

Peripheral nerve field stimulation for trigeminal neuralgia, trigeminal neuropathic pain, and persistent idiopathic facial pain

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Abstract

Objective: Peripheral nerve field stimulation (PNFS) is a promising modality for treatment of intractable facial pain. However, evidence is sparse. We are therefore presenting our experience with this technique in a small patient cohort.

Methods: Records of 10 patients (five men, five women) with intractable facial pain who underwent implantation of one or several subcutaneous electrodes for trigeminal nerve field stimulation were retrospectively analyzed. Patients' data, including pain location, etiology, duration, previous treatments, long-term effects and complications, were evaluated.

Results: Four patients suffered from recurrent classical trigeminal neuralgia, one had classical trigeminal neuralgia and was medically unfit for microvascular decompression. Two patients suffered from trigeminal neuropathy attributed to multiple sclerosis, one from post-herpetic neuropathy, one from trigeminal neuropathy following radiation therapy and one from persistent idiopathic facial pain. Average patient age was 74.2 years (range 57–87), and average symptom duration was 10.6 years (range 2–17). Eight patients proceeded to implantation after successful trial. Average follow-up after implantation was 11.3 months (range 5–28). Using the visual analog scale, average pain intensity was 9.3 (range 7–10) preoperatively and 0.75 (range 0–3) postoperatively. Six patients reported absence of pain with stimulation; two had only slight constant pain without attacks.

Conclusion: PNFS may be an effective treatment for refractory facial pain and yields high patient satisfaction.

Keywords

Peripheral nerve field stimulation, neuromodulation, trigeminal neuralgia, trigeminal neuropathic pain

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Introduction

In recent years, peripheral nerve field stimulation (PNFS) has been gathering a growing body of evidence as a treatment option for patients with chronic pain syndromes refractory to conventional therapy forms. This surgical approach denotes the subcutaneous insertion of one or several electrodes in the painful area and subsequent electrical stimulation. In analogy to spinal cord stimulation or direct peripheral nerve stimulation, a trial, usually lasting several days to several weeks, is performed and the definite system is implanted afterwards in the case of a successful trial period.

Most notably, occipital nerve stimulation, sometimes in combination with subcutaneous electrode placement in the supraorbital, temporal or frontal region, has been increasingly and successfully used in

patients with migraine, cluster headache or other primary headache syndromes (1–6). Furthermore, the use of PNFS in the treatment of low back pain has been established through several prospective studies (7–9). Other indications under which patients have benefited from this minimally invasive procedure include inguinal

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post-herpetic neuropathy, abdominal pain, post-thoracotomy syndrome, and hip pain (10–13).

For patients with facial pain who have either experienced a relapse after microvascular decompression (MVD) for classical trigeminal neuralgia or suffer from a pain syndrome not amenable to MVD, further options are called for. Therapies in question include radiofrequency rhizotomy or radiosurgery. Being destructive procedures that can cause irreversible facial numbness as a side effect, they may be regarded as options of last resort in the era of neuromodulation. A thorough review of diagnostic and therapeutic options in trigeminal neuralgia has been provided elsewhere (14).

There is an increasing number of reports dealing with PNFS in patients suffering from facial pain. For the most part, painful trigeminal neuropathy following craniofacial surgery or trauma as well as post-herpetic trigeminal neuropathy have been identified as indications well amenable to this neuromodulatory intervention when more established therapies have failed (15–18). Evidence, however, does not exceed case reports or small patient series (Table 1). Moreover, experience with stimulation for classical trigeminal neuralgia has rarely been reported at all. Here, we present a retrospective analysis of patients who have received PNFS for different kinds of facial pain.

Methods

Patient population

Between August 2012 and December 2014, 10 patients in our institution had PNFS electrodes inserted for trial because of intractable facial pain. Five were male and five female, the mean patient age was 74.2 years (range 57–87 years). All had facial pain in any one or two of the innervation areas of the trigeminal nerve, although in some cases an exact anatomical attribution was difficult. Mean symptom duration was 10.6 years (range 2–17 years); all participants had undergone complex medical, interventional and/or surgical therapies before. A positive trial was considered if the patients experienced a 50% decrease of pain on the visual analog scale. As facial pain syndromes are often difficult to distinguish from one another and referring physicians may lack experience with more specific etiologies, the reported diagnoses were reviewed and in some cases corrected after thorough study of the individual patient's medical history, interview and neurologic examination. One patient had a post-herpetic trigeminal neuropathy; another had a painful post-traumatic trigeminal neuropathy following radiation treatment for mucosa-associated lymphoid tissue (MALT) lymphoma. Two patients suffered from painful trigeminal

