Technical Aspects of Peripheral Nerve Stimulation: Hardware and Complications

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Abstract:

Although commonly used in clinical practice, peripheral nerve stimulation (PNS) for treatment of chronic pain is performed mainly with devices developed and marketed for spinal cord stimulation applications. This may be one of the reasons why PNS approach is marked by a very high complication rate, as the anatomy of peripheral nerves and the surrounding soft tissues is quite different from epidural spinal space for which the current devices are designed.

The chapter reviews integral components of PNS systems and accessories. It also lists variety of complications observed with PNS approach and points to the ways to minimize their incidence. Based on the literature data and the analysis of the author's experience with PNS procedures it appears that although the rate of complications is relatively high, the morbidity associated with PNS approach is very minor and most problems may be resolved with simple re-operations, usually on outpatient basis.

The reduction in complication rate is expected to occur when the hardware used in PNS procedures is appropriately adapted for PNS applications.

Key words: peripheral nerve stimulation, migration, erosion, hardware failure, device components

Introduction

Electrical stimulation of peripheral nerves is used in a variety of medical applications. The most common ones include testing neuromuscular conduction in anesthesia and intensive care units; motor stimulation of phrenic nerves in cases of diaphragmal palsy and somatic nerves of the extremities in patients with hemiplegia and paraplegia; vagal nerve stimulation for treatment of intractable epilepsy and refractory depression; autonomic stimulation for urinary and gastrointestinal disorders; carotid sinus stimulation for hypertension and angina pectoris; and, finally, the stimulation of peripheral nerves for control of neuropathic pain [1].

Although peripheral nerve stimulation (PNS) has been a part of the neurosurgical armamentarium in treatment of chronic pain for almost a half of century, the entire approach is still far from perfection. Unfortunately, this includes not only absence of strong scientific evidence of its effectiveness, but also relatively high incidence of technical complications and re-operations, some or even most of which are related to the fact that most of the devices used for PNS today are neither designed nor approved for this application. Although there are some hardware choices that include PNS in its labeling, vast majority of presently used PNS hardware are in fact designed and approved exclusively for spinal cord stimulation (SCS).

Components of PNS Systems

In general, neuromodulation devices consist of several distinct components and the terminology that describes them seems to be non-uniform among the implanters and the device manufacturers. Below is an attempt to provide a unified approach to this terminology and then use it for review of technical complications that may be in one way or another related to the hardware choices.

The electrical energy is delivered to the peripheral nerve by small metal contacts that are arranged on a lead, or electrode. The leads come in different shapes and sizes; and the ones that are used today for treatment of pain are generally divided into (a) socalled percutaneous, cylindrical, or wire-like leads and (b) flat leads, that are also called paddles, surgical leads or laminectomy-type leads.

In the past, before both of these lead types became available, the electrodes were custom made or manufactured in small quantities. First electrodes were essentially wires that were inserted into the nerve or immediately next to it. This kind of electrodes was used by Wall and Sweet when they were testing "gate-control" theory of pain by stimulating their own infraorbital nerves [2]. At about same time, cuff electrodes were created for long-term direct stimulation of the peripheral nerves. This type of electrodes was used by Shelden and colleagues in the early 1960-s, even before the "gate-control" theory of pain (that became a theoretical basis for electrical stimulation for pain control) was introduced [3]. At that time, a Silastic ring that included a metal contact for nerve stimulation would be wrapped around the exposed segment of the nerve.

This technique of electrode application, not surprisingly, was associated with scarring around the dissected nerve as well as with development of fibrosis and nerve constriction from the lead itself. In addition to that, there was an issue related to preferential stimulation of only the nerve segment that was located under the metal contact. This was not a problem in case of smaller and homogeneous sensory nerves, but in case of larger mixed nerves, such arrangement might cause predominantly motor effects and as a result, desired paresthesias might be associated with muscle contractions. To overcome this problem, it was suggested to use "button"-type electrodes [4]. These small electrodes could then be sutured directly to the perineurium over the part of nerve circumference that corresponded to underlying sensory fascicles. Although time consuming and requiring a great deal of nerve manipulation, this approach was particularly useful when dealing with sciatic nerve or the brachial plexus.

Neither cuff-type nor button-type leads are used any more in the field of pain surgery, but in the neighboring fields of neuromodulation these wrap-around (cuff) leads are still being used on regular basis. Two best examples of this are vagal nerve stimulators (Cyberonics, Houston, TX) used for treatment of refractory epilepsy and treatment-resistant depression, and phrenic nerve stimulators (Avery Biomedical Devices, Comack, NY) that are implanted for diaphragmal pacing in treatment of respiratory failure.

