CLINICAL REPORT

High-Frequency Supraorbital Nerve Stimulation With a Novel Wireless Minimally Invasive Device for Post-Traumatic Neuralgia: A Case Report

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Abstract

Background: Post-traumatic neuropathic pain in the head and face is a condition that is often refractory to medical management. Peripheral nerve stimulation (PNS) can be an effective treatment. Successful implantation of a novel minimally invasive wireless device is reported here.

Objective: To assess analgesic effects of a minimally invasive wireless PNS device in the treatment of post-traumatic supraorbital neuralgia (SON).

Case Summary: The patient presented with SON following multiple post-traumatic cranioplasty surgeries, which were complicated by infections. Medical and interventional management failed, and the patient reported a numeric rating scale (NRS) pain score of 8 out of 10. Two octopolar implantable neural stimulators (INSs) (StimRelieve LLC, Pompano Beach, FL, U.S.A.) were implanted with a minimally invasive, percutaneous technique to stimulate the supraorbital nerves. Stimulation parameters were set at a frequency of 10 kHz and a pulse width of 30 microseconds.

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Submitted: June 25, 2018; Revised November 1, 2018; Revision accepted: November 7, 2018 DOI. 10.1111/papr.12747

© 2018 World Institute of Pain, 1530-7085/18/\$15.00 Pain Practice, Volume ••, Issue •, 2018 ••-• *Results:* At 12- and 24-month follow-up evaluations, the patient's NRS score was only 2 out of 10, and the patient occasionally required 1 g of paracetamol to control the pain. Stimulation was reported to be paresthesia free. There were no adverse events related to the procedure or the treatment until today.

Conclusions: High-frequency stimulation with an external pulse generator and minimally invasive, percutaneous, and bilateral placement of 2 passive INSs on the supraorbital nerves resulted in a significant pain relief in this patient with post-traumatic SON. The device was safe and effective, and the cosmesis was satisfactory.

Key Words: wireless, neuromodulation, supraorbital neuralgia, post-traumatic headache, peripheral nerve stimulation

INTRODUCTION

Cranioplasty, a neurosurgical intervention to repair the skull vault, is used primarily for brain protection and cosmesis following an operation or injury.¹ However, according to the MarketScan national database, cranioplasty is associated with a relatively high overall complication rate of 36.6%.^{2,3} Furthermore, 25% to 76% of patients experiencing post-cranioplasty complications may need to undergo additional procedures to correct these complications.^{2,3} The factors that

contribute to these complications are numerous and require further assessment. One negative side effect seen in a relatively small group of these patients is supraorbital neuralgia (SON), which must be differentiated from more common conditions such as chronic migraine, trigeminal neuralgia, cluster headache, and SUNCT (short-lasting, unilateral, neuralgiform headache with conjunctival injection and tearing) syndrome.⁴

The supraorbital nerve is a superficial nerve branching from the ophthalmic division of the trigeminal nerve.⁵ In some instances, the nerve may be entrapped in the scar tissue resulting from the trauma or the surgical procedures, thus leading to chronic, intractable headache.⁶ Often, neuroleptic drugs, such as tricyclic antidepressants (TAD), anti-epileptic drugs (AEDs), selective serotonin re-uptake inhibitors (SSRIs), and pain medication, do not offer long-lasting relief and induce too many side effects.

Treatment options include nerve blocks with local anesthesia or acupuncture,⁷ and eventually pulsed radiofrequency of the Gasserian ganglion.^{8,9} Neurodestructive procedures for trigeminal neuropathic pain entail the risk for inducing side effects such as hyperesthesia, allodynia, and, in the worst case, anesthesia dolorosa, worsening the condition of these patients. Injections of corticosteroids or anesthetics may provide short-term relief, but these require frequent repetitions.^{10,11}

Another option is reconstructive plastic surgery of the nerve, which is excised and end-to-end coaptated with a neural tube conduit to prevent neuroma formation.¹² However, recurrences due to scar tissue may recur.

Neurostimulation has been used for more than 4 decades and is widely accepted due to its minimally invasive percutaneous lead insertion technique.^{7,10} Gasserian ganglion stimulation provides good pain relief in trigeminal neuropathic pain.¹³ In our department, this technique is used as last resort therapy for trigeminal neuropathy. Peripheral nerve stimulation (PNS) for facial pain due to post-herpetic neuralgia and trauma has been reported to be effective.^{13–15}

Unfortunately, the superficial lead's location and the extensive wiring required by conventional PNS systems result in high complication and revision rates. According to Slavin et al.¹⁶ and Falowski et al.,¹⁷ migration of leads occurred in nearly 25% of patients. Schwedt et al.,¹⁸ reported 100% lead migration for occipital nerve stimulation to treat headache disorders in a 3-year long-term study. The use of Ankerstim[®] leads developed

in our center in collaboration with Medtronic resolved the problem of dislocation (JPVB, IS, MDV, NVQ, unpublished data) but not the burden and the cost of the battery and the extension.

We report a case of post-traumatic SON managed with a wireless PNS system, composed of an external wireless pulse generator (WPG) and 2 implantable neural stimulators (INSs).

CASE ILLUSTRATION

A 45-year-old patient suffered a severe head injury after a motor vehicle accident. The patient underwent repeated cranioplasties, which were complicated with infections, and developed severe bilateral postoperative/ traumatic headache in the forehead. The pain mainly affected the area innervated by the supraorbital nerve; it was often severe on the right side and was triggered by cold and wind. The patient was treated with multiple local anesthetic injections, pulsed radiofrequency, as well as anti-epileptics, antidepressants, and pain medication to control the neuropathic pain, characterized by hyperesthesia and allodynia. Despite the multiple treatments, the baseline numeric rating scale (NRS) pain score was 8 out of 10, with daily consumption of up to 2 g/day of paracetamol.

