Electrical stimulation of the trigeminal nerve root for the treatment of chronic facial pain

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Between March 1990 and December 1992, 23 patients with chronic intractable facial pain due to various forms of injury to the trigeminal nerve or nerve root underwent implantation of an electrical stimulating system to treat their pain. All patients had failed previous extensive pain treatment efforts. A monopolar platinum–iridium electrode was implanted on the trigeminal nerve root via percutaneous puncture of the foramen ovale. All patients experienced at least 50% reduction in pain intensity during a period of trial stimulation and underwent internalization of the electrode and connection to a completely implanted pulse generator. Independent assessment of the effect of stimulation was obtained by a specially trained nurse practitioner.

Over a mean follow-up period of 24 months, six patients reported nearly complete relief of pain and six others reported at least a 50% reduction in pain intensity using a visual analog scale. Thus, 12 (52%) of the 23 patients achieved 50% or greater reduction in pain intensity. Although changes in the patterns of analgesic medication usage were few, six patients (26%) now experience a normal life style. Only one complication was seen, namely a dislocated electrode, which was easily replaced. Chronic electrical stimulation of the trigeminal nerve root appears to be an easy and safe technique for providing relief of chronic facial pain related to injury to the trigeminal nerve in a significant number of patients.

KEY WORDS • trigeminal nerve • facial pain • nerve root stimulation • implanted stimulator

In 1980 and 1986, the Swedish neurosurgeons Meyerson and Håkanson described a technique to stimulate the gasserian ganglion by means of a bipolar electrode sutured to the dura over the ganglion and inserted via an open surgical subtemporal approach. Later, a percutaneous stimulation technique was used by Meglio and Steude. In 1986, Spaziante, et al., described a simplified percutaneous technique for insertion of a trigeminal stimulating electrode. Although it seems likely that the electrode used by Meyerson and Håkanson stimulates the trigeminal ganglion, because it is placed directly over the ganglion, it is not clear if the percutaneously inserted electrodes activate the ganglion or the trigeminal sensory root. It is also unclear whether this distinction between stimulation loci is of any practical importance.

Electrical stimulation of the trigeminal ganglion or nerve root has been used to treat chronic facial pain, usually associated with various forms of injury to either the peripheral branches of the trigeminal nerve or the trigeminal nerve root, so-called “trigeminal neuropathy.” The number of patients reported as being treated with a permanent percutaneously placed electrode, however, is very small and the follow-up intervals quite short. In addition, no electrode has been approved in the United States for trigeminal stimulation. The current study was undertaken to expand our knowledge of this potentially useful technique and to extend the application of electrical stimulation for treatment of chronic pain, which has been used successfully with spinal cord and deep brain stimulation.
to the trigeminal system and chronic facial pain. This report describes the author’s experience with the placement of a totally implanted, percutaneously placed electrode system for chronic electrical stimulation of the trigeminal sensory root for treatment of chronic facial pain in 23 patients between 1990 and 1993.

**Clinical Material and Methods**

This study was conducted under an Investigational Device Exemption from the United States Food and Drug Administration. All studies were performed according to the Helsinki II Declaration and were approved by the Human Subjects Review Committee of the University of California, Irvine. Informed consent was obtained from each patient with the full understanding that lack of participation or their desire to terminate their participation could occur without prejudice to their subsequent treatment.