neuropathy attributed to multiple sclerosis, five had classical trigeminal neuralgia, and one had a pain syndrome without any neuropathic quality that was difficult to categorize and most likely conformed to persistent idiopathic facial pain (PIFP). Four of the five patients with classical trigeminal neuralgia had undergone microvascular decompression surgery at least once before but experienced no lasting improvement. In one patient, microvascular decompression had initially been scheduled but was finally advised against in favor of PNFS because the patient suffered from meningitis before the surgery could be performed. Eight patients reported to have a positive trial and therefore proceeded with system implantation. Patients' characteristics and pain parameters are summarized in Table 2.

All patients filled out an extensive questionnaire upon their first presentation to our outpatient department, including exact description of localization, intensity and quality of their pain as well as the resulting limitations in activities of daily living. A rating scale for evaluation of pain intensity ranging from 0 (no pain) to 10 (maximum pain) was part of the questionnaire.

Trial stimulation

On the day before surgery, the patients were asked to exactly mark the painful facial area (Figure 1). Electrode placement was performed after sterile preparation and draping either in local or in general anesthesia, depending on patient choice and estimated compliance during the operation. Cefuroxime in the amount of 1.5 g was applied as a single shot antibiotic. A pre-auricular 1 cm–1.5 cm skin incision was made just behind the hairline above the zygomatic arch and an electrode (Pisces Quad Plus, Medtronic, Minneapolis, MN, USA) was placed subcutaneously from lateral to medial via a 15-Ga Tuohy needle into the center of the previously identified painful region (Figure 1). In patients with larger algescic areas, we preferred to insert two electrodes. If the patient was awake, a test stimulation was conducted to confirm the correct positioning of the electrode by covering the pain area with paresthesia. The lead was then fixated to the fascia with an anchor and connected to an extension cable that was passed to the retroauricular area and externalized. A loop allowed for redundancy of the cable in order to avoid dislocation of the lead. Following implantation, programming took place on the same day and the patients were trained in handling and adjusting the stimulation voltage. On day eight, the externalized cable was capped in our outpatient department. In three patients, the electrode was not connected to an extension cable during implantation but sutured to the skin. In these cases, the electrode was removed on day

Table 1. Literature review of PNFS for facial pain.

| Authors and year | Number of patients | Age (years), sex | Etiology | Area | Implant | FU | Outcome | Complications | |
|--|--------------------|------------------|----------|-----------|-------------------|--------|------------------------|-----------------------|--|
| Dunteman, 2002 (19) | 2 | 86, M | PH | Lt V1 | SON | 3 yrs | Improved | | |
| Johnson and Burchiel, 2004 (20) | 10 | 76, F | PH | Lt V1 | SON | 3 yrs | Improved | | |
| | | 39, F | PT | Rt V1 | SON | 2 yrs | 70% of pts with | Wound breakdown | |
| | | 86, M | PH | Rt V1 | SON | 2 yrs | >50% pain relief | None | |
| | | 44, M | PH | Rt V1 | SON | 2 yrs | | None | |
| | | 37, F | AFF | Lt V1 | SON | 2 yrs | | Wound breakdown | |
| | | 61, M | PH | Lt V1 | SON | 2 yrs | | Short extension cable | |
| | | 41, M | PT | Rt V1 | SON | 2 yrs | | None | |
| | | 83, F | PH | Lt V1 | SON | 2 yrs | | None | |
| | | 53, M | PT | Lt V1 | SON | 2 yrs | | None | |
| | | 45, M | PT | Lt V1 | ION | 2 yrs | | None | |
| Slavin et al., 2006 ^a (15) | 9 | 33, M | PT | Rt V1 | ION | 2 yrs | | None | |
| | | | | | SON (4); ION (3); | 35 mos | 73% of pts with | | |
| | | | | | ION + ON (1); | | >50% pain relief | | |
| | | | | | SON + ON (1) | | | | |
| | | | | | SON | 14 mos | Remission | None | |
| | | | | | | 4 yrs | VAS score from 10 to 2 | | |
| | | | | | | 30 wks | VAS score from | Superficial infection | |
| | | | | | | 30 wks | 7.5 to 3.5 (average) | in 20% skin | |
| | | | | | | 30 wks | | erosion, breakdown | |
| | | | | | | 30 wks | | of the postauricular | |
| Reverberi et al., 2009 (24) | 1 | 61, F | ETN | Rt V1, V2 | SON + ION | 5 mos | VAS score from 10 to 1 | Electrode dislocation | |
| | | | | | SON | 8 wks | Excellent | None | |
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| Narouze and Kapural, 2007 (21) | 1 | 35, M | CH | Rt V1 | SON | | | | |
| Asensio-Samper et al., 2008 (22) | 1 | 34, M | PT | Re V1 | SON | | | | |
| Amin et al., 2008 (23) | 10 | 35, M | SN | V1 | SON | | | | |
| | | 39, M | SN | V1 | SON | | | | |
| | | 36, F | SN | V1 | SON | | | | |
| | | 46, F | SN | V1 | SON | | | | |
| | | 40, F | SN | V1 | SON | | | | |
| | | 46, F | SN | V1 | SON | | | | |
| | | 46, F | SN | V1 | SON | | | | |
| | | 33, M | SN | V1 | SON | | | | |
| | | 56, M | SN | V1 | SON | | | | |
| | | 53, F | SN | V1 | SON | | | | |
| Suriya Prasad Upadhyay et al., 2010 (25) | 1 | | PH | V1 | SON | | | | |

