A Simple Technique for Surgical Placement of Occipital Nerve Stimulators without Anchoring the Lead

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Abstract

Introduction Greater occipital nerve stimulation is applied in the treatment of occipital neuralgia, headache, and fibromyalgia. Multiple techniques have been described along with their subsequent complications. The most frequent complications are related to lead migration, infection, and undesired stimulation effects. Revision surgery occurs in up to 60% of the cases.

Patients and Methods A total of 92 implantations, 51 trials (6–10 weeks), and 41 permanent implantations (follow-up: 36–72 months) were performed in a single center using a simple technique without an anchoring device. The electrode is tunneled at a 45-degree angle to prevent migration. Complications and additional surgeries were recorded during the follow-up period.

Keywords

- occipital nerve stimulation
- ► technique
- migration
- anchoring
- ► sharp angle

Results All patients had bilateral greater occipital nerve stimulation. A total of 16 complications (17.4%) occurred. Seven patients (7.6%) underwent additional surgery. The major complication was infection; lead migration made up only 3.3% of the complications.

Conclusions We present a simple technique without the use of an anchoring device that is feasible in achieving bilateral occipital nerve stimulation and decreases the complications, especially lead migration.

Introduction

Since Wall and Sweet came up with the concept of peripheral nerve stimulation for the treatment of pain in 1967, a lot of interest has been shown. However, the publications in this field were rare in those days because of the invasive methods used to apply the technique. Peripheral nerve stimulation included the dissection of the targeted nerve, placing an electrode next to it. This demanded big exposures and certain

surgical skills. Greater occipital nerve stimulation was performed in a similar way.²

Greater occipital nerve stimulation has been applied for a variety of pain syndromes such as chronic migraine, occipital neuralgia, cluster headache, and fibromyalgia.^{3–6}

Since the publication of Weiner and Reed in 1999, the burden of surgery has changed. They presented a minimally invasive method that places an electrode at the greater

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occipital nerve dermatome using a Tuohy needle.⁷ This method shifted the focus back to the treatment of pain by stimulating the peripheral nerve. Multiple techniques have been described making use of single leads, multiple leads, cylindrical percutaneous leads, and surgical leads in multiple directions and ways.⁴ Each of these methods has its own benefits and complications. However, each surgery involves complications and their management.

The complications are well described for occipital nerve stimulation. The most common ones are lead migration, infection, undesired stimulation effects, and hardware failure.^{8–10} Among them, lead migration gives rise to revision surgery rates up to 33% at 6 months after stimulation.^{8,10,11}

A few techniques are proposed to prevent migration. Anchoring of the lead, with or without anchoring devices, and the appliance of strain relief loops are widely used to prevent migration. ^{10,12,13}

Anchoring can be performed in multiple ways. It can be done with a simple nonresorbable stitch (which might increase the risk of damaging the electrode) or by making use of anchoring devices, produced by most of the major neuro-modulation industry companies. ¹⁰

The anchoring technique is important; however, the substance anchored to is even more critical. Solid vast tissue is needed to anchor the lead. Suitable tissue at the high cervical area may be difficult to find. The periost and the fascia are excellent tissues for this purpose.

Finding these tissues and fixing the anchoring device demands particular skills in dissection and sometimes a bigger exposure. The anchoring device also demands a certain exposure of tissue. Various techniques have been described ranging from medial fixation to lateral fixation behind the ear. ^{12–15} All of these techniques have their benefits and drawbacks. In surgery the simplicity of the technical procedure limits the number of complications.

We present a simple technique for occipital nerve stimulation that minimizes lead migration without the use of an anchoring device.

Methods

Patients

Overall, 92 implantations were performed at the University Hospital Antwerp. Patients were implanted during the period 2007 to 2012. Of these, 41 patients were implanted with a permanent system, that is, an electrode, an extension lead, and an internal pulse generator (follow-up time ranged from 36 to 76 months). Fifty-one patients were implanted with a trial lead for a period ranging between 6 and 10 weeks. All complications related to the device and the procedures were registered during the follow-up time.

Surgical Procedure

Patients get implanted under local anesthesia for the trial procedure and under general anesthesia for permanent implantation. Patients are positioned in the prone position with their head resting on a horseshoe headrest, creating a mild flexion of the cervical spine. The area of skin underneath the

inion is shaved, and the midline marked with a surgical marker. Subsequently a point is marked on the midline ~ 1 cm underneath the inion. This is defined as 0 cm on the horizontal axis where the center of the electrode has to be positioned. The electrode array length of the lead (Octrode, St. Jude Medical, Plano, Texas, United States) is 5.2 cm, so 2.6 cm of the array should be positioned to the left of the marked point and 2.6 cm to the right. A line of 5.2 cm is drawn at the back of the head, just underneath the inion on an imaginary line between the two pinnae of the ears, projecting the electrode location and incision location. Subsequently a second line is drawn to project the subcutaneous tunneling trajectory. This line departs from the incision side and is in a 45-degree angle with the electrode position. This angle prevents the electrode from migrating (**Fig. 1**).