**Implantation Technique**

The stimulating electrode (Quintatrigeminal, Medtronic, Inc., Minneapolis, MN) consisted of a monopolar platinum–iridium lead with two sets of four “tines” located 5 and 10 mm from the distal tip of the electrode and a central stylet (Fig. 1). The purpose of the tines was to prevent the electrode from becoming dislodged after implantation. The electrode was inserted percutaneously through a No. 14 needle via a puncture of the foramen ovale, under local anesthesia with intravenous sedation in 22 patients and under general anesthesia in one patient. The technique of insertion was identical to that used for percutaneous glycerol or radiofrequency trigeminal rhizolysis for treatment of trigeminal neuralgia, except that the needle was inserted via a 5-mm incision centered approximately 2.5 cm lateral to the labial commissure.\(^1\) Fluoroscopic monitoring using first the oblique and then the lateral views guided needle placement. With the foramen ovale observed on the oblique fluoroscopic view, the needle was directed toward the center of the foramen ovale. Lateral puncture of the foramen ovale was specifically avoided to prevent accidental puncture of the temporal lobe or insertion of the electrode subtemporally rather than in the trigeminal cistern.\(^2\) Once cerebrospinal fluid flow was obtained through the needle, the electrode was inserted and advanced under fluoroscopic guidance until paresthesias could be induced in the distribution of the patient’s pain by monopolar electrical stimulation between the electrode tip and an indifferent electrode pad attached to the skin of the shoulder. The electrode tip, as observed in the lateral fluoroscopic view, usually lay within a few millimeters of the shadow of the clivus.

As is seen with placement of electrodes for radiofrequency electrocoagulation of the trigeminal root, advancement of the electrode along the medial and posteriorly directed trajectory of the inserting needle caused the induced paresthesias to progress from the third to the second and finally to the first division of the trigeminal nerve sensory distribution. In some patients paresthesias could be induced in two or more (usually contiguous) branches simultaneously but in some patients only a single division could be electrically activated despite changes in electrode position and in stimulation parameters. If the patient’s pain involved the territory of more than one division and paresthesias could not be induced to cover that region completely, then the electrode was positioned to produce paresthesias distributed as widely as possible but concentrated to overlap the distribution of the most painful area. Typical stimulation parameters included pulse duration of 0.1 to 0.3 msec, frequency 50 to 60 Hz, amplitude 0.25 to 1.50 V. Subsequently, the introducing needle and central stylet were removed and the proximal end of the electrode was tunneled subcutaneously around the mandible and connected to a percutaneous extension lead, which was brought out via a transverse incision approximately 1.5 cm long in the upper part of the neck. Postoperative lateral (Fig. 2 upper) and anteroposterior (Fig. 2 lower) plain x-ray films confirmed the final electrode position.

Percutaneous trial stimulation was then performed over the next several days and evaluation was made of the patient’s pain intensity based on a visual analog scale (VAS) pain score, the analgesic medication needs, and the patient’s general level of satisfaction with the implant.
the VAS pain score decreased by at least 50% and if the patient was satisfied with the result, the electrode was internalized, usually with the patient under general anesthesia but sometimes under local anesthesia with intravenous sedation. Trial stimulation periods ranged from 1 to 5 days. At the internalization procedure, the percutaneous extension lead was removed and the proximal electrode was connected to an extension lead which was passed subcutaneously from the neck incision to the upper chest area. A transverse incision was made parallel and approximately 1 cm caudal to the clavicle, and a subcutaneous pocket was created. The distal end of the extension lead was connected to a lithium battery-powered completely implanted pulse generator system (ITREL, Medtronic, Inc., Minneapolis, MN) (Fig. 3). After the patient recovered from the anesthesia, the pulse generator was programmed to induce paresthesias in the distribution of the pain without producing undesirable side effects (such as new pain, paresthesias in nonpainful area, or contraction of the muscles of mastication). Patients were usually discharged from the hospital 1 to 2 days after the final implantation and followed on an outpatient basis at least every 3 months.

**Patient Characteristics**

Twenty-three patients (17 women and six men) aged 44 to 78 years (mean 51 ± 15.2 years) underwent electrode implantation for treatment of chronic facial pain that had been present for 6 to 360 months (mean 105.65 ± 99.7 months). All patients had sustained various forms of trauma either to peripheral trigeminal nerve branches or to the trigeminal nerve root. Nine patients had undergone a variety of surgical procedures to treat dental pathology and disorders of the temporomandibular joint, seven patients had sustained accidental external mechanical injuries to the face including facial fractures, five patients had undergone surgical treatment of trigeminal neuralgia and suffered anesthesia dolorosa, and two patients sustained surgical injuries to the trigeminal nerve root with associated anesthesia dolorosa during excision of cerebellopontine angle tumors.

