Peripheral Nerve Stimulation for the Treatment of Occipital Neuralgia and Transformed Migraine Using a C1-2-3 Subcutaneous Paddle Style Electrode: A Technical Report

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▪ **ABSTRACT**

In this article we will discuss the treatment of Occipital Neuralgia (ON) and Transformed Migraine (TM) using a paddle style surgical stimulator lead. A paddle style electrode may have advantages to the cylindrical style in reducing migrations from cervical flexion or anchor dislodgement. It should be considered in refractory [illegible] syndromes such as ON and TM before moving on to more aggressive surgical interventions. ▪

INTRODUCTION

Transformed Migraine (TM) and Occipital Neuralgia (ON) are distinct, clinically diverse, cervicocranial syndromes involving the posterior occiput (1–5). Both often manifest with life altering, disabling pain refractory to conventional therapy (6–9). As such, cylindrical peripheral nerve stimulators (PNS) have recently been implanted percutaneously in both conditions over the distal C1-2-3 spinal nerves (10–14). Results include better than 75% reduction in pain and 88% reduction in disability when paresthesia is maintained within these dermatomes (10–12,14). When paresthesia is not maintained (such as when spasm or anchor dislodgement leads to cylindrical electrode migration), recurrent pain and disability mandate surgical revision (11,12). This technical report describes the placement of a subcutaneous, C1-2-3, peripheral paddle style electrode to minimize this occurrence. The objective of this article is to describe the use of a paddle style electrode(s) (Resume II/Resume TL, Medtronic Inc., Minneapolis, MN) for the treatment of chronic ON and TM.

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ON is a pain syndrome characterized by lancinating pain extending from the suboccipital region to the cranial vertex (1,2,6,7). The etiology of ON includes trauma, fibrositis, myositis, fracture of the atlas and compression of the C-2 nerve root (C1-2 arthrosis syndrome, adantoaxial lateral mass osteoarthritis, hypertrophic cervical pachymeningitis, cervical cord tumor, Chiari malformation, and a variety of medical conditions including meningitides, temporal arteritis, and migraine (1,7,15–20). Conservative treatment includes nonsteroidal analgesics, opioids, neuromodulators, transcutaneous electrical nerve stimulation, external orthosis, steroid injection, and nerve blocks (1,7). In chronic refractory cases, a number of surgical treatments have been performed including rhizolysis and decompression (6,21), neurectomy (7), rhizotomy and ganglionectomy (18,22–24), C1-C2 fusion (25), and radiofrequency ablation (26). PNS has been proposed as a treatment for ON (21,27–31). More recently, Weiner and Reed (17) have reported on the subcutaneous placement of C1-2-3 cylindrical PNS for ON at the level of C1 and the skull base.

TM is a nonparoxysmal cervical tension and secondary radiating posterior headache pain syndrome occurring daily or almost daily, the etiology of which is unknown (3–5,8). Patients have a prior history of International Headache Society classification (IHS) episodic migraine with increasing headache frequency and decreasing severity of migrainous features (8). Most experience episodic symptoms, including aura (15%), and respond to pharmacologic management (4,8). A significant number (up to 6% of 38,000,000 migraine sufferers in 2,280,000) however, develop in the setting of symptomatic medication overuse and/or are refractory to conservative pharmacologic treatments (3,5,32). Recent theory suggests that this disabling TM 'neuropathic subset' may be refractory due to the involvement of the trigeminocervical complex (9,12,33). Popeney and Aló have recently described a clinical correlation between subcutaneous, cylindrical C1,2,3 (PNS) and the reduction of CTMS central sensitization and disability (12).

Figure 1. Quadripolar resume I electrode. (Courtesy of Medtronic, Inc.)

