Case Report on Chronic Shoulder Pain and Response to Peripheral Nerve Stimulation Twenty-Four Months After Placement

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Background:	Effects of chronic shoulder pain are suffered by millions each year. What options are there for patients who were nonresponsive to conservative treatments and are deemed nonsurgical candidates?
Case Report:	We present an 82-year-old woman with chronic left shoulder pain secondary to rotator cuff injury. She was nonresponsive to attempts at conservative treatment and pharmacotherapy and was not deemed a surgical candidate. The patient underwent peripheral nerve stimulator (PNS) placement targeting supra- scapular and axillary nerves. She participated in a survey 24 months post-PNS placement that evaluated her chronic pain and response to PNS and reported an 80% reduction in pain.
Conclusions:	This case illustrates positive short-term reduction in overall chronic shoulder pain after PNS placement, but also highlights the effects of the PNS device 24 months after stimulator placement. As this is just one case highlighted, continued validated research is needed to further support use of PNS devices in this patient population.
Key words:	Peripheral, nerve, stimulator, shoulder, pain, chronic, relief

BACKGROUND

Millions of people each year suffer from chronic shoulder pain, with the number one cause being rotator cuff pathology. When surveying the general population, rotator cuff tear prevalence exceeds 20% and this increases with age (3). There are many studies (1,2) citing evidence showing no appreciable differences in conservative treatment vs surgical treatment. In one study (5), a 10-year follow-up after surgery was most favorable, but the measured difference seen was not clinically significant. In the same meta-analysis, data for other endpoints, such as range of motion, muscle strength, and quality of life, were extremely limited and the group differences were slight between the surgical vs nonsurgical groups (5). Most sources (1) note that conservative treatment is less expensive and offers fewer complications, so this should be advocated as the initial treatment modality. Traditional conservative treatment encompasses physical/occupational therapy, pain management with pharmacotherapy, and steroid injections to the joint or surrounding areas (4). Depending on the age of patients, some treatments could be contraindicated given the side effects of many classes of pain pharmacotherapy, including sedation, confusion, and constipation, which can put patients at a higher risk for falls and could prevent them from the ability to safely perform their activities of daily living (ADLs). This is ironically what pain control is trying to improve, not

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prevent. What options are there for patients who were nonresponsive to multiple conservative treatments and are deemed nonsurgical candidates? Peripheral nerve stimulator (PNS) placement has been shown to be an excellent treatment option for this patient population in recent literature (6). Where the gap in knowledge lies, is addressing long-term outcomes for pain relief with PNS. This case report evaluates an 82-year-old woman who met the above criteria and elected to undergo PNS placement to decrease her shoulder pain and was subsequently evaluated 24 months post-PNS placement for long-term pain relief.

CASE REPORT

The patient is an 82-year-old woman who presented to the Pain Clinic, in September 2020, with a history of C1-C6 fracture status post-C1-C6 fusion (April 2018) along with hypertension, osteoarthritis, and congestive heart failure. She had left arm pain since 2018 and left shoulder pain since 2020. She described burning dull aches in the left shoulder radiating down her medial arm into the dorsum of her hand, but the patient was unable to describe which fingers in her hand were affected. The patient reported a pins and needles sensation in the same distribution. The pain was exacerbated by movement, especially abduction of the left shoulder. Her initial exam was notable for deficits in abduction secondary to pain, Hawkins' and Jobe's tests positive, and negative for Speed's, Hornblower's, and Apprehension tests. The patient had prior magnetic resonance imaging of the left shoulder, in 2020, confirming full thickness tear of the supraspinatus tendon, fraying of the infraspinatus and teres minor, thinning of the glenohumeral cartilage, and degenerative disease of the acromioclavicular joint with subacromial spurs. Prior to evaluation at the Pain Clinic, she had trialed 3 weeks of physical therapy, and several weeks of multiple medications, including gabapentin, Tylenol, ibuprofen, and topical agents, none of which provided relief to her left shoulder or arm pain. She was switched from gabapentin to Lyrica given neuropathic symptoms and poor response to gabapentin, given a prescription for tizanidine, and was sent for electromyography (EMG) of the left upper extremity which showed left C7 radiculopathy. Given the EMG results, the patient elected for a C7-T1 interlaminar cervical epidural spinal injection (CESI) which was performed in January 2021. At her next follow-up appointment, she reported 90% relief in pain in her left arm after the CESI lasting only for a few days. She also felt that tizanidine was not helpful, so this was discontinued, and baclofen was started at 5 mg at night; at this time, the patient had reached the maximum dose of Lyrica at 75 mg twice daily given her diminished kidney function. A repeat CESI was performed at C7-T1, in March 2021, which provided 90% relief in her left arm pain for 3 weeks. At the next appointment in April 2021, she reported her arm pain had vastly improved with the CESIs, but her left shoulder pain was persistent. She visited multiple surgeons for repair of her rotator cuff, but all had recommended against surgery given her age and medical comorbidities. A discussion between the patient and the pain management physician was held about PNS to improve her left shoulder pain, and the patient agreed to proceed given poor response to physical therapy and pharmacotherapies. She was scheduled for PNS placement at the end of May 2021, and meanwhile, she underwent a third CESI at C7-T1 for her left arm pain, which she reported continued significant relief from.

