Pulsed Radio Frequency Energy Therapy Use for Pain Relief Following Surgery for Tendinopathy-Associated Chronic Pain: Two Case Reports

Jane Cortes, DPM*; Nicole Kubat, PhD†‡; Christopher Japour, DPM*

ABSTRACT  Chronic tendon pain from overuse is a common condition, with limited options for ongoing pain management. Two cases are presented in which pulsed radio frequency energy (PRFE) therapy was used for pain relief following surgical intervention for chronic tendinopathy–associated pain, unresponsive to conventional therapies. Both patients showed a dramatic reduction in pain following PRFE therapy after 2 to 3 weeks of treatment, and at the 7-month (case 1) and 6-month (case 2) follow-up visits, both patients reported that pain had not returned. Recent molecular evidence suggests a possible mechanism underlying PRFE-mediated pain relief. Further study into this promising technology is warranted.

INTRODUCTION
Chronic tendon pain from overuse is a common condition, with limited options for ongoing pain management. Such conditions are often the result of sports-related or occupational activities in which the tendon is exposed to intense, repetitive, or long-duration activity. Excessive tendon loading is thought to be a primary factor promoting tendon degeneration, and mechanical strain is thought to result in altered cell activity within the tendon. Intrinsic and extrinsic factors implicated in tendinopathy include prolonged or intense use, frequent microtrauma, obesity, age, and certain anatomical factors. Additionally, genetic predisposition may contribute in some cases.

Histologically, tendinopathy often show degeneration and/or disorganization of collagen bundles, altered tenocyte morphology, increased cellularity, and in many cases an absence of inflammation, though it has been suggested based on studies in animal models that inflammatory changes may occur early before outward signs of tissue injury. Tendinopathy can be a difficult condition to treat, and although many treatment options are available, there remains a lack of high-quality, evidence-based efficacy data available for many tendinopathy treatments. Conservative measures used to treat tendinopathy include ice, relative rest, orthotics and braces, and, in the case of foot and ankle tendinopathy, elevation (Table I). There is evidence to support the use of eccentric strengthening for some tendinopathy and stretching. Oral and/or local nonsteroidal anti-inflammatory drugs (NSAIDs) may provide short-term pain relief for certain types of tendinopathy; however, there is little support for their long-term use. Similarly, although data suggest local corticosteroid injections may provide relief from acute-phase tendinopathy-associated pain, data are lacking regarding long-term benefits. For patients who fail conservative therapy, surgery is also an option; however, it is invasive and does not relieve pain in all cases.

In clinical practice, many physical modalities are under study for the management of tendon disorders and resulting pain. Here, we describe pain relief in 2 patients following surgery for tendinopathy-associated chronic pain using pulsed radio frequency energy (PRFE) therapy, a biophysical treatment modality that involves delivery of nonionizing radio frequency energy to soft tissue to provide pain relief, and indicated for the adjunctive, palliative treatment of postoperative pain and edema in superficial soft tissue.

Results from in vitro studies, as well as recent clinical findings, indicate that PRFE can trigger a biological cascade of events in human skin cells and wounded tissue that results in the expression of factors that function in soft tissue repair and pain signaling. PRFE therapy has been used to provide relief for pain of various etiologies, including postoperative pain and pain associated with ankle sprains and inversion injuries, heel neuroma, hand and finger injuries, neck pain and whiplash, algoneuropathy, and cutaneous wound pain. PRFE therapy has also been associated with a reduced consumption of analgesics and a shorter hospital stay following foot surgery. In addition, a recent meta-analysis of 25 controlled trials involving over 1,300 patients treated with PRFE demonstrated statistically significant benefit in the treatment of pain, edema, and wound healing, with p values of <0.0001.

Here, 2 cases of tendinopathy-associated chronic pain are reported. In both cases, PRFE therapy was prescribed after conventional therapies and surgical intervention failed to provide...
Case Report

TABLE I. Measures Used for the Treatment of Tendinopathy

<table>
<thead>
<tr>
<th>Conservative Treatment</th>
<th>Other Treatments</th>
</tr>
</thead>
</table>
| Ice 
| Relative Rest 
| Orthotics and Braces 
| Elevation (Foot/Ankle) 
| Tendinopathy 
| Eccentric Strengthening and Stretching 
| NSAIDs (Acute Pain, Short-Term Use) |
| Corticosteroid Injections (Certain Tendinopathies for Acute Pain; With Caution Because of Citations of Tendon Rupture) 
| Physical Modalities (Under Study) 
| Surgery (in Select Patients if Conservative Measures Fail) |

In each case, pain relief occurred soon after initiation of PRFE treatment, and with long-lasting effects.