(continued)

Table 1. Continued.

| Authors and year | Number of patients | Age (years), sex | Etiology | Area | Implant | FU | Outcome | Complications |
|--|--------------------|-------------------------|-----------------------------|--|--|----------------------------|--|--|
| Yakovlev and Resch, 2010 (26) | 1 | 72, F | AFP | Lt V3 | MN | 12 mos | Excellent | |
| Stidd et al., 2012 (17) | 3 | 71, M 52, M 44, M | PT PT PH | Lt V1, V2 Lt V1, V2 Rt V1 | SON + ION SON + ION SON (2 electrodes) | 27 mos 23 mos 6 mos | VAS score from 10 to 0 VAS score from 8 to 0 60% pain relief | Occasional HA Electrode dislocation |
| Lenchig et al., 2012 (16) | 1 | 42, F | PS | Rt V1, V2 | SON + ION | 3 mos | >50% pain relief | None |
| Feletti et al., 2013 (18) | 6 | 22, F 58, M 41, F | PIFP PT PT | Lt V1, V2, ON Rt V1, ON Lt > rt V2, V3 | SON, ION, ON ON ION | 15 mos 32 mos 19 mos | VAS score from 10 to 2 VAS score from 9 to 4 VAS score from 10 to 0 (lt), 5 (rt) | None None Traumatic rupture |
| Verrills et al., 2014 ^a (6) | 10 | 54, F 77, F 67, F | PS (chemical) PH PIPF | Lt V1, V2, V3 Rt V1 Rt V2 | ON, ION, MN SON ION | 12 mos 24 mos 3 wks | VAS score from 10 to 2 VAS score from 10 to 3 VAS score from 10 to 3 | Infection None None |
| Ellis et al., 2015 (27) | 15 | | | | SON + ION (3); combination of ON, SON, ION (7) | 12.9 mos (average) | 68% of pts with >50% pain relief | |

Modified after Feletti et al. (18).

AFP: atypical facial pain; CH: cluster headache; ETN: essential trigeminal neuralgia; F: female; FU: follow-up; HA: headache; ION: infraorbital nerve; Lt: left; M: male; MN: mandibular nerve; mos: months; ON: occipital nerve; PH: post-herpetic; PIPF: persistent idiopathic facial pain; PNF: persistent idiopathic facial pain; PNF: persistent idiopathic facial pain; PS: post-surgical; PT: post-traumatic; pts: patients; Rt: right; SON: supraorbital nerve; wks: weeks; VAS: visual analog scale; yrs: years.

^aData are the mean values referring to a wider series including occipital nerve stimulation.

Table 2. Characteristics of patients treated with PNFS for facial pain at our institution.