MATERIALS AND METHODS

Patients

Between October 1997 and December 2002, 10 patients with the diagnosis of ON and 10 with the diagnosis of TM underwent subcutaneous placement of a C1-2-3 paddle style electrode. Patients were implanted consecutively at two centers (ON, Pittsburgh, PA and TM, Houston, TX). The diagnosis of ON and TM were made according to the definition of the Headache Classification Committee of the IHS (2). All patients had predominately "neuralgic" pain, described as electric, shooting, tingling, exploding, jabbing, and "like an electric shock" in the ON group, and "progressive cervical/skull base tension" with secondary radiating posterior occipital, vertex, or retro orbital migrainous symptoms in the TM group. Surgical intervention was offered only to patients who had failed at least three modes of conservative treatment (medication, physical therapy, blockade), who had temporary complete or near complete (>70%) relief of pain with occipital local anesthetic field block, and in whom psychological screening revealed no major behavioral drug habituation, or significant unresolved issues of secondary gain. All ON patients had a single paddle style electrode (Resume II/Model 3587A, Medtronic Inc.) placed for their unilateral symptoms via a retro mastoid C1-2-3 subcutaneous approach with a two-stage "extended trial" operation (see Procedure A below, and Figs. 1,2,5). All TM patients had dual paddle style electrodes (Resume TL/Synergy, Medtronic

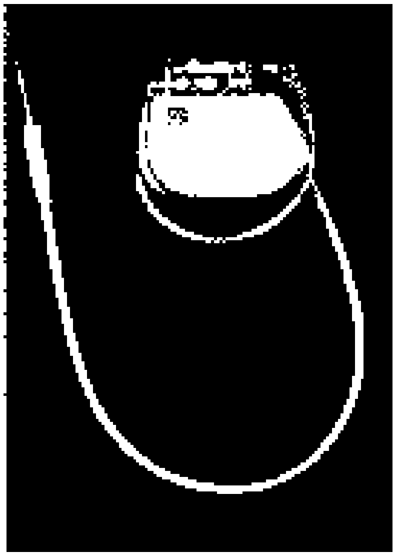

Figure 2. ITREL 3 Generator. (Courtesy of Medtronic, Inc.)

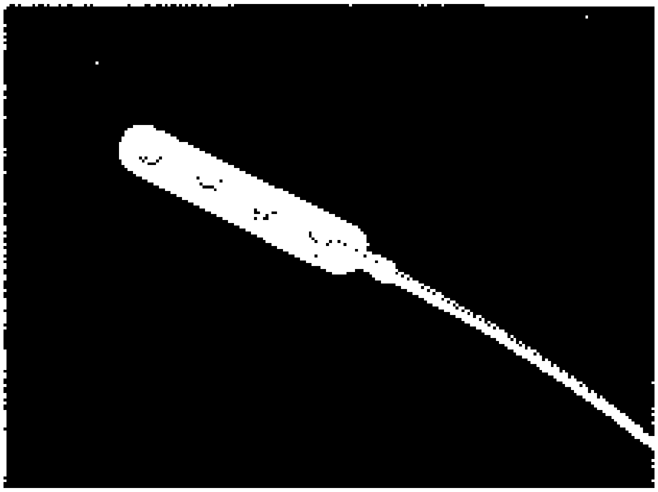

Figure 3. Quadripolar Resume II electrode. (Courtesy of Medtronic, Inc.)

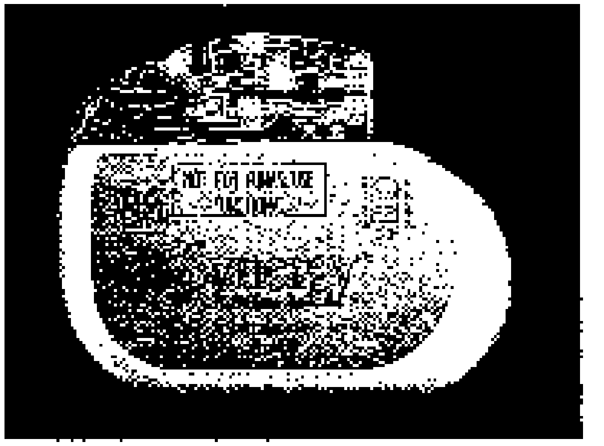

Figure 4. [illegible] Generator [illegible] Stimulation.

