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A novel miniature, wireless neurostimulator in the management of chronic craniofacial pain: Preliminary results from a prospective pilot study☆

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HIGHLIGHTS

- Technological and cosmetic limitations inhibit use of PNS for craniofacial pain.
- Management of craniofacial pain with a wirelessly powered PNS system.
- 10 patients implanted with wireless stimulators, powered by an external transmitter.
- Patients monitored for pain relief and AE's for 4 weeks.
- All patients reported pain relief over primary pain areas with no reported AE's.

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ABSTRACT

Objective: To report a novel wireless neuromodulation system for treatment of refractory craniofacial pain.

Background: Previous studies utilizing peripheral nerve stimulation (PNS) of the occipital and trigeminal nerves reported positive outcomes for alleviating neuropathic pain localized to the craniofacial and occipital areas. However several technological limitations and cosmetic concerns inhibited a more widespread acceptance and use of neuromodulation. Also, a relatively high incidence of adverse events like electrode erosions, dislocation, wire fracture and/or infection at the surgical site mandates a change in our approach to neuromodulation technology and implant techniques in the craniofacial region.

Methods: We report a novel approach for the management of craniofacial pain with a wirelessly powered, minimally invasive PNS system. The system is percutaneously implanted and placed subcutaneously adjacent to affected facial nerves via visual guidance by the clinician. In this feasibility study, pilot evidence was gathered in a cohort of ten subjects suffering from a combination of chronic headaches, facial pain for at least 15 days per month and for at least 4 h/day.

Results: At four weeks post-implant follow up, all patients reported sustained pain relief of the primary pain area. Electrode location and total number of electrodes used per subject varied across the cohort. The average pain reduction using the visual analog scale was ≥82%. The procedure had no adverse events or side effects.

Conclusion: Percutaneous placement of a wireless neurostimulation device directly adjacent to affected craniofacial nerve(s) is a minimally invasive and reversible method of pain control in patients with craniofacial pain refractory to conventional medical managements. Preliminary results are encouraging and further larger scale studies are required for improved applications.

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1. Introduction

Chronic craniofacial pain (CCFP) or atypical facial pain or persistent idiopathic facial pain or atypical trigeminal neuralgia are a few of the names applied for the debilitating/refractory painful conditions with a varied lifetime prevalence [1,2]. Facial pain affects nearly 26% of people during their lifetime [3] while typical trigeminal neuralgia in population occurs in 0.3% [1].

CCFP arises from abnormal peripheral activation of cranial nerves that convey pain information to the brain and can result from events including but not limited to, infection, trauma, surgery, or invasive dental procedures. It is characteristically similar to pain due to trigeminal neuralgia and these disorders possibly are located on the same spectrum in a temporal sequence [2,4,5]. Intractable headache and/or migraine affect nearly 40 million Americans and in spite of various treatment protocols 3–5% of these patients does not improve but suffer from overwhelming despair in dark quiet rooms consuming high doses of narcotics [6–8].

Opioids are the most commonly prescribed for treatment of CCP along with anticonvulsants and anti depressants. Longstanding usage of opioids is associated with tolerance and dependence while opioid dose escalation over time to maintain analgesic effects become regular events. Additionally, chronic opioid use has the potential for increased risks of diversion, abuse, addiction, and can cause opioid induced side effects including nausea, sedation, constipation and hyperalgesia. A recent FDA recommendation for opioid use calling for reductions in chronic opioid prescription is another reason to consider neurostimulation treatment for pain control [9].

Lack of effective medical management resulting in persistent pain and significant decrease in quality of life has led to the development of destructive procedures including hot or cold radiofrequency nerve ablation. Surgical/chemical neurectomy or decompressive neurotomies were common treatments [10]. These, however, may result in irreversible side effects including sensory or motor loss and subsequent differentiation pain along the ablated nerve [11]. Neither radiosurgery nor sphenopalatine ganglion ablation or neurectomy yielded successful results in CCFP conditions [12,13].

Peripheral nerve stimulation (PNS) for craniofacial pain has proven to be a viable therapeutic option in the treatment of chronic disabling pain because of its non-destructive and reversible nature [14,15].