| Age (years), sex | Etiology | MVD | Area | Implant | FU (mos) | VAS score preop | VAS score postop | Analgesics preop | Analgesics at latest FU | Complications |
|------------------|----------|-----|-----------|-----------|----------|-----------------|------------------|------------------------------|-------------------------|------------------------------|
| 72, M | CTN | Yes | Rt V2 | ION | 28 | 10 | 0 | CBZ | None | Electrode defect |
| 78, M | CTN | Yes | Rt V1, V2 | SON + ION | 20 | 10 | 0 | PGB, OXC, BAC | PGB, OXC, BAC | Wound breakdown |
| 75, M | MS | No | Lt V3 | MN | 12 | 9 | 0 | PHT, CBZ, BAC, HYD | None | None |
| 76, M | MS | No | Lt V2, V3 | ION + MN | 8 | 10 | 0 | GBP, OXC, Act | GBP, OXC | None |
| 87, F | CTN | Yes | Rt V1, V2 | SON + ION | 5 | 10 | 0 | GBP, Act, OXC, BAC | OXC | None |
| 57, F | CTN | No | Rt V2 | ION | 5 | 10 | 3 | GBP, LTG, PHT, TRA, Act, BAC | GBP, LTG, PHT, TRA, BAC | IPG dislocation ^a |
| 76, F | CTN | Yes | Rt V2, V3 | ION + MN | 7.5 | 8.5 | 0 | PGB, TRA | PGB, TRA | None |
| 73, F | PIFP | No | Rt V2 | ION | 5 | 7 | 3 | GBP, CBZ | GBP, CBZ | None |

^aNo revision surgery performed.

Act: acetaminophen; BAC: baclofen; CBZ: carbamazepine; FU: follow-up; GBP: gabapentin; HYD: hydromorphone; ION: infraorbital nerve; IPG: implantable pulse generator; Lt: left; LTG: lamotrigine; MN: mandibular nerve; mos: months; OXC: oxcarbazepine; PHT: phenytoin; PIFP: persistent idiopathic facial pain; PNFS: peripheral nerve field stimulation; SON: supraorbital nerve; TRA: tramadol; VAS: visual analog scale; yrs: years.

eight and had to be replaced upon implantation of the definite stimulation system.

Implantation

After a positive trial period, the implantation of the permanent system was performed in a second procedure under general anesthesia. Cefuroxime in the amount of 1.5 g was administered and after routine preparation and draping, either the preauricular incision was reopened to implant a new electrode or both the pre- and retroauricular incisions were reopened to replace the extension cable. In either case, the electrode was passed to the retroauricular area where it was connected to a (new) extension cable. A subcutaneous pocket for the implantable pulse generator (IPG) was created either in the abdominal or the chest wall. After tunneling, the extension cable was connected to the IPG (PrimeAdvanced, Medtronic, Minneapolis, MN, USA), which was then inserted and fixated to the fascia with non-absorbable sutures. After an impedance check, assurance of hemostasis and irrigation of the pocket with gentamicin solution, the wounds were closed. We didn't use intraoperative fluoroscopy. However, a postoperative X-ray was performed in all patients for documentation of correct implantation (Figure 2). Stimulation began on the day after surgery and the patients were discharged on day three after having been trained in handling the programming device.

Stimulation settings

Stimulation settings were determined for each patient individually with regard to best effect and avoidance of side effects. Our aim was to induce slight but persistent paresthesia. Depending on the patient's pain characteristics, some were trained in reducing stimulation intensity to achieve subthreshold stimulation during pain-free intervals. However, the patients were advised not to completely turn off the stimulation, even when they were pain free. Usually, a frequency of 60–80 Hz and impulse duration of 450 μ were chosen. All four contacts were activated in the order anode-cathode-anode-cathode.

Follow-up and outcome analysis

The patients returned to our outpatient department 10 days after implantation for suture removal, wound examination and evaluation of the therapeutic effect. If necessary, stimulation parameters were adjusted and handling of the programming device was again explained to the patients and their relatives. In addition, all patients were routinely evaluated twice a year in our outpatient department.