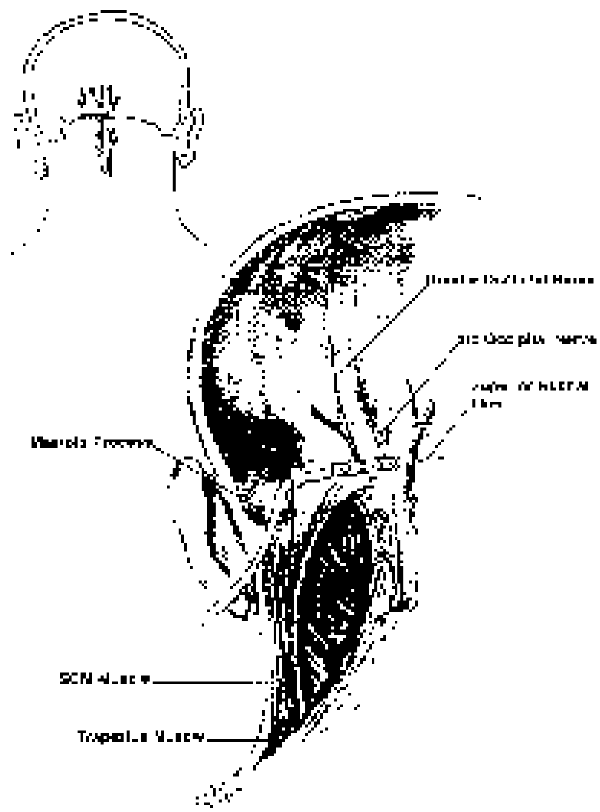

Figure 5. A 2-cm vertical incision was made 2 cm medial to the mastoid body just inferior to the superior nuchal line. The electrode is then passed through a subcutaneous tunnel extending to the midline above the trapezius fascia.

…ne 2) placed for their bilateral symptoms via a midline C1-2-3 subcutaneous approach with an "on the table trial" and immediate battery internalization (see Procedure B, below, and Figs. 5A, 6,7). The clinical characteristics of these two patient groups are given in Tables 1 and 2.

Procedure and Follow up

Occipital Neuralgia

A two-stage operation for the placement of a single Resume II electrode and Itrel III generator was performed (Figs 2 and 3). In the first stage the patient was placed in the prone position under light intravenous sedation. A 2-cm incision was marked 2 cm medial to the posterior margin of the mastoid process and 2 cm inferior to the

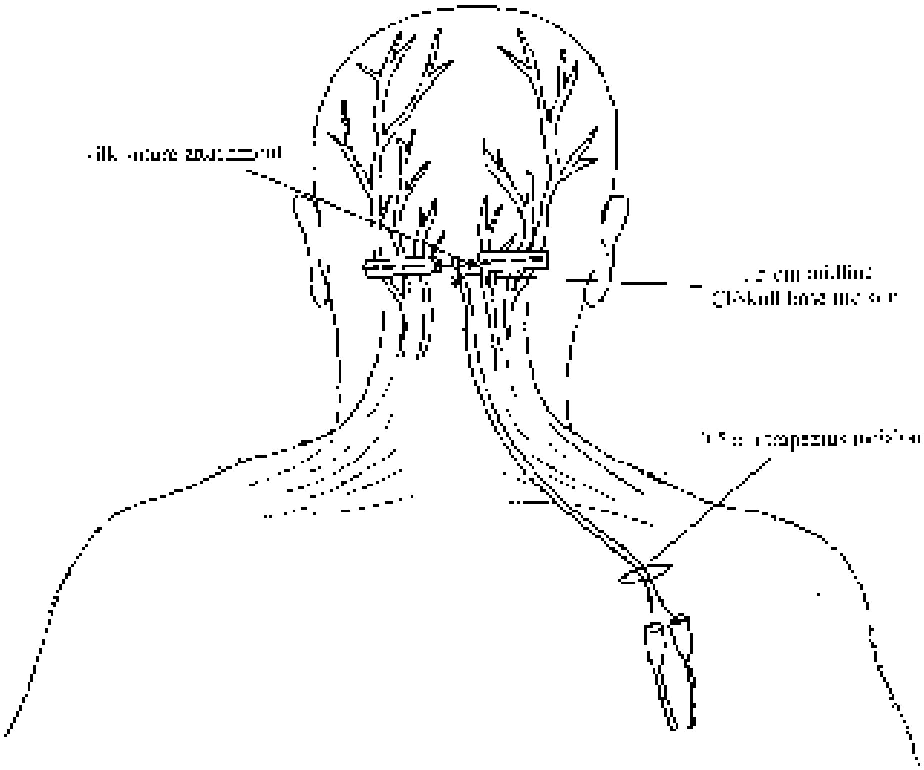

Figure 6. A [illegible] cm midline incision over C1 at the skull base for placement of dual midline C1-2-3 paddle style electrodes. Dissection is medial to create for right and left electrode placement. Electrodes are then tunneled with a straw to a [illegible] cm trapezius level incision and then to the IPG site on the respective hip. (Courtesy of [illegible])