The trigeminal nerve pain was located in the distribution of the third division only in eight patients, of all three divisions in six, of the first and second divisions in five, and of the second and third divisions in four. No patient experienced isolated pain in either the first or second division. Eighteen patients exhibited varying degrees of orofacial sensory loss within the distribution of the trigeminal nerve division that gave rise to their pain. In 10 patients the sensory loss was described as marked, in five as moderate, and in three as mild. Fifteen patients had undergone an average of 2.4 surgical procedures in an attempt to obtain relief of their pain, whereas eight patients had had no prior surgical intervention for pain. Ten patients used various forms of narcotic analgesics for pain relief on a chronic basis, 10 used nonnarcotic analgesics, and three took no regular medication for pain. All patients had been treated with tricyclic antidepressant and anticonvulsant medications prior to implantation and nine were taking such agents at the time of electrode implantation. A variety of other treatment techniques had been used to treat the patients’ pain, including transcutaneous electrical stimulation, nerve blocks, sympathetic blocks, acupuncture, biofeedback, and psychological therapy. Patients with psychoses or severe personality disorders with major components of hysteria, hypochondriasis, and somatization were excluded from consideration for electrode implantation.

Preoperative pain was assessed using the VAS and a modified form of the McGill Pain Questionnaire (MPQ). Follow-up evaluations were performed at 3, 6, 12, and 24 months after treatment. Although clinical follow-up visits were conducted by the author, the data in this report concerning the patients’ pain levels and their responses to the treatment were obtained by an independent, specially trained nurse practitioner.

**Results**

All 23 patients in this series experienced substantial pain relief (more than 50% on VAS evaluation) during trial screening stimulation using the percutaneous lead extension, and all underwent permanent implantation. Relief of the patient’s original pain was almost always easily separated from any pain related to the implant procedure itself. Cessation of stimulation resulted in return of pathological pain, usually within a few minutes. Thus, stimulation effectiveness could be reassessed on multiple occasions (usually at least four) within a 24-hour period.

**Pain Relief**

All patients have been followed for at least 1 year since the time of implantation and the mean follow-up period is 24 months (range 12 to 45 months). Eight patients discon-
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Table 2: Relation of pain relief to etiology of pain

<table>
<thead>
<tr>
<th>Pain Etiology</th>
<th>No. of Cases</th>
<th>Pain Relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental/TMJ*</td>
<td>9</td>
<td>2 Complete</td>
</tr>
<tr>
<td>Trauma</td>
<td>7</td>
<td>2 Complete</td>
</tr>
<tr>
<td>Anesthesia dolorosa</td>
<td>5</td>
<td>2 Complete</td>
</tr>
<tr>
<td>Tumor</td>
<td>2</td>
<td>0 Complete</td>
</tr>
<tr>
<td>Total</td>
<td>23</td>
<td>6 Complete</td>
</tr>
</tbody>
</table>

* TMJ = temporomandibular joint.

Table 3: Relation of pain relief to extent of sensory loss

<table>
<thead>
<tr>
<th>Sensory Loss</th>
<th>No. of Cases</th>
<th>Pain Relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>5</td>
<td>1 Complete</td>
</tr>
<tr>
<td>Mild</td>
<td>3</td>
<td>1 Complete</td>
</tr>
<tr>
<td>Moderate</td>
<td>5</td>
<td>1 Complete</td>
</tr>
<tr>
<td>Marked</td>
<td>10</td>
<td>6 Complete</td>
</tr>
<tr>
<td>Total</td>
<td>23</td>
<td>6 Complete</td>
</tr>
</tbody>
</table>

Table 4: Mean percentage decrease in McGill Pain Questionnaire ratings

<table>
<thead>
<tr>
<th>Follow Up</th>
<th>Sensory</th>
<th>Affective</th>
<th>Evaluative</th>
<th>Total Pain Rating Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 mos</td>
<td>57.48</td>
<td>87.50</td>
<td>62.50</td>
<td>67.85</td>
</tr>
<tr>
<td>6 mos</td>
<td>39.32</td>
<td>54.37</td>
<td>49.09</td>
<td>47.88</td>
</tr>
<tr>
<td>12 mos</td>
<td>67.57</td>
<td>74.58</td>
<td>48.48</td>
<td>70.62</td>
</tr>
<tr>
<td>24 mos</td>
<td>73.61</td>
<td>82.61</td>
<td>100.00</td>
<td>82.64</td>
</tr>
</tbody>
</table>

* Data from patients who continued to use their stimulator, expressed as a percentage of preoperative score.

