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Subthreshold Peripheral Nerve Stimulation with a High Frequency Electro-Magnetic Couple Powered Implanted Receiver for the Treatment of Chronic Shoulder Pain

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Background: Shoulder pain has an estimated population prevalence of up to 26%. The most common source of shoulder pain is the rotator cuff, which is a group of muscles and tendons that surround the shoulder joint, accounting for over two-thirds of cases.

Case Report: A 65-year-old man presented with sharp, localized pain on abduction of the left shoulder due to a left rotator cuff tear. A diagnostic nerve block provided 100% short-term pain relief. Subsequently a peripheral nerve stimulator trial was offered to the patient, which was successful. The permanent peripheral nerve stimulator was implanted at the supraspinous fossa with the middle electrodes at the suprascapular notch. A receiver was inserted into the inner lumen of electrode array and the neurostimulator was coiled and fixated to the fascia. The following stimulation settings were used: frequency at 1.5 kHz, pulse width at 30 µs, and amplitude of 3.5 mA.

Conclusion: At one year after implant, the patient had close to 100% pain relief and reported excellent mobility of the shoulder. Wirelessly powered peripheral nerve simulation was a successful option for this patient suffering from debilitating left shoulder pain due to a left rotator cuff tear.

Key words: Chronic shoulder pain, glenohumeral osteoarthritis, peripheral nerve stimulator, suprascapular neuralgia

BACKGROUND

Shoulder pain has an estimated population prevalence of 4% to 26%. About 1% of adults aged over 45 years in the United Kingdom consult their general practitioner with shoulder pain every year. The most common source of shoulder pain is the rotator cuff, accounting for over two-thirds of cases (1). Other sources of shoulder pain are avascular necrosis, brachial plexus injury, broken arm or collarbone, bursitis, cervical radiculopathy, dislocated shoulder, frozen shoulder, impingement, osteoarthritis, polymyalgia rheumatica, rheumatoid arthritis, rotator cuff injury, separated shoulder, septic arthritis, sprains, tendinitis or tendon rupture, and torn cartilage, among others.

Neurostimulation has been used effectively for the treatment of pain syndromes of multiple etiologies (2-4). A 4- or 8-contact peripheral nerve stimulator (PNS) can be implanted percutaneously in the targeted area using an introducer, and a small, external transmitter worn over the patient's clothing provides the stimulation parameters and energy to power the neurostimulator through high frequency electromagnetic coupling (HF-EMC). The Stimwave Technologies device is based on the principle of powering microelectronic devices with radiative electric field coupling through tissues at microwave frequencies (GHz) rather than the more commonly used lower frequencies (100-500 kHz) of the inductive range of frequencies, which is the electromagnetic field approach typical of most implanted medical devices.

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The implantation of an implantable pulse generator (IPG) and the tunneling of the extensions required for traditional neurostimulation are not necessary.

Therefore, externally powered peripheral nerve stimulation therapy offers a minimum invasive system that can be used to target difficult anatomical areas with fewer potential complications; this benefits both the patient and the physician.

CASE

The patient is a 65-year-old man who presented with sharp, localized pain on abduction of the right shoulder, which he had experienced since 2011. Several right shoulder intraarticular (IA) steroid injections were done through the years, but these never provided significant or longer-lasting pain relief.

A right rotator cuff repair was done in 2015, and he reinjured his right shoulder a few months later and didn't want to consider shoulder surgery again.

The patient developed left shoulder joint pain in 2015, and in March 2016, bilateral shoulder injections of stem cells were performed. Eight weeks later he noticed less pain by 30% and improved range of motion, close to 100% in the left shoulder joint and 70% in the right shoulder. Subsequently, bilateral shoulder IA steroid injections were done in June 2016.

In September 2016, after a bilateral IA shoulder joint injection of stem cells, the patient reported that his left shoulder pain and range of motion had improved by 80% or better compared to the original condition prior to the injection. His right shoulder had no resting pain, and his range of motion had notably improved and was close to normal, but he had severe pain with sudden motions.