Due to this unsatisfactory condition, the patient was offered wireless PNS. Two octopolar INSs were placed bilaterally to cover the supraorbital nerve.

STIMWAVE WIRELESS PNS SYSTEM

The Stimwave neuromodulation system (StimRelieve LLC, Pompano Beach, FL, U.S.A.) comprises 2 octopolar INSs that are coupled via radiofrequency with the WPG worn in a baseball cap by the patient (Figure 1). The INSs are passive, powered by the WPG, and can be programmed by the physician to meet the indicated requirements. The stimulation parameters are controlled by the physician, and the wavelength of the carrier signal that connects the WPG and the INSs has been set to a safe range (869 to 915 MHz) to minimize any kind of risk to the patient while the stimulation parameters are reliably transferred.¹⁶

THE IMPLANTATION PROCEDURE

The patient was placed in a supine position, and the face and the neck of the patient were draped for a sterile procedure. Implantation of the INSs was performed



Figure 1. External pulse generator in a baseball cap.

under local anesthesia with light sedation using propofol and alfentanil. Small incisions were made near the supraorbital nerves on the forehead, which was the area in which the patient reported chronic pain. To reach this area of the skull, a 14-gauge Tuohy needle was contoured to the shape of the skull and inserted through the small incisions. The INSs were inserted through the needle under fluoroscopic guidance, allowing the correct placement of the INSs on the targeted area. The needle was removed, and the system was programmed. The stimulation parameters were adjusted until the patient perceived paresthesia. Final placement of the INSs was chosen once the subject reported sensory stimulation over the primary pain area (Figures 2 and 3). The INSs were not fixated since it was expected that the anatomical surroundings would stabilize their position. Fourteen months postimplantation x-rays confirmed original placement (Figures 4 and 5).

Stimulation settings were initially set at the conventional low-frequency range (60 to 100 Hz) but were subsequently changed to a pulse width of 30 microseconds with a frequency of 10 kHz, which was reported to be more efficacious and less bothersome, due to the absence of paresthesia. There were no complications during the procedure, and the patient was sent home with the necessary information to operate the system.

Postoperative Evaluation

Following the procedure, the patient had good relief of pain with no adverse events. At 12-month follow-up, the NRS pain score was reported to have decreased to 2 (from a preoperative NRS score of 8), and the patient required paracetamol only occasionally for pain relief. The stimulation was reported to be paresthesia free. At 24-month



Figure 2. Skull x-ray lateral view showing the 2 wireless implantable neural stimulators in place.



Figure 3. Skull x-ray anteroposterior view showing the 2 wireless implantable neural stimulators in place.

follow-up, the patient had sustained pain relief, reporting an NRS pain score of 2 out of 10. The patient global impression of change (PGIC) was 6 out of 7, indicating that the patient had a substantial improvement.



Figure 4. Skull x-ray lateral view showing the 2 wireless implantable neural stimulators in place 14 months postimplantation.

DISCUSSION

The supraorbital nerve runs superficially on the forehead and may be easily damaged by either an external force or during surgery.¹⁰ Minimal pain experienced from SON can be treated with medications such as gabapentin, pregabalin, and amitriptyline.^{11,12,19} However, the options for patients with chronic pain are relatively limited and risky. Failure of medical management and the irreversible nature of other invasive procedures, along with the technological advancements in the field of PNS, facilitate the use of neurostimulation.^{15,20} PNS is a highly effective therapy for managing craniofacial pain caused by a variety of conditions, including occipital neuralgia, post-herpetic neuralgia, cluster headache, cervicogenic headache, SON,^{10,12,15-18,20,21} and trigeminal neuropathic pain of different etiologies.

Nevertheless, when using traditional PNS systems, equipment-related adverse events and cosmetic concerns are a main concern. Common adverse events include high rates of complications like lead erosion, fracture, and migration, with infections also playing a significant role in discouraging the widespread application of PNS.^{13,15} In a systematic review of occipital nerve stimulators, Jasper and Hayek²² reported that 30 out of 115 patients had lead displacement. In addition, in cases reported by Schwedt et al., as the follow-up time



Figure 5. Skull x-ray anteroposterior view showing the 2 wireless implantable neural stimulators in place 14 months postimplantation.

lengthened, the revision rate increased. Dunteman reported a revision rate of 33% at 6 months, 60% at 1 year, and 100% at 3 years.¹⁵ IPG-related problems were encountered in 42% at 2 years.

The wireless technology presented in this case report proposes a promising solution to decrease the adverse events seen in traditional PNS systems while maintaining the effectiveness of the treatment. The Stimwave PNS system does not employ any implantable device other than the INSs, thus avoiding the surgical procedure required for implantation of the IPG, connectors, and extension leads. Without these components, 42% of the adverse events reported in Kasper and Hayek's study are eliminated, indicating a substantial potential reduction in adverse events when using the Stimwave PNS with only 1 or 2 implantable components. In addition, without the need for tunneling or placement of bulky materials, the cosmetic results in the head, face, and neck improve substantially. Improved cosmetic results are also associated with a better emotional attitude towards the therapy and better therapy acceptance. Due to the easier implantation technique, operating time is shortened. The new PNS system also eliminates the surgical replacement of batteries, lowering the costs for maintenance of the system.²³

This case report demonstrates the advantages of wireless stimulation. The typical adverse events of traditional PNS systems were eliminated, and the treatment yielded the desired results. The patient's NRS pain score demonstrated a long-term pain reduction of 75% compared to preoperative levels.

Stimwave's wireless minimally invasive PNS technique proved to be valid, safer, and simpler, with better cosmesis results, and a more cost-effective option when compared to conventional systems.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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