**CASE 1**

A 27-year-old male presented with a 4-year history of left fifth metatarsal pain (level 4 out of 10; Wong–Baker FACES pain scale) with increasing inability to work. The original injury occurred during military service when the patient fell while running. He was diagnosed with probable tendon or ligament rupture and fracture of the fourth and fifth metatarsals. Treatment included a removable cast/walking boot, casting, and physical therapy. Despite these interventions, pain had persisted. The patient also suffered from headaches, which were treated with topiramate followed by gabapentin.

Over the preceding 2 years, the patient had failed NSAIDs, injections (lidocaine plain 2% 1 cc with Kenalog-40 1 cc and Marcaine 0.25% plain), immobilization, physical therapy, and orthotics. The pain became shooting in character and progressively worsened, particularly with prolonged periods of standing and walking. At presentation, he favored his right foot. His pain level was 8 out of 10 (Wong–Baker FACES pain scale) with tingling sensation. Nonweight bearing with casting and crutch walking was initiated. Oxycodone and/or acetaminophen (325 mg) were prescribed for pain.

PRFE therapy (Proviant Therapy System; Regenesis Biomedical, Scottsdale, Arizona) was initiated for pain. Provant is a portable, noninvasive medical device that delivers PRFE via a spiral antenna placed adjacent to the treatment area (Fig. 2). The device generates pulses that are 42 μs long, 1,000 times per second, creating an electromagnetic field that bathes the treatment area and generates the therapeutic effect. The electromagnetic field has an electrical field strength of 591 V/m and a magnetic field strength of 6.4 A/m at a distance of 5 cm from the treatment applicator. The dosage is preset and self-regulated, to ensure consistent and therapeutic dosing. Therapy can be administered directly through clothing and bandages. Treatment is generally self-administered in the home without nursing supervision and performed twice daily for 30 minutes. The device shut off automatically at the end of the 30-minute treatment, and unlike TENS and electrical stimulation devices, the treatment is noncontact and does not involve electrodes or administration of direct current. Unlike other pulsed electromagnetic field devices designed for bone stimulation, which operate at very low frequencies (1–300 Hz), the device operates at a frequency of 27.12 MHz. In both cases described here, PRFE therapy was self-administered in the home by placing the treatment applicator over the site of pain for 30 minutes twice a day in accordance with the manufacturer’s instructions. In general, PRFE treatment is imperceptible to the patient.

Following the first week of PRFE therapy, the patient reported less pain with pain medication needs decreased to episodic use at night for severe pain. The patient also began removable cast/walking boot, which he subsequently discontinued because of back pain. The patient progressed to crutches, and over the next month, the pain remained consistent, with oxycodone and acetaminophen required every 6 hours routinely. At 6.5 weeks postsurgery, the patient’s pain remained at a level of 6 out of 10 and still required opioids for relief. PRFE therapy (Proviant Therapy System; Regenesis Biomedical, Scottsdale, Arizona) was initiated for pain. Provant is a portable, noninvasive medical device that delivers PRFE via a spiral antenna placed adjacent to the treatment area (Fig. 2). The device generates pulses that are 42 μs long, 1,000 times per second, creating an electromagnetic field that bathes the treatment area and generates the therapeutic effect. The electromagnetic field has an electrical field strength of 591 V/m and a magnetic field strength of 6.4 A/m at a distance of 5 cm from the treatment applicator. The dosage is preset and self-regulated, to ensure consistent and therapeutic dosing. Therapy can be administered directly through clothing and bandages. Treatment is generally self-administered in the home without nursing supervision and performed twice daily for 30 minutes. The device shut off automatically at the end of the 30-minute treatment, and unlike TENS and electrical stimulation devices, the treatment is noncontact and does not involve electrodes or administration of direct current. Unlike other pulsed electromagnetic field devices designed for bone stimulation, which operate at very low frequencies (1–300 Hz), the device operates at the Federal Communications Commission designated short-wave frequency of 27.12 MHz. In both cases described here, PRFE therapy was self-administered in the home by placing the treatment applicator over the site of pain for 30 minutes twice a day in accordance with the manufacturer’s instructions. In general, PRFE treatment is imperceptible to the patient.