Figure 7. Bilateral midline placement of C1-2-3 [illegible] electrodes [illegible] placed subcutaneously over the skull base at C1. Electrodes are tunneled with a straw to a small trapezius level incision and then to the IPG site on the respective hip (see Fig. 6).

Table 1. Patient Characteristics (ON)

Patient No.	Age	Sex	Suspected Diagnosis/Etiology	DOS[1]	Previous Treatment	Response to diagnostic occipital block[2]
1	44	M	Trauma	5 year	Opioids, NSAIDs, TENS, PT	Complete
2	[illegible]	M	Surgery (posterior cervical)	4 year	Antidepressants, neuromodulators, opioids, NSAIDs, TENS, PT	Partial ([illegible])
3	55	F	Herpes zoster	10 year	Opioids, NSAIDs, Chiropractor, trigger point injections, TENS	Complete
4	40	M	Surgery (anterior cervical)	3 year	PT, TENS, Opioids, NSAIDs, facet injection	Complete
5	56	F	Surgery (anterior cervical)	3 year	Opioids, NSAIDs, PT, ES	Complete
6	46	F	Trauma	8 year	Opioids, NSAIDs, neuromodulators, PT, ganglionectomy, SCS	Partial (75%)
7	32	F	Trauma	2 year	Opioids, NSAIDs, neuromodulators, PT, RF rhizotomy	Partial (90%)
8	44	F	Trauma	4 year	Opioids, NSAIDs, neuromodulators, PT, [illegible]	Partial (80%)
9	39	F	Unknown	6 mo	Opioids, NSAIDs, neuromodulators, PT	Complete
10	25	F	Trauma	[illegible] year	Opioids, NSAIDs, neuromodulators, PT	Partial (90%)

[1] DOS = Duration of symptoms.
[2] Bilateral occipital field block of the greater, lesser and third occipital branches as indicated.

superior nuchal line. The area was prepped and draped in the usual sterile fashion, leaving the posterolateral neck exposed for the extension cable to exit. Local anesthetic (1% lidocaine with epinephrine, 1:200,000) was placed along the incision line only to avoid anesthetizing the occipital nerves medially. The incision was taken down to the subcutaneous tissue, and then using a curved hemostat, a tract was started in the subcutaneous plane. The paddle electrode dissector (provided in the Resume II kit) was passed medially to the midline taking care to keep the tract narrow in order to prevent electrode motion or migration. The electrode was placed into the subcutaneous tunnel with the contacts facing towards the skull with the distal end of the electrode near the midline (Fig. 5). This ensures that the contacts covered the course of the occipital nerves as they ascended to pierce the fibers of the semispinalis capitus and passed through the aponeurotic attachment of the trapezius and sternocleidomastoid muscles at the superior nuchal line. Intraoperative testing was performed to assess whether stimulation produced paresthesias over the entire area of the patient's pain. The electrode was repositioned until satisfactory coverage of the pain area was obtained, then it was secured to the subcutaneous tissue using silk suture at the base of the electrode array. Extension wiring was tunneled from the incision site to the exit site in the posterior cervical skin so that the extended trial could be performed. Excess wire was coiled in a generous subcutaneous pocket to prevent possible erosion during the extended trial period. A pressure dressing was applied in order to minimize the space between the electrode contact and the underlying tissue. The patient was instructed on how to adjust the hand-held pulse generator and

Table 2. Patient Characteristics (ON)