The use of flat (paddle-type) leads in PNS was introduced in late 1980-s [5]. Here,

the lead was implanted under the nerve in a way that all 4 flat metal contacts of that quadripolar lead were facing the nerve. Such innovation made an impact on the consistency and versatility of stimulation as having multiple contacts along the same nerve gave more freedom in terms of stimulation programming. In order to further reduce incidence of perineural fibrosis, it was then recommended to use a fascial "padding" between the metal contacts and the nerve, and then, in a logical progression of this approach, a lead with a mesh attached to it was developed specifically for PNS applications (OnPoint, Medtronic, Minneapolis, MN) [6]. Most commonly used paddletype leads are listed in Table 1.

Introduction of percutaneous PNS technique in the mid 1990-s [7] changed the landscape of hardware used for this application. Both quadripolar (4-contact) and octopolar (8-contact) electrode leads have been used for this purpose, initially in occipital nerve stimulation, followed by stimulation of trigeminal branches, and then in peripheral nerves of the trunk and extremities. Percutaneous electrodes from three major neuromodulation manufacturing companies (Medtronic; Advanced Neuromodulation Systems (ANS – currently St. Jude Neuromodulation), Plano, TX; and Advanced Bionics (currently Boston Scientific), Valencia, CA) have been successfully used for PNS applications (Table 1).

The number of contacts in a lead, as well as the number of leads in a patient has traditionally been limited by another part of each neuromodulation device – electrical generator of stimulation. Early neuromodulation experience was based on radiofrequency (RF) coupled systems. Here the generator of impulses and all control units are located outside the patient's body. The receiver is implanted subcutaneously and connected to the electrode lead(s) either directly or with special extension cables. The impulses are transmitted through the skin with a special flexible pancake-shaped antenna that is placed (usually with support of tape or adhesive pad) over implanted receiver and the power source/programming module is worn externally. Main advantages of this system are its ability to deliver high-power complex stimulation and extreme ease in replenishing power supply as most external generators are powered by regular household batteries (1.5 or 9 Volts). Theoretically, RF-coupled devices may serve forever without additional surgical interventions.

Most RF-coupled systems allow operations with two or more independent channels and are capable of covering 4, 8, or 16 electrode contacts. This has been particularly important in patients with complex pain patterns and in those cases where pain areas change with time, since in the past implantable generators had very limited power and programming capabilities. On the other hand, RF-coupled systems require a significantly higher degree of patient participation, which may be difficult for some chronic pain patients. Some RF system users develop dermatitis or other local skin reactions that prevent them from wearing the antennas for extended periods of time. Also, some patients stated that having a permanent external device limits their freedom, eliminates ability to maintain stimulation while showering, bathing or swimming, and they were often willing to trade some of the benefits of RF-coupled systems for a completely implantable system [8]. In the past, RF-coupled devices manufactured by Medtronic and ANS were able to provide an alternative to implantable pulse generators (IPG) – and, as the matter of fact, today the RF-coupled systems remain the only devices that are approved for PNS applications. However, it appears that in treatment of chronic pain these systems are hardly ever used any more, and it is conceivable that one of the reasons they are still listed in the product catalogues is to have this indication (stimulation of peripheral nerves for treatment of pain) open for clinical and marketing purposes. The breathing pacemakers (Avery Biomedical Devices), on the other hand, continue using RF-coupled technology. The company that manufactures them was a major pioneer in the field of PNS hardware but left the pain surgery arena to focus exclusively on the diaphragm pacing products.

The alternative to externally-powered RF systems is a completely internalized device. Here the power source and impulse controller are contained in a pacemaker-like device – an implantable pulse generator (IPG). Fully implantable devices are more convenient for patients because the entire stimulation system is placed inside the patient's body and the need for external attachments is eliminated. Patients can swim or shower without stopping the stimulation and do not have to worry about poor contact between the antenna and receiver. IPG systems, particularly the non-rechargeable ones, have only limited internal battery power, and, therefore, must be replaced every several (usually between 1 and 10) years, depending on the system usage, battery size and stimulation

parameters. This obviously increases the long-term cost of the hardware.

The first generation of IPG's accommodated 4 contacts and was routinely limited to using a single quadripolar lead. The first three consecutive models representing this generation were made by Medtronic (ITREL, Itrel II and Itrel 3) and this line of devices is still in production as some patients continue to enjoy benefits of stimulation with a single 4-contact lead. Subsequent generation (Synergy and Synergy Versitrel from Medtronic and Genesis / Genesis XP from ANS) of IPG's accommodated up to 8 contacts and allowed patients to have more than one stimulation program. The latest generation of devices extended this capacity to 16 contacts – and in the meantime, the rechargeability became a common feature. Introduction of Precision system (Boston Scientific) was followed by other rechargeable 16-contact devices from Medtronic (Restore) and St. Jude (Eon), and soon thereafter smaller devices (Restore Ultra, Medtronic, and Eon Mini, St. Jude) completed the lineup of most commonly used devices (Table 2). The rechargeable batteries make it possible to cover larger areas with stimulation using multiple electrode leads, and the usage-limiting issues related to a continuous use of the device (versus cycling or turning it off at night in order to lengthen battery life), higher frequencies and amplitudes of stimulation are not as overwhelming any more as the batteries may be recharged as needed and are expected to last between 7 and 10 years.