Table 5: Mean electrical stimulation parameters in the study period

<table>
<thead>
<tr>
<th>Time of Measurement</th>
<th>Amplitude (V)</th>
<th>Pulse Duration (μsec)</th>
<th>Frequency (Hz)</th>
</tr>
</thead>
<tbody>
<tr>
<td>At implant postop</td>
<td>0.67 ± 0.64</td>
<td>165 ± 84.8</td>
<td>41.25 ± 19.09</td>
</tr>
<tr>
<td>3 mos</td>
<td>0.52 ± 0.42</td>
<td>168 ± 98.9</td>
<td>63.05 ± 36.97</td>
</tr>
<tr>
<td>6 mos</td>
<td>0.86 ± 0.66</td>
<td>166.15 ± 80.9</td>
<td>52.31 ± 27.58</td>
</tr>
<tr>
<td>12 mos</td>
<td>0.82 ± 0.40</td>
<td>197.78 ± 100.97</td>
<td>67.22 ± 41.99</td>
</tr>
<tr>
<td>24 mos</td>
<td>0.70 ± 0.26</td>
<td>170 ± 17.32</td>
<td>50.33 ± 14.5</td>
</tr>
</tbody>
</table>

Continued stimulation due to ineffective pain control between 1 and 18 months after implantation. In four of these it was impossible to completely cover the distribution of their pain with stimulation-induced paresthesias. The mean VAS pain scores before implantation and at 3, 6, 12, and 24 months after implantation are shown in Table 1. There was a significant decrease in pain intensity at all follow-up intervals. Of the 15 patients who continued to stimulate regularly, six reported nearly complete relief of pain, six described a decrease in VAS score of 50% or more, and three reported less than 50% pain relief. Thus, 12 (80%) of 15 patients who continued to stimulate regularly reported reduction in pain intensity of greater than 50%. Five (56%) of nine patients with pain due to dental or temporomandibular joint etiology achieved the same degree of pain relief, whereas four (57%) of seven with posttraumatic pain, three (62%) of 13 patients with postrhizotomy pain, and none of two with neuropathic pain and facial anesthesia dolorosa achieved the same degree of relief (Table 2). There was a suggested correlation between the degree of sensory loss and the likelihood of stimulation achieving 50% or greater reduction in pain intensity (Table 3). Eight (62%) of 13 patients with mild, moderate, or no loss of facial sensation achieved 50% or greater reduction in pain intensity whereas only four (40%) of 10 with marked sensory loss achieved the same degree of pain relief.

The MPQ, a series of three major classes of word descriptors (sensory, affective, and evaluative), was also used to measure the effectiveness of treatment. Table 4 depicts mean changes in the three major subtest scores and the overall Pain Rating Index (PRI), expressed as a percentage of the patients’ baseline preoperative scores. All of the scales confirmed significant reductions in pain ratings. It is important to note that these ratings were obtained only from patients who were actively using their stimulating devices. Those who had discontinued stimulation or whose stimulator had been removed were not evaluated.

Despite these improvements in reports of pain intensity and despite the fact that 12 of the 15 patients who continued to use their stimulators reported “beneficial” results, there were few changes in analgesic medication usage. Only two patients who received narcotic analgesics preoperatively discontinued their use after electrode implantation, although three others reduced the amounts of narcotic agents ingested. Five patients did not use narcotic analgesics either pre- or postoperatively.