Patient No.	Age	Sex	Suspected Diagnosis/Etiology	DOS*	Previous Treatment	Response to diagnostic occipital block†
11	66	F	Unknown/ idiopathic, [illegible]	20+	Neuromodulators, PT, NSAIDS, TCADS, SSRI, anticonvulsants, [illegible], migrated percutaneous C1-2-3 PNS	Complete
12	47	F	Trauma	3+	Same meds as pt 11, chiropractic	Complete
13	[illegible]	F	Failed cervical fusion	4	Same meds as pt 11, Percocet, TENS, migrated/fractured percutaneous C1-2-3 PNS	Partial (50%)
14	42	F	Unknown/idiopathic	10+	Same meds as pt 11, TENS, migrated percutaneous C1-2-3 PNS	Complete
15	[illegible]	F	Unknown/idiopathic	7+	Same meds as pt 11, blocks, TENS, massage, Botox	Complete
16	41	F	Unknown/idiopathic	25+	Same meds as pt 11, TENS, Botox, PT, massage, chiropractic, migrated percutaneous C1-2-3 PNS	Complete
17	22	F	Unknown/idiopathic	10+	Same meds as pt 11, TENS, topical anesthetic, [illegible] massage, migrated percutaneous C1-2-3 PNS	Complete
18	71	F	Unknown/idiopathic S/P cervical fusion	20+	Same as pt 16	Complete
19	[illegible]	F	Failed cervical fusion	15+	Same as pt 16	Complete
20	[illegible]	F	Unknown/idiopathic	15+	Same meds as pt 11, chiropractic, Botox, blocks, massage	Complete

* DOS = Duration of symptoms.
† Bilateral occipital field block of the greater, lesser and/or third occipital branches as indicated.

given a pain diary to record the results of trial stimulation. All 10 ON patients had successful trial stimulation (>50% relief of pain) over a two-week period and were subsequently brought back for battery (Itrel III) internalization.

The second stage of the procedure, internalization of the internal pulse generator (IPG), was performed under general anesthesia. The patient was placed in the supine position with a shoulder roll and the head turned to the contralateral side. The cranial incision and the chest were prepped and sterile draped. The occipital incision was reopened and the electrode was disconnected from the externalized extension wire. An assistant removed the extension wire by pulling it through beneath the drapes. A subcutaneous pocket was created in the ipsilateral infraclavicular space. The extension cable was tunneled from the retromastoid incision to the pocket through a clean tunnel and connected to the electrode. The distal end of the extension wire was connected to an Itrel III (IPG) that was secured in an infraclavicular subcutaneous pocket. The patient was taken to the recovery room before being discharged home.

Transformed Migraine

A single stage operation for placement of dual Resume II electrodes and Synergy IPG was performed with an "on the table trial" and immediate battery internalization (Figs 3 and 4). To facilitate

this the patient remained awake, was positioned in the prone position, and underwent prep and drape from the skull base to the posterior buttocks. No intravenous antibiotic was given at the onset of the procedure. A 1.5 cm vertical midline incision was then performed over C1 at the skull base under local anesthesia (1% lidocaine with epinephrine, 1:200,000) and carried down to the subcutaneous tissue (Fig. 6). Again, a subcutaneous tunnel was achieved using a curved hemostat. This time from the midline laterally at the skull base separately left and right. The paddle electrode dissector provided in the Restore TL kit) was then passed laterally from the midline left and right taking care to keep the tracts narrow in order to prevent motion on either side. Each paddle electrode was placed into the respective subcutaneous tract with the contacts facing towards the skull and the proximal end of each electrode near the midline (Fig. 7). This ensured coverage of the left and right electrode contacts over the occipital nerves as they ascended to pierce the fibers of the semispinalis capitis as described above. Each electrode was repositioned until satisfactory coverage of the pain area was obtained, then sutured to the midline to the subcutaneous tissue using silk suture at the base of each paddle (Fig. 6). All 20 patients obtained immediate IM paresthesia and pain relief of >50% "on the table" and proceeded directly to IPG pocketing (with intravenous sedation) to the hip.

To do this, extra electrode tails of both Restore TLs were tunneled together to a second 0.5 cm inferior level subcutaneous incision with the "plastic sheath" tunneling tool. These were then connected to dual extensions and tunneled to a 3rd IPG pocket 2 cm below and lateral to the midposterior iliac crest. This second tunnel was performed with the "dual arrow" tunneling tool. After closure of all wounds and fluoroscopic/xray confirmation, the patient was taken to the recovery room where they were monitored and discharged home. Follow-up was obtained in the implanting physician's office or by phone interview by one of the authors of the study (JO, KA). Follow-up was obtained on all patients at 1 month, 6 months, and as needed thereafter. The outcome measures reported are subjective percent reduction in pain. This was obtained by asking patients to rate their pain reduction. No visual analog scale was used (see Results).