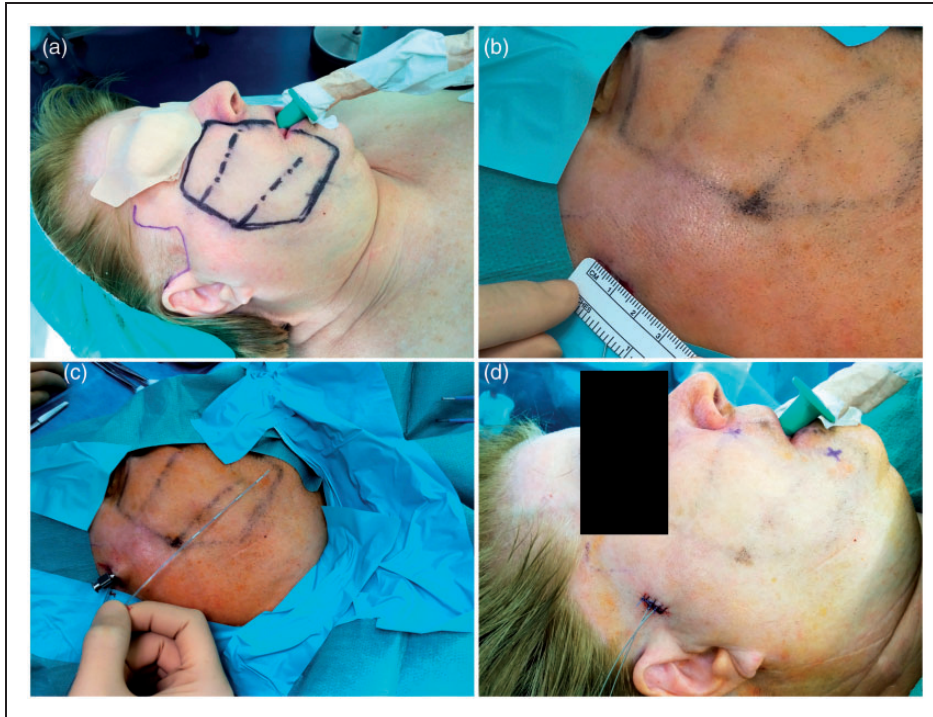


Figure 1. Implantation of two electrodes for trial stimulation in the right ION and MN areas. (a) The painful area and the planned trajectories of the electrodes have been delineated preoperatively. The hairline has been marked and a small area shaved. (b) A 1 cm–1.5 cm incision is made and dissection is performed to visualize the fascia. (c) A 15-Ga Tuohy needle is inserted subcutaneously to allow for advancement of the electrode. (d) Both electrodes are externalized and sutured to the skin. The crosses beneath the ala of the nose and the lower lip mark the tips of the electrodes. ION: infraorbital nerve; It = left; MN: mandibular nerve.



Figure 2. Postoperative radiograph in a patient after definite implantation of two PFNS electrodes in the left ION and MN areas. PFNS: peripheral nerve field stimulation; ION: infraorbital nerve; MN: mandibular nerve.

The follow-up was complemented by telephone interviews about current maximum pain intensity on the numeric rating scale, complications, side effects, and changes in medication. All patients signed a written informed consent form for publication of their data. The stated maximum pain intensity was then compared to the preoperative value.

Results

In eight patients, 12 permanent electrodes and eight generators were implanted (four patients had one and four had two electrodes). Average follow-up time was 11.3 months after the implant (range 5–28 months) with no patient lost. Two more patients underwent trial stimulation: An 85-year-old man with post-herpetic trigeminal neuralgia stated contradictory effects, thus the trial was regarded as negative. A 64-year-old woman with painful trigeminal neuropathy following radiation treatment for MALT lymphoma showed no marked improvement upon trial stimulation.

In our series, all patients with permanent electrode implantation experienced a lasting and significant pain reduction. The mean pain intensity during the most intense intervals, such as during a pain attack or with constant pain when attacks were absent, was 0.75 (range 0–3), compared to 9.3 before electrode implantation. Six patients (75%) were completely pain free at the time of latest follow-up. Five patients were able to reduce medication; two of them no longer took any analgesics (Table 2). Of the two patients who were not pain free, both stated a maximum pain intensity of 3 at the latest follow-up. One never had attacks but a PIFP with constant pain, and the other had a classical trigeminal neuralgia with constant background pain that did not vanish completely; however, no attacks occurred anymore as compared to several attacks per week preoperatively.

Two patients required revision surgery because of minor complications. In one, an electrode had to be replaced a year and a half after implantation because of an electrode defect. Another had a minor wound healing deficiency that necessitated debridement four months after implantation. No hardware removal had to be performed. In one patient, a dislocation of the IPG in the abdominal wall arose, probably because of insufficient fixation during its implantation. However, function was uncompromised and the patient decided against a revision. We observed no infections or other serious complications. Stimulation-dependent side effects were virtually absent: One patient reported hypoesthesia of the scalp on the stimulated side and one has noticed a sensitivity to weather changes with slight dull

sensations on the stimulated side that were difficult to localize but not painful in character.

Discussion

This retrospective analysis of 10 patients with intractable facial pain suggests that PNFS could turn out to be an effective treatment option for refractory trigeminal neuropathic pain even in an elderly population with comorbidities, provided the results can be confirmed in randomized controlled trials.

In our series, five individuals suffering from classical trigeminal neuralgia, along with two patients having painful trigeminal neuropathy attributed to multiple sclerosis and one dealing with PIFP, have benefitted from PNFS. Overall, the outcome was excellent, with six of the individuals being pain free after implantation and two showing marked improvement. Some minor complications arose but none of them were severe.