Of the 12 patients who continued to use stimulation and reported greater than 50% reduction in pain intensity, six functioned normally in their daily lives. The other six patients continued to function in the mode of chronic pain patients with frequent physician visits, strong focus on their pain complaints, and significant restrictions in activities of daily living and interpersonal relationships. Stimulation parameters did not vary greatly over the follow-up period (Table 5). Alterations in amplitude, pulse duration, and frequency of stimulation were made in patients who reported suboptimal pain relief, and the final settings were those that produced the most effective relief. Attempts to use intermittent rather than continuous stimulation did not improve the incidence or magnitude of pain relief, and all patients eventually achieved their best pain relief with continuous rather than intermittent stimulation.

Complications

No serious complications occurred. One patient experienced displacement of an electrode shortly after implantation (Fig. 4). The electrode was removed and a new one...
was implanted uneventfully. In two patients relatively heavy intravenous sedation and in one case general anesthesia was used for the initial electrode implantation because of the patients’ concerns about pain during the procedure. Postimplant stimulation in all three elicited paresthesias that did not encompass the orofacial distribution of the patient’s pain. In each case, the electrode was successfully repositioned under local anesthesia. No instances of electrode breakage, infection, or delayed lead displacement were encountered.

Discussion

Peripheral nerve stimulation was the first clinical application of the gate control hypothesis of pain to use an implanted electrode system.\(^\text{10,20}\) It is not clear to what extent electrical stimulation of the trigeminal ganglion or nerve root may be similar to or different from peripheral nerve stimulation. In fact, there is no clear understanding of the mechanism by which either peripheral nerve or trigeminal nerve stimulation relieves pain or if pain relief so engendered has anything at all to do with the proposals of the gate hypothesis.\(^\text{10}\) Further speculation about mechanisms at this time appears to serve little useful purpose.

Beginning in 1977, Meyerson and Håkanson\(^{11,12}\) employed chronic stimulation of the trigeminal ganglion by way of an electrode placed directly on the dura overlying the trigeminal cistern via the extradural subtemporal approach. They described 14 patients with chronic facial pain related to various forms of injury to the trigeminal nerve from surgery on the paranasal sinuses, surgical treatment of trigeminal neuralgia, dental extractions, and (in three patients) unknown causes. These patients were followed for a mean of 4 years (range 1 to 7 years) and eight (57%) of the 14 reported complete or very good pain relief. In 1984, Meglio\(^{17}\) and Steude\(^{18}\) each described a percutaneous trigeminal stimulation technique. The system used by Meglio was identical to that employed in this study except that Meglio used a radiofrequency-coupled external stimulator rather than the completely implanted battery-powered pulse generator that we used. Meglio reported satisfactory pain relief in all of his five patients. On the other hand, Broggi, et al.,\(^{1}\) described eight patients with chronic facial pain treated with the identical stimulation technique used by Meglio but only three of their patients achieved nearly complete pain relief, two achieved 50% relief of pain, and three had no significant benefit. Their follow-up period was 7 to 20 months. Six of their patients suffered complications, four due to electrode disconnection and two with infections that required removal of the entire system and subsequent reimplantation.

Lazorthes, et al.,\(^{6}\) described 21 patients treated using trigeminal ganglion stimulation, in some cases via a percutaneous technique and in some cases via the open technique of Meyerson and Håkanson.\(^{11,12}\) At their 2-year follow-up examination, three patients had “stable and excellent analgesia.” Only seven of 21 patients were considered to have sufficient pain relief during a 3-week percutaneous stimulation trial to warrant a permanent implant. Nevertheless, Lazorthes, et al., thought that they had “confirmed the efficacy” of chronic trigeminal stimulation for treatment of chronic facial pain. Thus, although all authors believe trigeminal nerve stimulation to be beneficial, the success rates and complications vary.