RESULTS

The self-reported pain relief is given in Table 3. At one-month follow-up, 17 patients reported excellent pain relief with stimulation (>90% pain reduction), and three patients reported good pain control (75–90% pain reduction). Of the 18 patients who had completed 6-month follow-up, 14 reported continued excellent pain relief, two reported good pain relief, one fair pain relief (50–75% pain reduction), and one reported poor pain relief with stimulation (<50% pain reduction). Nineteen patients (95%) reported improvement in quality of life with stimulation and would undergo the procedure again.

Long-term follow-up was obtained in the first patient (#1 in the ON group) in this series. After 3 years of successful stimulation, he had loss of pain control and paresthesia, and was again taking narcotic pain medications. Interrogation of the pulse generator revealed battery depletion. The pulse generator was replaced and at 4 years follow-up, he continues to have complete relief of his ON and was again off all narcotic medications.

Alternatively in the 10 patient (TM) group, near total resolution of migraine disability and medication requirement (90.8% reduction) was seen, validating a recent report (12).

Complications included an infection in two patients (13,14). One (patient 13) was successfully treated with IV antibiotics, and the other (patient 14) required electrode removal with replacement 2 months later. Patient 2 reported that his cervical pain was made worse with stimulation, although his occipital pain was significantly improved, and requested that his neurostimulator be explanted. Patient 3 felt that she was "allergic" to the metal, having developed severe pain at the pulse generator site, and had the stimulator explanted. Seven of the 10 TM patients were initially implanted with dual percutaneous cylindrical electrodes, but suffered electrode migration (within 6 weeks) due to anchor dislodgement from recurring skull base spasm. These patients were revised using the dual paddle style electrode technique described in this report (Fig. 7) without further dislodgement. At the time of data collection, none of the 20 paddle style implants had suffered migration or device related failure. Some of these devices have been in place for greater than 5 years.

Table 3. Percentage Relief of Pain[a]

Patient No.	1 Month % Relief[a]	6 Months % Relief[a]	Narcotic Use at Last Follow-up	Would Have Surgery Again?
1	Excellent	Excellent	No	Yes
2	Good	Fair	Yes	No
3	Good	Poor	Yes	Yes
4	Excellent	Excellent	No	Yes
5	Excellent	Excellent	No	Yes
6	Excellent	Excellent	No	Yes
7	Excellent	Excellent	No	Yes
8	Excellent	Excellent	No	Yes
9	Excellent	Excellent	No	Yes
10	Excellent	Good (3 mos)	No	Yes
11	Excellent	Excellent	No	Yes[b]
12	Excellent	Excellent	No	Yes
13	Excellent	Excellent	Yes	Yes[b]
14	Excellent	Excellent (3 mos)	No	Yes
15	Excellent	Good	No	Yes
16	Excellent	Excellent	Yes	Yes[b]
17	Excellent	Excellent	No	Yes[b]
18	Excellent	Excellent	No	Yes[b]
19	Good	Good	Yes	Yes[b]
20	Excellent	Excellent	No	Yes

[a] Excellent (>90% pain relief); Good (75%–90% pain relief); Fair (>50% pain relief); Poor (<50% pain relief).
[b] Indicates conversion from cylindrical to paddle-style C1-2-3 PNS, explanted due to migration.

DISCUSSION

There are many reports on the effective treatment of peripheral neuropathies with PNS (21,27–34). Historically these were usually designed as surgically applied "cuff" electrodes placed around a peripheral nerve proximal to an area of injury within an extremity. Waisbrod et al. (34) reported on 31 cases of painful neuropathies treated with PNS. Their results showed 58% complete and 27% partial relief of pain with an average of 11.5 months follow up. Picaza et al. (21,32) reported on 37 patients with painful peripheral neuropathy treated by PNS followed for greater than 1 year. They found greater than 50% long-term success in nerve injury after trauma. They concluded that sciatic and ulnar nerve stimulation was most successful. Of note, there was no correlation between preoperative testing with transcutaneous nerve stimulation and outcome in their study. Similarly, other published reports by Sweet (35) and Campbell and Long (27) reported success rates between 45% and 51%. In a review by Long (30), PNS for painful neuropathies of nerve injury origin was reported to have good effect in 82.5%, whereas the response rate in other kinds of pain were 25–50%.

