Pulsed Radiofrequency Energy for Treatment of Chronic Pain Syndromes

Retrospective case series finds reduced pain scores following PRFE treatments.

Ravi G. Mirpuri, DO
Physical Medicine and Rehabilitation
University of California, Irvine Medical Center
Orange, California

Patricia W. Nance, MD
Physical Medicine and Rehabilitation
University of California, Irvine Medical Center
Orange, California

Pulsed radiofrequency energy (PRFE) has multiple medical applications including pain modulation, wound healing, and bone repair.\(^1\)\(^2\) PRFE refers to a noninvasive, nonthermal method of delivering nonionizing electromagnetic energy to a targeted area with a frequency ranging from 1 to 1000 Hz. The pulsatile delivery, with bursts lasting from 10 µsec to 1 msec, allows for dissipation of heat making this method non-ablative. The FDA has cleared such shortwave diathermy devices for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.\(^3\)\(^4\)

Mechanisms for proposed analgesia include modulating calcium and calmodulin pathways,\(^5\) increasing endogenous opioid precursor mRNA,\(^6\) altering transcription of cytokine and matrix metalloprotease levels,\(^7\) increasing chondrocyte proliferation,\(^8\) and enhancing noradrenergic and serotonergic descending inhibitory pain pathways.\(^9\) However the exact mechanism is still not completely understood at this time.

There are several studies that have demonstrated some effectiveness with PRFE. In a recent meta-analysis of 16 controlled trials, 11 trials with PRFE had positive outcomes and 5 trials with neutral outcomes that were measured across different pain conditions.\(^1\)\(^2\)\(^3\) There were 2 double blind randomized controlled trial that showed PRFE was more effective than sham in shoulder pain and knee osteoarthritis.\(^10\)\(^11\) Additionally other trials and case series have shown PRFE to provide significant pain reduction in chronic back pain, non-specific wrist pain, plantar fasciitis, and postoperative pain.\(^12\)\(^13\)\(^14\)

The role and effectiveness of PRFE in treating various chronic pain conditions is still being defined, and it is unclear if certain conditions fail to respond. Additionally there is very little literature detailing whether treating beyond 4 weeks is beneficial. Our goal for performing this review was to determine whether PRFE was beneficial for chronic pain and if additional benefit occurred with those who received 8 week treatment.

Study Method and Design

The objective of this observational series was to record the effects and duration of PRFE treatment across various pain syndromes. A retrospective analysis was performed via chart review on 40 patients in an outpatient Veteran’s Affairs (VA) Physical Medicine and Rehabilitation Clinic in Long Beach, California. Internal Review Board (IRB) approval was attained through the Southern California Institute for Research and Education before collecting any data. Inclusion criteria comprised of every patient that received PRFE treatment within the principal investigator’s patient population at the VA.

Eligible patients were required to demonstrate chronic pain unrelieved by a recent procedure or injection. Exclusion criteria comprised of any patient who did not take a PRFE device home after the initial office trial. It should be noted that the treating physician did not offer this treatment to anyone with active infection, cancer, or an implantable electronic stimulating device.

Patients prescribed PRFE were first offered an outpatient initial trial of transcutaneous PRFE. A treatment applicator pad was placed directly over the site of maximal pain and a nonionizing, nonthermal carrier frequency energy was emitted at 27.12 MHz for 30 minutes. The pulsed RF (pulsed width 42 µsec, pulse frequency 1 kHz) has a predicted electrical field strength of 591 V/m at 5 cm above the applicator.

After receiving the trial, patients were then instructed to take the PRFE device home to use twice daily for 30 minutes. Patients were then instructed to return to the clinic within 4 weeks to evaluate their pain and activities of daily living (ADL). If the patient’s pain improved but their ADL had not, they had the option to extend their trial for an additional 4 weeks.

The reviewer collected each subject’s medical diagnosis as determined by radiographs, laboratory results, and clinical judgment. Numeric pain scores were also collected via chart review, which included pain before initial trial (initial), 30 minutes after trial (post-trial), 4 weeks, and 8 weeks. This was scored on a numeric rating scale of 0-10 with 0 reflecting no
Numerical pain scores were averaged for each stage of the study (7.9 initial, 5.7 post-trial, 4.6 at 4 weeks, and 3.0 at 8 weeks), which showed consistent reduction of pain over time (Figure 1). Statistical analysis using the Wilcoxon Signed Rank Test for a nonparametric two-tailed test was performed across the 40 patients. Results showed that the post-trial, 4 weeks, and 8 weeks average pain scores were reduced compared to initial pain (P<0.001). Also there was statistical improvement from post-trial to 4 weeks (P<0.006), but there was no statistical change from 4 to 8 weeks. There were 40 patients at the beginning of the study. Dropouts occurred at week 4 (n=36) and week 8 (n=21) for multiple reasons, including early resolution of symptoms, lack of significant relief, noncompliance, and other miscellaneous reasons.

