on a visual analog scale [1], and by assessing the patient's reaction to palpation of the involved heel.

3. Results

As shown in Table 1, all patients reported that they had recently experienced high levels of pain due to typical stimuli such as first steps in the morning or first steps after rest (post-static dyskinesia). In all patients, conservative standard techniques failed to effectively reduce these pain levels. After these conservative measures (Table 1) failed to provide relief, PRFE was prescribed and used by patients for 3–3.5 months.

Table 1
Summary of patient demographics, treatment, and response.

Patient #	Medical history		Plantar fasciitis history			Initial standard treatment		PRFE treatment	
	Age/gender	Co-morbidities	PF location	Duration (months)	Pain at presentation	Description	Pain outcomes	Duration	Pain outcomes
1	67 male	• Diabetes mellitis • Controlled hypertension • Hypertriglycemia • Gastric reflux • Nephropathy	Left	9	10/10 at first steps in morning	• Corticosteroid injection • Insoles (Spenco) • Stretching • Ice massage	6/10 at 4 months	3	0/10 with no tenderness
2	44 female	• Pes planus • OA of hip • Depression • PTSD • Obesity • Hyperlipidemia • Radiculopathy	Left and right	>24	10/10 while walking	• Corticosteroid injection • Insoles (Poron) • Analgesic cream	No relief	3.5	2/10 (bilateral) with minimal tenderness
3	49 male	• Pes planus • OA • Hallux valgus • Gingivitis	Left and right	>24	10/10 at first steps in morning and after rest	• Insoles • NSAIDs • Education	7/10 (bilateral) at 4 months	3	2/10 (bilateral) with no tenderness
4	63 male	• Pes cavus • Flexor hallucis longus tendinitis • Degeneration of intervertebral disc • Hypothyroidism • Radiculopathy • Hyperlipidemia • Prior CVA w/no residuals	Left	7	10/10 Mostly when rising from bed in the morning	• Heel cushions • Removable boot cast • Corticosteroid injection • Stretching • Ice massage • Insoles (Spenco)	Tendinitis improved; PF pain rated 10/10 at 5 months	3	6–8/10 at 1 month;0/10 at 3 months with no tenderness
5	48 male	• Type 2 diabetes mellitus • Controlled hypertension	Right	9	10/10 at first steps in morning and after rest	• Corticosteroid injection • Stretching • Ice massage • Insoles	7/10 at 4 months	3	0/10 at 1and 4 months post-treatment with no tenderness
6	60 male	• Radiculopathy • Herpes simplex • Depression • PTSD • Gastroesophageal reflux disorder • Benign prostatic hypertrophy • Degenerative joint disease • Hypertension • Prior PF (right) 2 years prior; resolved with corticosteroid injection and physical therapy	Left	12	10/10 Morning	• Stretching • Ice massage • Insoles (Poron) • Night splint	10/10 at 2 months	3	0/10 at 1 month post-treatment with no tenderness

At the end of the PRFE treatment, four of the six patients reported no pain (score 0/10) and experienced no tenderness on palpation. The two patients with bilateral plantar fasciitis did not achieve total pain relief, but their pain levels were dramatically reduced (score 2/10). One of these patients had minimal tenderness (patient 3) on palpation, and the other reported no tenderness (patient 2).

No adverse events were reported which is consistent with the evidence on the safety of PRFE over the past 40+ years [15]. Our patients found the device painless and very easy to use.

4. Discussion

The Provant Therapy System is an FDA cleared (Class III) device that, according to its manufacturer, has been used in over 5000 patients since 2004 with few adverse events. The technology has been used primarily in outpatient clinics associated with 120 Veterans Administration hospitals across the US. Due to its self-contained and extremely portable nature, as well as simplicity of operation, it is suitable for self-administration at home. Rarely do patients feel any sensation with therapy.

While much of the evidence is pre-clinical, a picture is emerging which may help to explain the pain relief seen with this device in clinical practice. *In vitro*, PRFE can stimulate cell proliferation [13], and has been shown to modulate transcript levels of a large number of gene products, including numerous cytokines and matrix metalloproteases (MMPs) and their inhibitors (TIMPs) [29]. It is interesting to note that an imbalance between many of these same molecular factors is implicated in different types of pathogenesis, including delayed wound repair [6,11,35], neuropathic pain [19], and tendonopathies [25,43], suggesting that PRFE may function to restore balance between factors involved in these processes. This may also provide a possible molecular mechanism underlying PRFE-mediated pain relief as described in the current case review. While acute pain relief may be the result of PRFE-mediated effects on pain signaling [30], long-term effects could potentially be due to promotion of tissue healing, for example through mitogenic stimulation of fibroblasts, the key cells of connective tissue, and stimulation of collagen production through the up-regulation of growth factor and cytokine expression [15,24,29].

Heel pain is a common medical complaint in adults, which, anatomically, may be the result of conditions involving the plantar fascia, tendons, or bursae, nerve entrapment, or abnormalities involving bone or the heel fat pad [10,31]. While plantar fasciitis has been reported as the most common foot condition treated by health professionals [28], current non-surgical treatments for recalcitrant plantar fasciitis are not effective in a subset of patients. For patients who do not improve after initial treatment, corticosteroid injection or dexamethasone iontophoresis may provide short-term benefit [46]. However, steroid therapy, although a mainstay of therapies used, does not always improve long-term outcomes, and in some cases, may be associated with complications [3,10,21,27,46,48]. The benefit of extracorporeal shockwave therapy is still controversial with some studies reporting efficacy and others finding no significant benefit [8,10,16,18,21,32,33,39]. It is also expensive and can be very painful.

In these six patients with severe, recalcitrant plantar fasciitis, PRFE therapy appeared to have a dramatic pain-reducing effect. Four of the six patients experienced total pain relief and the others experienced an 80% reduction in pain. Moreover patients reported that they could resume activities that were previously limited by their condition. While it is interesting to note that the two patients with bilateral plantar fasciitis reported less relief than other patients following treatment, the reason for this is difficult to assess since this is not a controlled study *per se*, but a report of individual cases. Still, these two patients, who also presented with the condition for the longest duration of all cases in this report (over two years duration), appeared to respond well to the therapy (80% pain reduction). It is important to reiterate that these effects occurred after conventional therapies such as corticosteroid injections, physical therapy, stretching, and orthotics had failed. In addition, at least for these patients, the use of PRFE therapy seemed to provide a nonsurgical option.

5. Potential clinical significance

Reference to clinical observation in a qualitative fashion may offer some insight into to the true clinical merit of PRFE technology for recalcitrant patients. This therapy may provide relief for recalcitrant pain where prior therapies have failed. Potential benefits include:

- Possible greater efficacy in cases where other more conservative measures have failed.
- Demonstrated safety.
- Demonstrated ease of use by the patient in the home.
- Painless administration in most patients.

6. Conclusion

These findings are consistent in this subset of patients, and support the hypothesis that PRFE therapy assists in the treatment of recalcitrant plantar fasciitis. Therefore, the use of this technology warrants further study and evaluation in patients suffering chronic pain in this indication.

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