Aside from the early reports of Shelden and colleagues\(^{13,14}\) and Cook, et al.,\(^{2}\) the present report describes the only patient population in the United States studied using a single technique. The spectrum of pain types we treated is essentially identical to that described by other authors, except that we did not attempt to treat facial pain due to postherpetic neuralgia. Unlike the author’s experience with other forms of electrical stimulation (peripheral nerve, spinal cord, brain), all patients in this series experienced at least a 50% reduction in pain intensity with
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trigeminal nerve root stimulation during the trial interval and underwent permanent implantation of the electrode. Reduction of the patient’s pain usually was virtually immediate after electrical activation via the percutaneous extension lead and external battery power supply. Cessation of stimulation led to a return of pain, usually within a few minutes and therefore repeated assessment of the effectiveness of trial stimulation was possible during a relatively short time (1 to 5 days). Unfortunately, no aspect of the patient’s response to trial stimulation (complete or partial pain relief) and no aspect of the underlying pain complaint or its cause could effectively predict the relatively early failure observed in eight patients, who discontinued stimulation during the first 18 months after implantation.

Our overall success rate in providing satisfactory pain relief (12 of 23 patients, or 52%) using a percutaneous technique compares favorably with the 57% success reported by Meyerson and Håkanson11 and avoids the need for craniotomy with its attendant risks and costs. Lasting pain relief was confirmed both by a persistent reduction in pain intensity of at least 50% on the VAS scale and by a persistent decrease in all of the MPQ scores. The MPQ is used to assist patients in describing their subjective pain experiences and has been quantified by the assignment of intensity values to the various descriptions.9 Subsequent studies using the MPQ have questioned whether the major subtest scores (sensory, affective, and evaluative) or other more detailed subscores represent the better method of assessing pain or if the overall score, the so-called PRI is preferable. In the patients in this study both the major subtest scores and the PRI decreased.5,8,21 Like other authors, we have found that facial pain associated with complete loss of facial sensation does not respond well to chronic stimulation, because only 40% of our patients with marked sensory loss achieved greater than 50% relief of pain, whereas 60% of those with no sensory loss or only mild or moderate sensory loss, achieved the same degree of pain relief. The exact etiology of the patient’s facial pain seemed less useful as a determinant of the likelihood of pain relief than the degree of sensory loss. It is also important to realize that, although only 40% of patients with marked sensory loss achieved good pain relief, three of the six patients in the overall series who achieved virtually complete relief of pain had marked loss of facial sensation. Gorecki, et al.,3 also noted effective relief of neuropathic facial pain by electrical stimulation of the trigeminal ganglion.

These results were achieved without any major complications and with only a few minor problems of any kind. Only one patient experienced a hardware complication (electrode migration); this can be prevented by the simple use of an anchoring suture around the connection between the stimulating electrode and the extension lead. The stimulation parameters have remained relatively constant over long follow-up periods. The electrode could be improved to provide multiple active stimulation sites near the tip. This would be particularly useful for achieving stimulation-induced paresthesias in patients with pain in all three trigeminal divisions. With the current monopolar electrode, it may be impossible to obtain paresthesias throughout the entire orofacial distribution of the trigeminal nerve. Four of the eight patients who discontinued stimulation due to ineffective pain relief might have benefited from a multicontact electrode, which would permit greater flexibility in activation of a wider area of the trigeminal nerve root. A multicontact electrode would also provide the possibility for bipolar electrical stimulation, which in other neurostimulation settings (such as involving spinal cord and brain) has proved to be more effective than monopolar stimulation. The open surgical technique of Meyerson and Håkanson12 uses a multicontact electrode but has the disadvantage of requiring a craniotomy, with its attendant risks and costs, for implantation. Lazorthes, et al.,5 adapted a percutaneously placed multicontact spinal cord stimulating electrode for this purpose but such an electrode is not approved for use in the United States.

Conclusions

Electrical stimulation of the trigeminal sensory nerve root provides pain relief for a significant proportion of patients with intractable facial pain related to various forms of injury to the trigeminal nerve. The technique is simple, nondestructive, and reversible, and the complications are minor and correctable. This method may be preferable to thalamic stimulation, thalamotomy, or trigeminal dorsal root entry zone lesions, all of which carry greater risks, are more expensive, and provide no better success rates. Nevertheless, it is recognized that exact indications for these procedures do not exist. These latter techniques could be reserved for situations in which trigeminal nerve root stimulation has proved ineffective.

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References


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