PRFE, pulsed radiofrequency energy

Study Results

Forty subjects met inclusion criteria, and no patient was excluded due to trial failure. Therefore 40 patients completed the initial trial, which was reduced to 36 subjects at 4 weeks and 21 subjects at 8 weeks. Patient dropout occurred for various reasons: pain resolved with treatment, twice daily frequency was inconvenient, insufficient efficacy, and patient inability to access electricity to run device. It is important to note that no subject was reported to discontinue treatment secondary to adverse side effects.

Numeric pain scores were averaged for each stage of the study (7.9 initial, 5.7 post trial, 4.6 at 4 weeks, and 3.0 at 8 weeks), which showed consistent reduction of pain over time (Figure 1). Statistical analysis using the Wilcoxon Signed Rank Test for a nonparametric two-tailed test was performed across the 40 patients. Results showed that the post-trial, 4 weeks, and 8 weeks average pain scores were all statistically reduced compared to initial pain scores (P<0.001). Additionally, there was statistical improvement from post-trial to 4 weeks (P<0.006), which was maintained without further change from 4 weeks to 8 weeks.

The data was analyzed by patient diagnosis. Each of the patients treated had at least one diagnosis and 3 patients met criteria for two diagnoses that explained their pain symptoms (eg, spinal stenosis and lumbar radiculopathy). As a result, the 40 patients had a total of 43 diagnoses after being grouped into the following categories: rotator cuff tear, failed back syndrome, myofascial pain, radiculopathy, spinal stenosis, diabetic neuropathy, knee osteoarthritis, lumbar facet arthritis, ankle osteoarthritis, and postsurgical abdominal pain (Table 1).

Due to the low sample sizes, statistical significance of the diagnoses was not reported to prevent false comparisons. Nevertheless, all 10 diagnoses showed a generalized trend of improvement over time with few exceptions: slight worsening of failed back syndrome from post-trial to 4 weeks, no change in diabetic neuropathy during post-trial to 8 weeks, no change in knee osteoarthritis at 4 and 8 weeks, and some worsening of postsurgical abdominal pain at 8 weeks (Figure 2, page 4). However it should be noted that these exceptions occurred only in diagnoses with low sample sizes of 3 or less, but regardless all diagnoses showed improvement from their initial pain scores.

PRFE Reduces Pain

Although conclusions are limited by the observational nature of this review, the data demonstrates that PRFE was clinically and statistically effective in reducing pain over time for up to 4 weeks. There was no statistically significant further reduction of pain after 4 weeks, but maintenance of analgesia was preserved. It should be noted that only patients who benefited at 4 weeks could be eligible for 8 weeks treatment.

When performing a literature review for the average length of PRFE treatment, there is inconsistent durations ranging from a single session to 6 weeks. In a 6 week study by Foley-Nolan et al, significant improvement in persistent neck pain was seen at both 3 and 6 weeks. In our specific study, we provided no evidence of improvement from PRFE beyond 4 weeks treatment other than maintenance of current levels of analgesia.

Despite the low sample sizes when comparing numeric pain scores based on diagnosis, every patient showed improvement from baseline with PRFE treatment. Therefore we have no recommendation against trialing PRFE for the following conditions: rotator cuff tear, failed back syndrome, myofascial pain, radiculopathy, spinal stenosis, diabetic neuropathy, knee pain.
osteoarthritis, lumbar facet arthritis, ankle osteoarthritis, and postsurgical abdominal pain. Additionally this further evidence that PRFE is effective in treating chronic pain conditions. Future studies should be considered to analyze a larger patient population that received PRFE in order to perform large scale statistical comparisons across diagnoses.

In our review, none of the 40 patients were reported to have a treatment related adverse event. This corresponds with other literature reviews that have not reported any adverse effects related to PRFE. Regardless there still is a general consensus to avoid usage in patients who have the following: implanted leads, cardiac rhythm devices, pregnancy, malignancy, and joints of immature bone development.\textsuperscript{3,17,18}

In our study, patients were required to fail conventional therapies such as physical therapy, corticosteroid injections, orthotics, and pharmacologic treatments. Due to the limited side effect profile, PRFE may be a great alternative for those who failed conventional treatment.

Since PRFE treatment is considered relatively painless and easy to use at home, this approach provides a nonsurgical option for chronic pain management. There still is uncertainty about the duration of analgesia beyond 8 weeks, which we hope to follow in a future study. It would be beneficial for future studies to determine whether PRFE is needed daily like transcutaneous electrical nerve stimulation (TENS) device, or whether it has a long lasting analgesic effect after treatment is discontinued. One study already compared TENS to percutaneous pulsed radio frequency and found no difference in treating shoulder pain, but this approach varies significantly from the PRFE approach.\textsuperscript{19} Thus, it would be beneficial to compare TENS and PRFE in a future study.