In January 2017 (and without a triggering event), his left shoulder became the predominant pain location. The pain was not a classic neuropathic pain since it was not burning and there was an underlying low rate of exacerbation with physical activity.

A computed tomography (CT)-guided arthrogram in May 2017 revealed a full-thickness tear of the supraspinatus muscle, degenerative tearing of the inferior and superior labrum, degenerative hypertrophy of the acromioclavicular (AC) joint, and mild-to-moderate glenohumeral (GH) joint degenerative arthritis. Several left IA shoulder steroid injections through 2017 and 2018 were repeated but brought no significant long-term improvement.

On November 14, 2018, a left suprascapular nerve block was performed, and 100% pain relief was obtained that lasted about 6 hours. Based on the clinical results, it was decided to implant a left suprascapular PNS.

Device Description

The Stimwave Technologies Freedom PNS System (Stimwave Technologies Incorporated, Pompano Beach, FL) uses high frequency electromagnetic coupling. The Stimwave Technologies device is based on the principle of powering microelectronic devices with radiative electric field coupling through tissues at microwave frequencies (GHz) rather than the more commonly used lower frequencies (100-500 kHz) of the inductive range of frequencies, which is the electromagnetic field approach typical of most implanted medical devices.

Microwave-based neurostimulation uses an electrodearray with embedded electronics and a receiver that intercepts high-frequency microwave electromagnetic fields, producing an oscillating electric field across the receiver to drive a current flow.

Procedure

Trial Procedure: On January 2019, a suprascapular 8-contact peripheral nerve stimulator was trialed (Fig. 1), and the pain went from a Visual Analog Scale (VAS) score of 3 to 7 out of 10 to 100% relief within 48 hours post implant. The stimulation settings were as follows: frequency of 1.5 Hz, pulse width of 30 μs, and amplitude of 3 mA. The patient's pain was successfully treated with these settings. The patient was satisfied with the results of the trial and opted for a permanent implant.

Permanent Implant: After informed consent was obtained, the patient was taken to the operating room and placed in the prone position on the fluoroscopy table. Standard America Society of Anesthesiology monitors were applied. A 22-g intravenous catheter was placed and 2 g of cefazolin was administered intravenously in the preoperative area.

A 4-contact electrode array with tines was laid on the prepped skin and the distal electrode at the tip of the device was placed at the proximal anatomical (osseous) location where the suprascapular nerve was identified by fluoroscopy. Using a skin marker, a one-cm sagittal line was marked over the needle entry location proximally. The skin and deeper tissues were anesthetized using a mixture of 1% lidocaine with epinephrine and 0.5% bupivacaine. Using a #11 blade, an incision was made with a scalpel to allow insertion of the introducer, which was passed through the sub-

cutaneous tissues toward the desired nerve target. The introducer was placed at a shallow angle (no more than 10 degrees) and advanced using a "tenting" approach to stay within the subcutaneous layer and to prevent diving into the muscular fascia. The electrode array was inserted through the introducer and advanced towards the target nerve under fluoroscopic guidance. At this point, the skin was infiltrated with local anesthetic and a one-inch incision was made to create a receiver pocket, about 10 cm medial to the electrode array entry-site incision. After thorough irrigation with an antibiotic solution, good hemostasis was achieved. The needle was passed subcutaneously and directed from the receiver pocket to the electrode array entry site. The proximal end of the electrode array was threaded through the distal tip of the needle to the subcutaneous receiver pocket. After withdrawal of the needle, the receiver was inserted into the inner lumen of the electrode array and intraoperative testing was completed with an external transmitter. Good paresthesia coverage of the painful areas was obtained. A knot was tied in the electrode array containing the receiver and the remaining end of the neurostimulator was coiled, sutured to itself to eliminate any sharp ends, secured to the fascia with fixation suture, and the pocket closed using 4-0 Monocryl. The patient was taken to the recovery room area, where several stimulation settings were tested and established. The stimulator was activated using multiple electrode settings and a good pain coverage pattern was obtained. The patient tolerated the procedure well and was observed for an adequate period. He was discharged home in stable conditions with the following stimulation settings: frequency at 1.5 Hz, pulse width at 30 μs. and amplitude of 3.5 mA.