Depending on the side of the permanent implantable pulse generator (IPG), a knife-stab incision is made either at the left end or the right end of this line (the lead will cross the midline, so the incision is made at the opposite site of the permanent IPG). A slightly curved Tuohy needle is marked at 5.2 cm, the length of the electrode, measured from the tip. The Tuohy needle is inserted in the subcutaneous tissue just above the periost and deep enough to prevent lead tip erosion. The needle is advanced until the mark of 5.2 cm is reached. The next step is to tunnel the subcutaneous trajectory for the electrode. A sharp tunneling device is used to tunnel the electrode to the cutaneous exit site for a trial electrode or to a

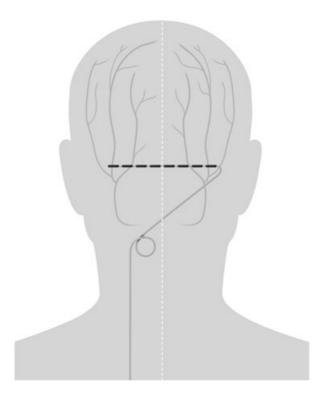


Fig. 1 A schematic overview of the trial implantation. The electrode is positioned just underneath the inion in that way that four contact points are positioned at the left side and four contact points at the right side. The electrode is tunneled at a 45-degree angle to prevent migration. The lead exits the subcutaneous tissue just underneath the hairline.

subcutaneous pocket at the cervical area for the permanent implantation. As soon as both the tunneling device and the Tuohy needle are in place, the stylus is removed and the lead is advanced inside the Tuohy needle until the tip of the needle is reached. The Tuohy needle is retracted making use of the hold-pull technique, and the lead is advanced through the plastic sheet of the tunneling device. The plastic sheet is removed, and the lead is pulled through just until it fits into place in the incision and lies completely in the subcutaneous tissue. If desired, the electrode can be anchored at the 45-degree angle at the incision site with a nonresorbable stitch; however, we did not perform this in the patient population described here.

Concerning the trial implantation, the electrode can be tunneled to an exit point just at the hairline at the end of the tunneling trajectory. At this site, the electrode can be sutured to the skin with a nonresorbable suture or with the help of an anchoring device.

For the permanent implantation, a second incision is made at the midcervical area, just 3 cm lateral to the midline in a horizontal direction. A subcutaneous pocket is created ($\sim 1 \times 1$ cm) to provide space for a strain relief loop in the lead at this highly mobile point. After forming the strain relief loop, the electrode can be tunneled either to the IPG or to an extension lead, depending on the preferred location of the IPG.

We preferred the gluteal area to implant the IPG. A horizontal incision is made, in accordance with the size of the IPG, at the gluteal area, and a subcutaneous pocket is made.

At the midscapular area, a \sim 2-cm longitudinal paravertebral incision is made. The lead of the electrode is tunneled from the cervical pocket, after creating the strain relief loop, to this pocket. A connection with an extension lead is made, and after creating another strain relief loop at this location, the extension lead is tunneled to the IPG pocket at the gluteal area to connect it with the IPG (\succ Fig. 2).

Outcome Parameters

During the follow-up periods, the following complications were recorded:

- 1. Hardware-related complications: lead migration, lead tip erosion, erosion of the extension connection, lead breakage
- 2. Biological complications: infection, allergic response to material, local irritation by material
- Stimulation-related complications: muscle spasms, painful skin stimulation

Besides these complications, all patient-reported complications were recorded as well. Treatment and especially revision surgeries or explant surgical treatments of these complications were also noted.

Results

Patients: Trial Implantations

A total of 51 patients were implanted with trial leads (6 men and 45 women). The mean age was 47 years (mean: 46.62 ± 9.82 years). Mean duration of trial implantation

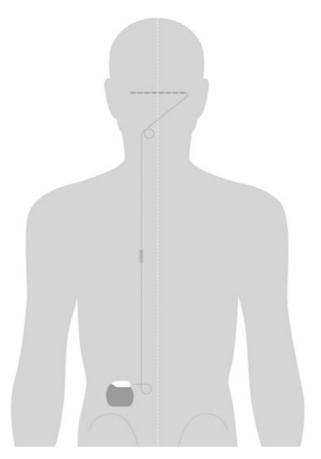


Fig. 2 A schematic overview of the permanent implantation. The electrode is positioned in a similar way as shown in Fig. 1. A strain relief loop is created at the midcervical area and underneath the connection with the extension lead at the midscapular area. The extension lead is tunneled to the pocket where the internal pulse generator is positioned.

was 7 weeks (mean: 6.77 ± 1.78 weeks). All patients were implanted in accordance with the technique previously described.