### Summary

PRFE treatment is an approach in chronic pain management that may be useful across a variety of diagnoses. In our observational study, patients continued to improve in pain up to 4 weeks, but further studies are needed to determine an appropriate duration of treatment. This nonsurgical approach is considered relatively safe and could be considered in patients who fail conventional therapies. It is also relatively easy to use at home and not reported to have sedating effects like opioids. Our study has several limitations including a relatively low sample size, retrospective analysis, and lack of control comparison. Nonetheless we feel our findings combined with previous literature results suggest that PRFE is an effective option to treat chronic pain.

### Authors’ Bios: Ravi Mipuri, DO, is Chief Resident in Physical Medicine & Rehabilitation at the University

---

**Table 1. Analysis of Diagnosis and Average Numeric Pain Scores During Each Stage of Trial**

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Initial NPS</th>
<th>Post-Trial NPS</th>
<th>4-weeks NPS</th>
<th>8-weeks NPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotator Cuff Tear</td>
<td>9 (n=7)</td>
<td>6.7 (n=7)</td>
<td>5.7 (n=5)</td>
<td>2.8 (n=3)</td>
</tr>
<tr>
<td>Failed Back Syndrome</td>
<td>9 (n=2)</td>
<td>7.5 (n=2)</td>
<td>7.8 (n=2)</td>
<td>3.5 (n=1)</td>
</tr>
<tr>
<td>Myofascial</td>
<td>7.8 (n=6)</td>
<td>5.7 (n=6)</td>
<td>4.5 (n=6)</td>
<td>3.7 (n=3)</td>
</tr>
<tr>
<td>Radiculopathy</td>
<td>7.6 (n=11)</td>
<td>5.3 (n=11)</td>
<td>5.0 (n=11)</td>
<td>2.2 (n=5)</td>
</tr>
<tr>
<td>Spinal Stenosis</td>
<td>7.9 (n=6)</td>
<td>6.6 (n=6)</td>
<td>5.0 (n=5)</td>
<td>4.0 (n=2)</td>
</tr>
<tr>
<td>Diabetic Neuropathy</td>
<td>7.0 (n=1)</td>
<td>5.0 (n=1)</td>
<td>5.0 (n=1)</td>
<td>5.0 (n=1)</td>
</tr>
<tr>
<td>Knee Osteoarthritis</td>
<td>8.0 (n=3)</td>
<td>6.3 (n=3)</td>
<td>4.3 (n=2)</td>
<td>4.3 (n=2)</td>
</tr>
<tr>
<td>Lumbar Facet Arthritis</td>
<td>8.3 (n=4)</td>
<td>6.1 (n=4)</td>
<td>4.5 (n=4)</td>
<td>4.0 (n=2)</td>
</tr>
<tr>
<td>Ankle Osteoarthritis</td>
<td>7.0 (n=2)</td>
<td>3.8 (n=2)</td>
<td>2.0 (n=2)</td>
<td>1.3 (n=2)</td>
</tr>
<tr>
<td>Postsurgical Abdominal Pain</td>
<td>6.0 (n=1)</td>
<td>3.0 (n=1)</td>
<td>0.0 (n=1)</td>
<td>2.5 (n=1)</td>
</tr>
<tr>
<td>Total # of Subject Diagnoses</td>
<td>n=43</td>
<td>n=43</td>
<td>n=39</td>
<td>n=22</td>
</tr>
</tbody>
</table>

n, number of diagnoses during each stage of the experiment; NPS, numeric pain score

Note: The number of diagnoses may be more than the number of patients in the study; some patients had more than one pain diagnosis.
of California, Irvine. He received his Doctorate in Osteopathy from Lake Erie College of Osteopathic Medicine in 2011. Patricia W. Nance, MD, is currently Chief of Rehabilitation Services at the VA Long Beach Healthcare System and a Clinical Professor in the Department of Physical Medicine & Rehabilitation at the University of California, Irvine. She received medical degree from the South Florida University in Tampa in 1980. She completed her postgraduate medical training and residency in Physical Medicine & Rehabilitation at Dalhousie University, in 1984. Her research interests have included neurophysiology (spinal and cortical evoked potentials and physiological quantification of spasticity), neuropharmacology (particularly involving the management of spasticity), chronic pain, and gait enhancement strategies.

The authors have disclosed that they have no competing interests. There are no personal or financial disclosures to report in the context of this study.

Acknowledgements

The authors would like to acknowledge both Departments of PM&R at the University of California, Irvine and Long Beach VA Healthcare system in allowing physician resources to be used in developing this study. IRB approval was attained through the Southern California Institute for Research and Education (Project #1301).

References