On May 26, 2021, the patient underwent PNS placement using a SPRINT extensa® dual-lead system (SPR Therapeutics, Cleveland, OH) (11) with 2 separate leads targeting the left suprascapular and axillary nerves. To identify the suprascapular nerve, an ultrasound transducer was placed over the suprascapular spine with a slight anterior tilt. The suprascapular nerve was identified between the suprascapular notch and the spinoglenoid notch. The stimulating probe lead introduction system was then inserted in-plane from the medial side of the transducer and advanced laterally and advanced along the peripheral nerve. Electrical parameter combinations were tested, and the lead location was adjusted until the patient indicated paresthesia overlapping the distribution of pain. The final location was verified with electrical stimulation. The introducer needle was removed, and the exposed end of the percutaneous lead was attached to an external stimulator unit. This procedure was then repeated on the left axillary nerve. Approximately 8 weeks later, the patient had both the left suprascapular and axillary nerve leads removed with intact tips. At that 8-week follow-up appointment, the patient stated her left shoulder pain had been reduced from severe to mild pain.

At 2 years post-PNS placement and after receiving ethical institutional review board approval, the patient was contacted via telephone, and verbal consent was given by the patient to conduct a unique 21-question survey to gather information about her experience with the PNS placement and pain response. Prior to the PNS placement, the patient reported her left shoulder pain moderately impacted her ability to perform her ADLs; specifically, she had limitations in quality of sleep due to shoulder pain, deficits in combing her own hair, lifting items over 8 lbs (e.g., gallon of milk), and reaching above shoulder height to grab objects. She also reported a significant impedance in the range of motion of her left shoulder due to pain prior to PNS placement and rated her daily pain pre-PNS at an 8 on the Numeric Rating Scale (NRS-11). After PNS placement, she reported mild limitations in her ADLs and range of motion of her left shoulder stating that she was now able to do almost everything she wanted to do on a day-to-day basis, and thus keeping her independence. She was asked to rate her pain post-PNS placement at 2 months, 6 months, 12 months, 18 months, and 24 months on the day she was surveyed. Her pain gradually improved over time from a 5 out of 10 at 2 months post-PNS placement to a 2 out of 10 at 24 months post-PNS placement (Fig. 1). This was an 80% overall decrease in her pain from pre-PNS placement to 24 months after. The patient reported no complications with PNS placement and removal. She also stated she would recommend PNS placement for others suffering from chronic shoulder pain.

DISCUSSION

In general, PNS systems allow for noninvasive treatment of chronic pain with peripheral nerve origin. The SPRINT® PNS system, itself, has many benefits, including the patient's ability to maintain ADLs with minimal restrictions given the temporary nature of the device compared to other systems which are permanent. The system consists of one or two leads inserted percutaneously with an external pulse generator delivering continuous therapy with a rechargeable battery pack, a mounting pad holding the pulse generator, and a handheld remote for stimulation level control. This design allows for patients to control the intensity level of stimulation provided by the system during the treatment period. The ability to utilize ultrasonography for visualization of key targets during PNS placement allows for accurate and safe placement of the leads while reducing the risk of infection compared to open procedures (10). The most common side effects of the procedure include skin irritation, pain in the targeted area, lead migration, and rare infection in 1% to 2% of cases (11).