Following the first week of PRFE therapy, the patient reported less pain with pain medication needs decreased to episodic use at night for severe pain. The patient also began removable cast/walking boot, which he subsequently discontinued because of back pain. The patient progressed to crutches, and over the next month, the pain remained consistent, with oxycodone and acetaminophen required every 6 hours routinely. At 6.5 weeks postsurgery, the patient’s pain remained at a level of 6 out of 10 and still required opioids for relief. PRFE therapy (Proviant Therapy System; Regenesis Biomedical, Scottsdale, Arizona) was initiated for pain. Provant is a portable, noninvasive medical device that delivers PRFE via a spiral antenna placed adjacent to the treatment area (Fig. 2). The device generates pulses that are 42 μs long, 1,000 times per second, creating an electromagnetic field that bathes the treatment area and generates the therapeutic effect. The electromagnetic field has an electrical field strength of 591 V/m and a magnetic field strength of 6.4 A/m at a distance of 5 cm from the treatment applicator. The dosage is preset and self-regulated, to ensure consistent and therapeutic dosing. Therapy can be administered directly through clothing and bandages. Treatment is generally self-administered in the home without nursing supervision and performed twice daily for 30 minutes. The device shut off automatically at the end of the 30-minute treatment, and unlike TENS and electrical stimulation devices, the treatment is noncontact and does not involve electrodes or administration of direct current. Unlike other pulsed electromagnetic field devices designed for bone stimulation, which operate at very low frequencies (1–300 Hz), the device operates at the Federal Communications Commission designated short-wave frequency of 27.12 MHz. In both cases described here, PRFE therapy was self-administered in the home by placing the treatment applicator over the site of pain for 30 minutes twice a day in accordance with the manufacturer’s instructions. In general, PRFE treatment is imperceptible to the patient.

Following the first week of PRFE therapy, the patient reported less pain with pain medication needs decreased to episodic use at night for severe pain. The patient also began removable cast/walking boot, which he subsequently discontinued because of back pain. The patient progressed to crutches, and over the next month, the pain remained consistent, with oxycodone and acetaminophen required every 6 hours routinely. At 6.5 weeks postsurgery, the patient’s pain remained at a level of 6 out of 10 and still required opioids for relief. PRFE therapy (Proviant Therapy System; Regenesis Biomedical, Scottsdale, Arizona) was initiated for pain. Provant is a portable, noninvasive medical device that delivers PRFE via a spiral antenna placed adjacent to the treatment area (Fig. 2). The device generates pulses that are 42 μs long, 1,000 times per second, creating an electromagnetic field that bathes the treatment area and generates the therapeutic effect. The electromagnetic field has an electrical field strength of 591 V/m and a magnetic field strength of 6.4 A/m at a distance of 5 cm from the treatment applicator. The dosage is preset and self-regulated, to ensure consistent and therapeutic dosing. Therapy can be administered directly through clothing and bandages. Treatment is generally self-administered in the home without nursing supervision and performed twice daily for 30 minutes. The device shut off automatically at the end of the 30-minute treatment, and unlike TENS and electrical stimulation devices, the treatment is noncontact and does not involve electrodes or administration of direct current. Unlike other pulsed electromagnetic field devices designed for bone stimulation, which operate at very low frequencies (1–300 Hz), the device operates at the Federal Communications Commission designated short-wave frequency of 27.12 MHz. In both cases described here, PRFE therapy was self-administered in the home by placing the treatment applicator over the site of pain for 30 minutes twice a day in accordance with the manufacturer’s instructions. In general, PRFE treatment is imperceptible to the patient.

Following the first week of PRFE therapy, the patient reported less pain with pain medication needs decreased to episodic use at night for severe pain. The patient also began
to use compression stockings to decrease edema and lidocaine gel on occasion. With 3 weeks of PRFE, the patient’s pain was almost completely resolved. The patient progressed to wearing sneakers and sandals and continued with physical therapy for balance training, full-weight bearing, and muscle strengthening.

At 6 weeks following initiation of PRFE, the patient used oxycodone and acetaminophen occasionally at night for severe pain and was able to walk some distance before feeling tired. PRFE therapy was discontinued at 7.5 weeks. The patient reported that pain had not returned after 7 months postsurgery.