Patients: Permanent Implantation

A total of 41 patients were implanted with a permanent stimulation device (5 men and 36 women). The mean age was 49 years (mean: 49.02 ± 9.53 years). Mean duration of implantation was 45 months (mean: 45.38 ± 15.6 months).

Complications and Additional Surgeries: Trial Implantation

All the data of the 51 implantations were analyzed. During the trial implantation, 10 complications related to the device or procedure occurred and were registered (19.6%). Lead migration occurred in two patients (3.9%); six patients experienced infection of the subcutaneous tissue (11.8%); one patient had an allergic reaction to the material (2.0%); and one patient experienced undesirable stimulation effects that resulted in pain at the stimulation site (2.0%) (**Table 1**).

Four patients underwent surgery to treat the complication (9.8%). Both of the patients experiencing lead migration underwent lead revision. Infections were treated with oral

 Table 1 Complications in the trial implantations and in the permanent implantations population

	Complication	Trial implantations N = 51 (%)	Permanent implantations $N = 41$ (%)
Hardware related	Connection extension lead erosion	0	1 (2.4)
	Lead tip erosion	0	1 (2.4)
	Lead migration	2 (3.9)	1 (2.4)
Biological	Infection	6 (11.8)	1 (2.4)
	Allergic response to implant material	1 (2)	0
	Persistent pain at implant site	0	1 (2.4)
Simulation related	Muscle spasms	0	0
	Undesirable stimulation effects (pain, anxiety)	1 (2)	1 (2.4)
Total		10 (19.6)	6 (14.6)

antibiotics and resulted in complete resolution, except for two patients whose condition required lead explantation. The patient with an allergic reaction to the material underwent surgery to explant the lead. The undesired stimulation was treated by reprogramming the stimulation parameters (**-Table 2**).

Complications and Additional Surgeries: Permanent Implantation

All the data of the 41 implantations were analyzed. During the permanent implantation with a mean follow-up of 45 months, a total of six complications related to the device and procedure occurred (14.6%). Of these six complications, five patients required revision surgery (12.2%). Lead migration occurred in one patient, leading to revision surgery (2.4%). Lead tip erosion occurred in one patient, leading to revision surgery of the tip (2.4%). One patient experienced erosion of the connection piece of the extension lead, resulting in local revision surgery (2.4%). One patient got a subcutaneous infection at the lead insertion site that was resolved by local

wound debridement, leaving the electrode in place (2.4%), and one patient kept complaining of the undesirable effects of stimulation (skin fiber stimulation) that was resolved by revision of the lead tip (2.4%).

Discussion

We present a simple technique to perform greater occipital nerve stimulation that seems to be feasible in both achieving the desired effect (bilateral greater occipital nerve stimulation) and reducing complications related to the procedure and device. One of the advantages of the technique is that it does not require anchoring devices in the occipital area.

The goal of surgery is defined as stimulation of both of the main branches of the greater occipital nerve, without undesired stimulation that results in muscle spasms and/or skin stimulation. The position of the electrode is of major importance to achieve this goal. It should be neither too superficial nor too deep, which might cause undesired stimulation effects; nor should it be too low in the cervical area.

Table 2 Adverse events leading to additional surgery

Additional surgery	Complications	Total implantations N = 92 (%)	Trial implantations N = 51 (%)	Permanent implantations $N = 41$ (%)
Revision surgery	All	7 (7.6)	2 (3.9)	5 (12.2)
	Lead migration	3 (3.3)	2 (3.9)	1 (2.4)
	Lead tip erosion	1 (1.1)	0	1 (2.4)
	Extension erosion	1 (1.1)	0	1 (2.4)
	Infection	1 (1.1)	0	1 (2.4)
	Undesirable simulation effects	1 (1.1)	0	1 (2.4)
Leads explanted	All	3 (3.3)	3 (5.9)	0
	Allergic response to implant materials	1 (1.1)	1 (2)	0
	Infection	2 (2.2)	2 (3.9)	0

Hayek et al published their findings on lead positioning in relation to neurostimulation-induced muscle spasms. They advised lead placement at the level of the nuchal line to prevent undesired stimulation effects. 16 According to an autopsy study published by Bovim et al, the main branches arise in a square area of \sim 2 to 5 cm underneath the inion and up to 3 cm lateral of the inion. ¹⁷ This implies that placement just underneath the inion would likely result in stimulation of the main branches. Furthermore, it has the advantage of stimulating an area above the cervical muscles, preventing muscle spasms. In our experience we achieved stimulation in both branches without muscle spasms in all of our implantations, suggesting this one lead method is feasible in achieving the desired stimulation effects. One patient (2.2%) had undesired stimulation effects that stemmed from painful skin stimulation. This was caused by a superficial position of the tip of the electrode that required revision surgery. This confirms the importance of placing the electrode at the right depth.