Interestingly, only a handful of these initial reports describe the use of PNS for the treatment of ON (21,32,34). Waisbrod et al (34) reported on one patient who suffered from greater ON and had a "very good result" from PNS. Picaza et al (21,32) reported on six patients with ON treated with PNS. Two patients had excellent results, one had a good outcome, two had poor outcomes, and one case was reported as a failure.

More recently, Weiner (37) introduced, and Alo and Holsheimer (13) reviewed, an alternative to the use of surgically placed "cuff" electrodes for (PNS); namely percutaneously placed, subcutaneous cylindrical electrodes. Weiner and Reed initially performed this technique at the level of C1 and the skull base on 13 ON patients over a 6-year period (11). They reported excellent results (greater than 75% pain relief) in 55%, and good results (greater than 50% pain relief) in 30% of patients while stimulating the distal branches of the C1-2-3 spinal nerves (11). Weiner, Alo, and Reed then applied this same technique on a larger patient sample (63 patients over 22 months) with similar results (14). Finally, Alo and Popeney again applied cylindrical C1-2-3 PNS in 25 patients with TM over an 18-month period achieving an 88.7% reduction in migraine disability pre and post stimulation (12).

A significant complication, however, with the application of subcutaneous, cylindrical electrode C1-2-3 PNS has been electrode migration (11–14). In Alo and Popeney's study, nine of 25 patients suffered cylindrical electrode migration requiring surgical revision (12). In Weiner and Reed's original study, 13 of 35 patients required surgical revision for cylindrical electrode migration (11). In this technical report, seven of the 10 TM patients who were originally implanted with cylindrical electrodes suffered migration before they were converted to the dual paddle style Resume IIs described above. These patients reported loss of paresthesia overlap due to skull base tension and recurrent headaches after dislocation. Interestingly, these seven patients' average voltage thresholds were noted to be 25% less with their paddle style electrode post-conversion. Although not the primary focus of this report, it was postulated that if maintained long-term this could improve battery efficiency. The remaining three TM patients were implanted directly with the paddle style electrodes with similar thresholds and responses and did not dislocate or migrate due to skull base tension.

Thus, the procedure described in this report differs from that used initially by Weiner, Reed, Alo, and Popeney in that a subcutaneous paddle rather than cylindrical style PNS electrode is positioned over the distal C1-2-3 spinal nerve branches at the skull base. This electrode platform is less likely to migrate because it has a larger profile and can be secured by a suture to the subcutaneous tissue or underlying fascia with or without an anchor. It also has the advantage of directing the delivery of electrical current toward the nerve(s) "anteriorly" with less posterior spread (38). The anticipated benefit from this "anteriorly" directed current would be lower perception and usage ranges, and subsequent increased battery longevity (38). Finally, this technique appears to buffer recurring skull base tension responsible for repeated cylindrical electrode migrations in some TM patients (12,14).

Like percutaneous placements, this technique can be applied successfully to the C1-2-3 anatomy (midline and retro mastoid) for differing craniocervical pathophysiologies. Both approaches have been successfully predicated by diagnostic occipital field block of the greater, lesser and/or third occipital nerves (11–14,37). A potential drawback with this technique (as opposed to the percutaneous approach) is the fact that more dissection is required to dissect the subcutaneous electrode tract(s).

In addition, pain relief was assessed in this study by asking patients to report on percent reduction in pain. Knowing that patients can overestimate or underestimate the change in their pain scores, our results may not represent the exact degree of pain relief. The reduction in narcotic use and the percent reduction in disability, however, seems to be reliable and parallels previous reports (11,12).

CONCLUSION

For a carefully selected group of patients PNS for ON and TM can be an effective, minimally invasive, reversible, and adaptable procedure. A paddle style electrode may have advantages to the cylindrical style in reducing migrations from cervical tension or and/or dislodgment. It should be considered in refractory "neuropathic" cervicocranial syndromes (such as ON and TM) before more aggressive surgical interventions. Long-term follow-up studies are needed to assess the durability of the technique.

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