PNFS has been reported to yield success in facial pain syndromes before, yet reports remain rare. Slavin and Wess first described it as trigeminal branch stimulation (28). Johnson and Burchiel (2004) reported successful PNFS in 10 patients with trigeminal post-herpetic neuralgia and posttraumatic neuropathic pain (20). Amin et al. successfully used the technique in patients with supraorbital neuralgia (23). Narouze and Kapural reported on a patient suffering from cluster headache who benefitted from supraorbital stimulation (21). Out of two series including patients treated with occipital nerve stimulation, Slavin et al. reported on nine patients and Verrills et al. reported on 10 patients, which in both cases were not elaborated on in terms of etiologies or patient characteristics (15,6). Recently, Ellis et al. reported on PNFS testing in 35 patients and definite implantation in 15 patients with intractable facial pain (27). The patient population was distinctly different from ours with a mean age of 53 years and a mean symptom duration of 5.6 years compared to a mean age of 74 years and a mean symptom duration of 10.6 years in our study. Furthermore, as in many previous reports, the electrodes were placed according to anatomical landmarks. For example, for implantation into the supra-orbital or infraorbital region, the electrodes were inserted 1 cm above or below the orbital rim, respectively, while we did not follow anatomical landmarks, but determined the exact site of implantation according to the patient's individual pain distribution. Ellis et al. (27) report a benefit from trial stimulation in only 49% of patients, while in our study the response was 80%. This disparity may have to do with differences in patient characteristics or be a coincidence. However, a superior effect of implantation according to pain distribution rather than according to anatomical landmarks cannot be excluded.

Otherwise, only smaller patient groups or single case reports have been published (16–18,19,22,24–26).

There is no consensus about the optimal implantation technique and operative setting in PNFS. In both theoretical models and clinical findings an implantation depth of approximately 1 cm below the skin was found to result in the highest ratio of stimulated A β - to A δ -fibers (29,30). A deeper implantation may diminish stimulation effectivity while a more superficial placement implicates the risk of burning pain in the affected area. These data, however, refer to low back tissue and obviously facial skin rarely provides 1 cm of subcutaneous tissue. Yet, we have never observed stimulation-induced burning or other painful sensation in facial PNFS unless the amplitude was set too high.

In our opinion, trial stimulation is mandatory in order to select patients most likely to benefit from this treatment modality. As to local or general anesthesia during implantation of a lead for a stimulation trial, in our experience, intraoperative testing is not of paramount significance. We believe that careful and precise preoperative delineation of the relevant area is of higher importance than a subjective description of paresthesia during a brief stimulation under—the small scale of this minor surgical procedure notwithstanding—a stressful and unpleasant situation for the patient. In the elderly population of our series (only two patients were younger than 70 years) lack of compliance during electrode placement occasionally occurred, forcing us to rely on our preoperative markings. While we have no general objections to local anesthesia for such a small procedure even when refraining

from intraoperative testing, we argue that the decision should be made in accordance with the patient and that despite the briefness of the surgery, general anesthesia may be considered for patient comfort.

We didn't use intraoperative fluoroscopy as, in our opinion, it doesn't add to implantation accuracy when not relying on anatomical landmarks such as the supraorbital or infraorbital groove. Instead, we prefer to mark the painful area preoperatively, as described above.

Our study is limited by its retrospective, observational nature and the small patient cohort. Important data, such as activities of daily living and quality of life estimates, have not been systematically surveyed in the follow-up period. Prospective studies, especially randomized controlled trials, are needed to more reliably evaluate the efficacy of PNFS in intractable facial pain syndromes.

Conclusion

PNFS for chronic refractory trigeminal neuralgia and trigeminal neuropathy of different etiologies may be an effective procedure when first-line therapies have failed. Likewise, a patient with non-neuropathic PIFP showed significant improvement. Even in a mostly elderly patient population with long symptom durations, the response rate was excellent at follow-up times of up to 28 months and no serious complications arose. Prospective studies, especially randomized controlled trials, are needed to further evaluate the use of PNFS in intractable facial pain syndromes.

Clinical implications

- Peripheral nerve field stimulation (PNFS) lowered the average pain intensity in patients suffering from intractable facial pain from 9.3 to 0.75 on the visual analog scale.
- After a positive trial stimulation, all patients experienced a lasting significant improvement at follow-up times of up to 28 months.

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