Besides achieving the desired results, prevention of complications is of major interest. With our technique we had a total of 10 complications in the group of trial implantations; 5 of them required revision surgery. Most of the complications were biological and caused by infection at the lead exit site (6 of 10). One should keep in mind that the trial period ranged from 6 to 10 weeks, which is rather long and might provoke infection. Two electrodes were removed because of extensive infection; the other was treated with oral antibiotics. Lead migration occurred in two cases requiring revision surgery. During the trial period, the electrode was sutured to the skin at the exit point. If the sutures resorbed and patients were incautious by pulling on the electrode, migration might occur.

Concerning the permanent implantations, we saw a total of six complications (14.6%) five (12.2%) of which resulted in additional surgery. Lead migration occurred in one patient (2.4%) and resulted in revision surgery. This is a low number compared with the literature. The other complications arose out of erosion, infection, and undesired stimulation effects (skin stimulation).

The overall number of 16 complications makes up 17.4% of the implantations, requiring 7 additional surgeries (7.6%). This is low compared with the literature, which describes a revision rate between 10% and 60%. 10 Lead migration in particular seems to be one of the major problems, and the risk seems to increase with the follow-up period. 9 In our series we saw a total of 3 lead migration in 92 implantations (3.3%); in the permanent implants we saw one migration (2.4%). The follow-up in this group ranges from 3 to > 6 years. This migration occurred within 12 months after the initial implantation of the permanent electrode (>Fig. 3). In comparison with the numbers published in the review of Falowski et al, this is a very low percentage, which may imply that the presented technique is effective to prevent migration. 10 In our technique we make use of a sharp angle of 45 degrees after placing the contacts at the horizontal line underneath the occipital protuberans. This 45-degree angle might prevent migration of the lead because the lead is less bendable and flexible at the level of the contact points. Because of this, it is



Fig. 3 Migration of the C2 electrode.

unlikely that it will migrate in the direction of 45 degrees. One could be concerned about lead breakage because of traction at the electrode in the angle; however, we have not seen any lead breakage so far. Besides the 45-degree angle, we have created a strain relief loop at the cervical area. We did this because of the high mobility of this region. The strain relief loop provides extra movement possibilities without pulling on the lead at the level of the contact points.

Our most pronounced complication was infection. A total of seven patients (7.6%) suffered from infection at the implant site. This is relatively high in comparison with published data that report infection rates between 2% and 10%. 10 However, six of these infections occurred during the trial period, which was relatively long (6-10 weeks). Four of these infections were treated with antibiotics. Two electrodes needed to be removed because of the extensiveness of the infection. Concerning the permanent trials, we noticed one infection that could be treated with antibiotics and did not require further surgery. Taking into account these facts and numbers, we conclude that the high infection rate was due to the long trial

Two patients had erosion of the hardware, requiring additional surgery (2.2%). In one patient we noticed an erosion of the lead tip through the occipital skin; in the other patient the connection piece of the extension lead eroded through the intrascapular skin. This is caused by a overly superficial implantation of the material. This complication has been described elsewhere, as well as strategies to prevent it. 18 Both patients underwent local revision surgery in which the lead tip/extension were repositioned underneath the disinfected skin. No further inflammation or infection occurred in these two cases.

One patient experienced persistent pain at the implantation site of the internal pulse generator. This was treated with pain medication, and we noticed a spontaneous resolution.

The neurostimulation device had to be removed in one patient (2.2%) because of a systemic allergic reaction to the stimulation device. This is a rare complication; only a few cases have been published. ^{19,20} After removal of the system, all symptoms resolved.

One patient complained of feelings of anxiety and arousal during stimulation. We did not found any reports on that in the literature. However, by reprogramming the device, the symptoms decreased.

Conclusion

We presented a simple technique to perform occipital nerve stimulation with a single electrode without the use of additional anchoring devices. The technique achieves stimulation in both branches of the occipital nerves and reduces complications, more specifically lead migration.

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