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Peripheral Nerve Stimulation With a High Frequency Electromagnetic Coupled Powered Implanted Receiver at the Axillary Nerve for the Treatment of Chronic Shoulder Pain: Case Report

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Background: The axillary nerve is one of the most common peripheral nerve of the shoulder to be injured. If a patient does not desire invasive surgical intervention, then other options, such as neurostimulation, should be explored. Until recently, there were no specific devices for peripheral nerve stimulation (PNS), and the hardware for spinal cord stimulation was used, but these systems were powered by an implantable battery, which can be difficult to use for PNS. Externally powered systems are the ideal technology to target peripheral nerves.

Case Report: A 67-year-old man presented with chronic right shoulder pain after multiple surgeries following a fracture. It was determined that the patient would not likely benefit from any further surgical interventions, and thus the patient was referred to pain management for further evaluation. The decision was made to trial the patient for PNS of the right axillary nerve.

Results: The patient reported drastically reduced pain (pain reduction of approximately 90% at 6-month follow-up). Activities of daily living, quality of life, sleep, and range of motion were also all improved at 6 months after the permanent implant procedure.

Conclusions: Subthreshold, externally powered PNS at the axillary nerve was a successful choice for a patient suffering from chronic shoulder pain after multiple surgical interventions.

Key words: Peripheral nerve stimulation, shoulder pain, axillary nerve, externally powered stimulation

BACKGROUND

The axillary nerve is a commonly injured nerve to be injured, affecting the shoulder and is most often seen after glenohumeral joint dislocation, proximal humerus fracture, or a direct blow to the deltoid muscle. The axillary nerve is vulnerable to trauma and/or surgical repair. If axillary nerve recovery has not occurred within 6 months following injury then further surgical options should be considered (1). However, if the patient's pain persists after additional surgery or if the patient does not desire further invasive surgical intervention, then other options can be explored.

Spinal cord stimulation (SCS) is a well-recognized treatment for chronic pain. For regional pain disorders, such as chronic shoulder or knee pain, a more targeted approach is required to effectively treat these discrete structures (2).

Peripheral nerve stimulation (PNS) has been used

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to target local pain. Interestingly, the hardware most frequently used is designed for SCS and includes an implanted battery. This explains why the complication rate associated with PNS is quite high, since invasive surgery is required (3) with cosmetic concerns and pocket pain.

New externally powered PNS technology does not include an implantable battery, but instead consists of an electrode array, a separate receiver, and a small, externally worn rechargeable transmitter. As such, the potential complications related to the implant of a battery, which can be up to 40% (3,4), are potentially avoided.

CASE PRESENTATION

A 67-year-old man presented to the Orthopedic Center of Florida for a second opinion in regards to chronic right shoulder pain. The patient had a history of a right proximal humerus fracture and underwent emergent open reduction and internal fixation in 2016 and, subsequently, a hemiarthroplasty in 2019. He presented with chronic, intractable right shoulder pain and was initially seen by the orthopedic shoulder specialist for an additional opinion after consulting with multiple prior orthopedic surgeons. It was deemed that the patient would not likely benefit from any further surgical interventions, and thus the patient was referred to pain management for further evaluation. Patient underwent both diagnostic and therapeutic suprascapular and axillary nerve blocks in different treatment sessions with the initial goal of achieving more than 3 months of pain relief with the combined local anesthetic and corticosteroid nerve blockade. The patient reported significant relief, but only during the local anesthetic duration. Subsequently, a diagnostic local anesthetic-only injection was performed, blocking the suprascapular nerve with 60% pain relief and then the axillary nerve with 90% pain relief. Based on these results, the decision was made to trial the patient for PNS of the right axillary nerve. The trial procedure was performed in the office in a prone position using ultrasound guidance. The stimulator was placed and secured in a sterile fashion and the patient was sent home for a 5-day trial period. At the conclusion of the trial, the patient reported 90% relief of his right shoulder pain. The electrode was subsequently removed in the office without any complications. Approximately 3 weeks later, the patient was brought to an ambulatory surgical center for permanent implantation of the device without any complications (see Procedure Methods). Three days after the implantation, the patient reported 90% to 100% relief of his shoulder pain. In addition, the patient reported improvement in his right-sided axial neck pain. Three months postoperatively, the patient reported continued relief. He reported initially using the device 12-16 hours per day, but by 3 months postoperatively, the patient was using the device on an "as-needed" basis, occasionally with no need for an entire 24-hour interval.

Device Description

The Freedom PNS System (Curonix, distributor of Freedom PNS Systems, Pompano Beach, FL) uses high frequency electromagnetic coupling technology to power the implanted neurostimulator (Fig. 1). Each stimulator is comprised of an electrode array(s) with 4 or 8 contacts and the electrode array is connected to a separate receiver(s). A small, external rechargeable transmitter supplies the energy and data to the implanted neurostimulator through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Procedure Method