The mechanism of action of PNSs is based upon the gate control theory proposed by Melzack and Wall, in 1965, which outlines stimulation of nonnociceptive $A\beta$ fibers to excite inhibitory neurons in the dorsal horn

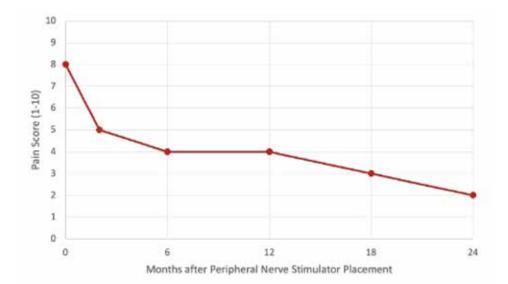


Fig. 1. Pain score on scale of 1-10 using the NRS-11 (y-axis) plotted against months after PNS placement. Overall, there was an 80% decrease in daily pain score from pre-PNS placement to 24 months post-PNS placement. NRS-11, numeric rating scale; PNS, peripheral nerve stimulator.

to stop pain signal transmission from the spinal cord to the brain (13). More recent studies have theories on the peripheral and central mechanism of action of PNS (7,13). At the peripheral level, one study (13) showed the analgesic effect occurred when stimulation was applied above the threshold of perception, but below that of pain. At the molecular level, the stimulation downgrades neurotransmitters and local inflammatory mediators (13). Centrally, analgesia with PNS has been linked to serotonergic, GABAergic, and glycinergic pathways (13). It can decrease central sensitization and hyperalgesia by decreasing activity of peripheral nociceptors in the spinal cord resulting in reduced $A\beta$ fiber activity in the medial lemniscal pathway within the brain (13). The low-frequency/high-intensity pulsations with PNS also inhibit spinothalamic tracts (13).

As PNS has grown in popularity in recent years, there have been numerous research studies validating its use in patients with acute and chronic shoulder pain. A study by Mansfield et al (7), in 2020, followed 8 patients for an average of 445 days who suffered from chronic shoulder pain but were not surgical candidates. They not only showed a significant reduction in pain scores, but secondarily gave evidence that PNS can reduce opioid use as patients that had used opioids prior to PNS placement reported an overall 88% reduction in opioid use after placement (7).

Another study by Wilson et al (8) looked at patients with shoulder impingement syndrome and their response to PNS. They again showed significant improvement in daily pain scores, as well as shoulder range of motion and disability, but this study was limited to only a 12-week follow-up (8). Many of the articles published on PNS placement for chronic shoulder pain, regardless of etiology of the pain generator, have followed patients on average for 12 weeks (6,8,9); with one anomaly study (7) following patients for 445 days. The study presented in this article is the first to follow a patient to the 24-month mark and evaluate their response in terms of pain relief, as well as ADL restrictions.

The continued reduction in pain scores illustrated in this case could be explained by taking advantage of cortical neuroplasticity by utilizing nonnoxious stimulation to reverse cortical contribution to chronic pain, thus leading to long-lasting relief after PNS (12).

CONCLUSIONS

This case illustrates not only a positive short-term reduction in overall chronic shoulder pain after PNS placement, but also highlights the effects of the PNS device 24 months after the stimulator was placed. This study continues to add to the current literature to support PNS placement in the treatment of chronic shoulder pain in patients who who were nonresponsive to other treatments and are not surgical candidates. As this is just one case highlighted, continued validated research is needed to further support use of PNS devices in this patient population, as well as to assess long-term outcomes. Following patients over longer periods of time, tracking long-term response to pain with the NRS-11, and utilizing the Disabilities of Arm, Shoulder, and Hand questionnaire would provide beneficial data for both patients and providers moving forward in the treatment of chronic shoulder pain.

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