The patient wears the antenna between the scapula and the spine and the transmitter in the pocket of his pants.

RESULTS

In June 2019, the patient answered the EQ-5D-5L Quality of Life questionnaire and reported excellent mobility of the shoulder, no problems with self-care or usual activities, no pain or discomfort, and no anxiety or depression. He scaled his health as related to the shoulder as 95% (100% best, 0% worst). He also reported the Patient Global Impression of Change as "a great deal better" and a "considerable improvement that has made all the difference."

The Oswestry Disability Index (ODI) 6 weeks post surgery was 4% (0% = no disability, 100% = bed ridden).

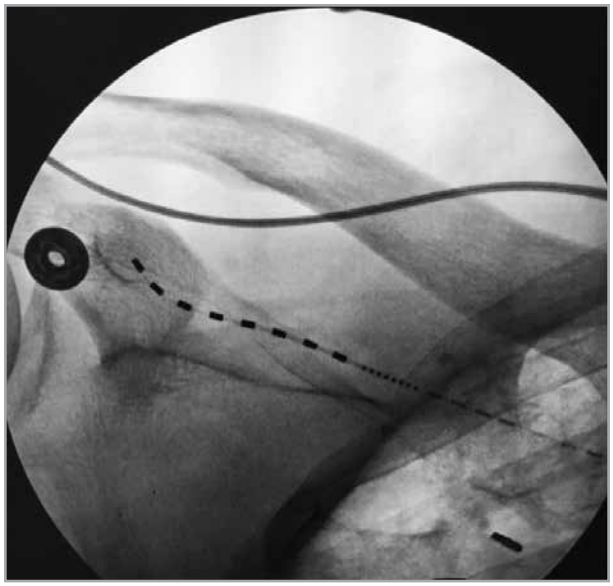

Fig. 1. Anteroposterior view of trial device placement.

Table 1. Medications and doses.

Medication	Daily Dose
Before and during trial	
MSER	15 mg 3 times per day
MSIR	30 mg 4 times per day
After permanent implant	
MSER	15 mg 2 times per day
MSIR	30 mg 3 times per day

Abbreviations: MSER, morphine sulfate extended release; MSIR, morphine sulfate immediate release

As of June 2020, the patient still had close to 100% pain relief, and was able to decrease his medication intake of morphine sulfate extended release 15 mg from 3 times a day to 2 times a day and morphine immediate release 30 mg from 4 times a day to 3 times a day (Table 1).

Unfortunately, since the patient has other sources of pain, no further pain medication reductions have been possible.

DISCUSSION

The anatomical conditions of the area are such that the implant of a conventional system's lead with an IPG would have been literally impossible. In general, PNS is difficult with conventional devices that require not only an IPG but also extensions to the site where the IPG is implanted. With an externally powered

system, these drawbacks are avoided and the implant of a single stimulator with the corresponding antenna, both smaller than conventional systems, enable neurostimulation in areas where conventional systems cannot be used (5,6).

Though the permanent system was a 4-contact neurostimulator, the trial was done with an 8-contact system. This strategy enables the testing during the trial period of multiple combinations with a broader area of coverage. Once the optimal contacts are found and the optimal area for stimulation is determined, a 4-contact stimulator with tines can be used which is smaller.

CONCLUSION

PNS was a successful option for this patient suffering from debilitating left shoulder pain due to a left rotary cuff tear of the supraspinatus muscle.

Externally powered neurostimulation systems allows PNS in difficult-to-access sites, and the procedure is much more straightforward for the physician since he/she does not have to consider how and where the extensions connecting the stimulation lead to the IPG could be tunneled.

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