The Neuromodulation Appropriateness Consensus Committee (NACC) after evaluation of peer reviewed literature, current research and clinical experience found evidence to support extracranial stimulation for treatment of facial pain and migraine [16]. Advancements in wireless energy transmission and microprocessor technology have recently enabled development of miniature, percutaneous neurostimulation hardware and software to help control these pain syndromes involving craniofacial peripheral nerves [19]. Several studies have shown encouraging results [17,18].

However, widespread use of PNS neuromodulation has been limited by multiple technological issues/concerns and remains underutilized [18–20]. Available neurostimulation systems have not been designed for use in the peripheral nerve space, especially in and about the craniofacial region and are associated with complications including electrode migrations and procedural complications due to cumbersome equipment as well as stimulation systems. Not only cosmetic concerns, but relatively high adverse event rates including such events as device erosion, fracture, and infection have also played a discouraging role [11,18–21]. Our experience with a novel wireless, minimally invasive design in the treatment of occipital neuralgia yielded good results [22]. We report this alternative approach for the management of CCFP. A minimally invasive, wireless stimulation system is percutaneously implanted and placed subcutaneously adjacent to affected facial and/or occipital nerves involved in intractable craniofacial pain. Initial data were gathered in a cohort of ten subjects suffering from chronic headaches, facial pain for at least 15 days per month and at least 4 h/day. The primary objective of this study was to determine the analgesic effect of wireless neuromodulation in controlling chronic pain as applied to various nerve distributions within the CCFP.

Table 1
Demographics and target nerves.

Sub	Sex	Age	Location of pain	Target nerve(s)
1	F	67	Right V3	Mental nerve
2	M	55	Left V3	Mental nerve
3	F	58	Left V3	Mental nerve
4	F	64	Right V2	Infraorbital nerve
5	F	76	Left V1, V3	Supraorbital, mental nerves
6	F	62	Right V2, V3	Infraorbital, mental nerves
7	F	42	Right V1, V3	Supraorbital, mental nerves
8	M	74	Left V2, V3	Infraorbital, mental nerves
9	M	75	Left V2, V3	Infraorbital, mental nerves
10	F	63	Right V2	Infraorbital nerve

2. Methods

Inclusion criteria: Patients of at least 22 years of age at the time of signing the informed consent and without anatomical defects that would compromise or complicate the study were included. The Subjects were on stable doses of pain medications for at least 4 weeks prior to screening. Subjects were willing to undergo the surgical implant procedure, attend visits as scheduled and comply with the study requirements. Patients were willing and able to operate the programmer, recharge the equipment and properly fill out the electronic diary. Subjects were good surgical candidates for the implant procedure and had a life expectancy greater than 12 months beyond the study period. Subjects had a decreased pain intensity of at least 50% from baseline after local anesthetic block of the targeted craniofacial nerves in the past.

Exclusion criteria: Patients with migraine, cluster headache, trigeminal autonomic cephalgia, other types of craniofacial pain considered to be of central origin and those who failed psychological evaluation were excluded. Subjects on anticoagulation therapy and/or unfit for surgical procedures were also excluded.

Demographics: Ten patients (7 female, 3 male) were enrolled (mean age of 60 years). All patients were selected based on a history of CCFP (Table 1) manifesting as chronic headache, facial or occipital pain for at least 15 days per month and at least 4 h/day. Pain was of neuropathic origin from direct or indirect neural injury to the trigeminal, supraorbital, infraorbital nerves. Root causes of CCFP included trauma, surgery, infection, congenital defects, and trigeminal neuropathy.

Device description: Subjects were implanted with one or more wireless stimulator systems (StimRelieve LLC, Miami Beach, FL, USA) each containing four or eight contacts (3 mm in diameter with 4 mm spacing). The stimulator system utilizes an implantable electrode contact array, microprocessor receiver and antenna embedded within the electrode wire that couples to an external transmitting antenna and pulse generator (Figs. 1 and 2) The implanted stimulator is 100% passive (i.e., no implanted power source). The external transmitting antenna was worn in a baseball cap (Fig. 3) and is wirelessly coupled to provide energy to the implanted stimulator. Subjects would have to wear the baseball cap on a daily base for at least 8 h/day. The antenna component would cover the location of the inbedded receiver, externally powering the electrode array and thus providing therapeutic stimulation

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