The patient was positioned in a prone position with arms at his sides and secured to the table. All pressure points were padded and the patient confirmed being comfortable prior to any anesthesia being performed. Prior to the start of the procedure, a surgical time-out was performed to confirm the correct patient, surgical site, and procedure. Before the surgical start, the patient received intravenous antibiotics as per the anesthesia record and was sterilely cleaned, draped, and appropriate drying time was performed in order to minimize any fire risk. Following this preparation, an ultrasound probe was sterilely covered and brought into the field and the axillary nerve was identified within the neurovascular bundle, including the circumflex artery. Next, the device package containing the electrode array was unpackaged and kept in the sterile field. The electrode array was laid on the skin with the distal tip of the device placed at the right axillary nerve. Measurements were made to plan the surgical approach. Monitored anesthesia care was used with light sedation upon patient's request with 1% lidocaine to infiltrate the skin and the subcutaneous tissues, including the triceps muscle. Additional anesthetic was injected consisting of 0.5% Marcaine mixed with 1% lidocaine and epinephrine 1:200,000 in order

to ensure prolonged analgesia after the procedure. At the initial skin infiltration site, a #15 blade was used to make a first-stab incision. A Coudé needle was advanced under live ultrasound guidance and placed approximately 0.25 cm above the circumflex artery and the axillary nerve. Next, the stylet was removed from the needle and the tined, 4-contact electrode array was inserted through the Coudé needle under live ultrasound. Visualization with ultrasound confirmed the electrode placement approximately 0.2 cm above the circumflex artery (Fig. 2). The needle and steering stylet were removed, and the receiver was connected to the electrode array. No sensory testing was performed during the procedure as anatomic landmarks were used to confirm placement.

A secondary pocket for the receiver was made using a second incision with a #15 blade and blunt dissection. When the pocket was confirmed to be of adequate size and appropriate hemostasis was achieved, the neurostimulator was tunneled from the initial incision to the receiver pocket. A knot was tied to permanently connect the separate receiver and electrode array. The distal portion of the neurostimulator was coiled, sutured to itself while eliminating any sharp ends, and then the coil sutured to the fascia within the pocket to prevent migration. After thorough irrigation and good hemostasis, the skin was closed using Dermabond (Ethicon, Somerville, NJ) only. The patient wears the transmitter and antenna on the right upper arm over the receiver. Preferred stimulation settings were discovered at 1 kHz and 2.0 mA.

RESULTS

Before the procedure, the patient presented with pain scores of 9/10 with restricted range of motion. The patient reported using pain medication, such as tramadol, Cymbalta, and oxycodone, on a daily base. Quality of sleep was heavily impacted by the pain and stiffness. Shortly after the procedure, the patient reported approximately 90% reduction in pain with improved activity, quality of life, sleep, and range of motion. Medication usage has reduced to being taken only when needed. These results remain consistent to this day, 6 months after the permanent procedure. The patient describes wearing the device for < 4 hours per day, only when needed for pain relief. No adverse events were reported.

DISCUSSION

Fig. 1. Freedom SCS/PNS systems.
SCS, spinal cord stimulation; PNS, peripheral nerve stimulation.

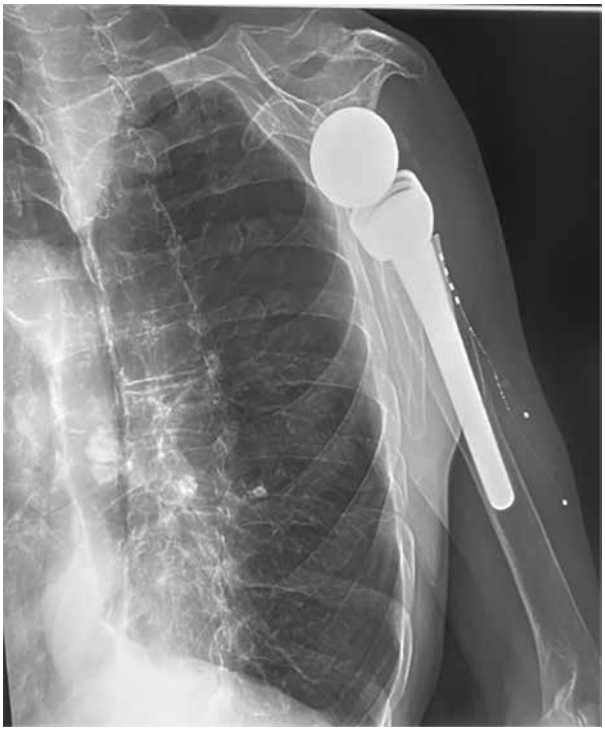

Fig. 2. AP of device placement.
AP, anteroposterior.

Chronic shoulder pain is a difficult pathology to treat with conventional neuromodulation technologies. Due to the nature of these devices with an implanted battery, cosmetic concerns and multiple types of complications, such as infection, dislodgement, and pocket pain, are typically associated with this treatment (4). The anatomical structure of the shoulder is such that PNS with implanted battery-dependent technologies should be discouraged.

Instead, externally powered systems should be con-

sidered for the treatment of chronic pain in difficult to reach structures, such as the shoulder. Externally powered technology is less invasive, more cosmetically pleasing, and has a smaller footprint, making these devices the appropriate choice for PNS.

CONCLUSIONS

Subthreshold, externally powered PNS at the axillary nerve was a successful choice for a patient suffering from chronic shoulder pain after multiple surgical interventions. This case report suggests that effective treatment is possible with only a few hours of therapy per day. As opposed to implanted battery systems, patients do not have to worry about the bulk of the system on a continuous basis as the external wearable antenna assembly can be removed at any time.

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