CASE 2
A 34-year-old male patient presented with a 2.5-year history of left ankle pain and was diagnosed with peroneal tendinopathy with lateral ankle instability. The patient twisted his ankle in a fall resulting in swelling and bruising of the lateral ankle. He underwent physical therapy for 3 months with minimal improvement. After a year of persistent lateral ankle swelling, the patient received a cortisone injection, which provided pain relief for approximately 1 month. Swelling and pain with activity continued. The pain became “shooting,” radiating from his foot to his knee, averaging 3 out of 10, with flares to 6 to 7 out of 10 (Wong-Baker FACES pain scale). He received minimal relief from conventional therapies, which included ibuprofen 3 to 4 times a week, medical massage, ice, warm water, changing shoes, an ankle brace, and weight loss. Radiography indicated marked widening of the lateral aspect of the talotibial joint space under inversion stress consistent with ligamentous injury on the lateral aspect of the ankle. A Brostrom procedure, repair of the anterior talofibular ligament, as well as a peroneal tendon repair, was performed. Postoperatively, the patient was casted and pain management consisted of ibuprofen (600 mg) every 6 hours and 2 tablets of oxycodone (5 mg)/acetaminophen (325 mg) every 6 hours. Relief was inadequate with pain upon standing starting within 5 to 10 minutes. Occasional tingling and burning sensations were noted. Trials of acetaminophen and codeine and gabapentin for neuritic pain were ineffective. Crutches, a removable cast/walking boot, and compression stockings completed the postoperative regimen. By postoperative week 9, the patient was unable to stand more than 10 minutes without pain, tingling, or burning. PRFE therapy was started.

The patient used Provant twice daily for 30 minutes in accordance with the manufacturer’s instructions. Within 2 weeks, the pain was almost completely resolved, requiring only occasional NSAIDs. Opioids were discontinued. The removable cast/walking boot and crutches were continued. Three weeks later, the patient returned to clinic in sneakers and without pain. The patient’s pain had not returned as of 6 months postsurgery.

DISCUSSION
In these 2 cases, PRFE therapy was used for pain relief following surgical intervention for chronic tendinopathy–associated pain that was unresponsive to conventional therapies. In both cases, pain relief occurred within weeks following the initiation of PRFE therapy. Since the therapy was initiated after surgical intervention, it is difficult to determine whether pain relief resulted from PRFE, surgical treatment of the tendinopathy, or the combination. In addition, a common limitation of individual case reports is that treatment outcomes are not compared to a control population and are limited by small sample size.

With that said, the outcomes reported here are in agreement with numerous other clinical studies that report successful postoperative pain relief using PRFE, and there is evidence to suggest that PRFE modulates molecular factors involved in pain signaling, including factors associated with postoperative pain. New in vitro research indicates that PRFE may stimulate the production of endogenous opioids by epithelial keratinocytes, interrupting pain sensation via the endothelin-1 pathway. Elevated levels of mRNA transcripts for endorphins, enkephalins, dynorphins, and endothelin-1 receptors have been identified following the exposure of cultured human keratinocytes to PRFE (J. Moffett, personal communication).

It is interesting to note that many of the molecular factors associated with tendinopathy appear to be modulated by PRFE (Table II). At the molecular level, strain can affect the expression and secretion of various factors by tendon cells, including endogenous opioids and their receptors, which may contribute to pain relief following PRFE therapy.
TGF-β downregulation of MMP-3 and upregulation of MMP-2 were found in Achilles tendinopathy. Stretching-induced secretion of collagen type I by human tendon fibroblasts. Physical modalities have long been used to treat tendinopathy, and modern molecular science is evolving to explain how these 2 cases may lead to an imbalance in the molecular microenvironment of the tendon, shifting from one that is primarily regenerative to a degenerative one. PRFE therapy after conventional treatment options had failed. Experimental evidence suggests overlap between molecular factors modulated by PRFE, and those associated with pain signaling and tendinopathy, providing possible insight into its therapeutic effectiveness. Further study of this promising technology is warranted.

**CONCLUSIONS**

Physical modalities have long been used to treat tendinopathy, and modern molecular science is evolving to explain how physical modalities may help to reduce pain. These 2 cases demonstrate a marked improvement in chronic pain following PRFE therapy after conventional treatment options had failed. Experimental evidence suggests overlap between molecular factors modulated by PRFE, and those associated with pain signaling and tendinopathy, providing possible insight into its therapeutic effectiveness. Further study of this promising technology is warranted.

**ACCREDITMENT**

Dr. Kubat is an independent contract consultant for Regenesis Biomedical and was paid by Regenesis Biomedical during the writing and preparation of this manuscript.

**REFERENCES**

Case Report