The recharging, however, may be an issue for some of the patients, particularly the elderly and those with memory and cognition problems, and for these circumstances there are non-rechargeable (primary cell) IPG choices that maintain same programming capacity (PrimeAdvanced, Medtronic, and EonC, St. Jude).

In addition to electrode leads and generators / receivers, there are multiple additional hardware pieces that are important in assuring lasting benefits from PNS. First are the extension cables (sometimes called simply extensions). With earlier Medtronic models, extensions were an integral part of the stimulation system, but with those devices that are used today, extensions are needed only if the electrode tail does not reach the IPG or if such reach results in tension at rest or during movements. The bulkiness of the connectors on the original extension cables was resolved with lower-profile devices, and in addition to that there are now new contraptions that convert old extensions into more standard in-line multi-contact tails.

There is another purpose for the extensions – these days such cables serve not only as true conducting devices, but also as means of connecting two 4-contact electrodes to a single channel in IPG (so-called bifurcated extensions). These are available with both Medtronic and St. Jude Medical devices. Moreover, there are now so-called splitters (Boston Scientific) that reduce number of used contacts on each electrode lead from 8 to 4 thereby allowing one to use only certain contacts from each lead for active stimulation (these active contacts may be, for example, the distal 4 out of 8 or the 1, 3, 6 and 8 contacts – depending on the splitter model). Both standard bifurcated extensions and splitters allow connecting up to four electrode leads to a single generator.

The extension cables, obviously, add to the complexity of the system but one of the benefits in having the extension is the reduction of stress on the electrode lead and the elimination of direct electrode lead manipulation during revisions and replacements of the IPG. In PNS, we prefer not to use extension cables – unless the bifurcated extensions or splitters are needed – primarily to decrease the number of the incisions and to keep lower profile for the relatively superficial (comparing to spinal or cerebral applications) implant.

The last implantable component of PNS system is an anchor – a device that holds the electrode lead in place and prevents its migration. Most electrode leads come with a set of anchors – and since these leads are designed for SCS applications, so are the standard anchors. The anchors are usually made of silicone. They come in several shapes: the cylindrical anchors that have grooves or bumps to prevent sliding of holding sutures, the anchors "with ears" that have side flaps with suture holes attached to a cylindrical shaft, and the wrap-on anchors that are applied to the electrode lead and sutured to the tissues.

All of these anchors are designed to hold electrode lead in place by virtue of tension created by the ties or sutures that are placed around them. It is routinely recommended to use non-absorbable sutures, and we prefer using synthetic polyfilaments, such as Dacron (Surgidac, Ethibond or Ti-Cron), whereas others may prefer natural (silk) or monofilament (prolene) materials. In addition to (but not instead of) the suturing, a medical glue may be used inside the anchor to assure better electrodeanchor coupling.

Recently, more complex anchors have been introduced – with either metal or polyetherethylketone (PEEK) inserts – for better grasp of the electrode lead outer insulation. These anchors – Titan (Medtronic) and Cinch (St. Jude) – have been widely used by the implanters since their introduction. It is important to remember, however, that anchoring technique does not compensate for excessive mobility of the electrode lead. If such mobility exists, loose anchoring will result in electrode lead migration, whereas anchoring that is too tight may result in electrode fracture.

PNS accessories

In addition to the implantable components, there are multiple important devices that facilitate proper placement of neuromodilation system components. These include insertion needles, stylets, guidewires, introducers, passers / tunnelers, dissecting tools and wrenches. Not all of these accessories are useful for PNS applications as they are designed for SCS – and this presents a major problem that has to be resolved by developing hardware dedicated to PNS use.

For example, straight and curved stylets that facilitate electrode lead advancement in the epidural space and guidewires and introducers that may be used for establishing a path for SCS electrode insertion have very little if any use in PNS applications as the electrodes inserted percutaneously are usually advanced through the needle that is inserted directly toward the target location.

The needles, on the other hand, are integral component of percutaneous PNS electrode lead insertion procedure. Straight shape of these needles is designed for SCS applications – but it does not conform to the body curvature when it comes to PNS procedures. Here the needle straightness may result in bringing electrode tip too close to the surface of the skin thereby increasing the chance of electrode tip erosion (Figures 1 and 2). To overcome this, most implanters have been bending he needle prior to its use, although this may be sometimes difficult to do as the needle and its stylet have different mechanical properties and it becomes very challenging to remove the stylet once the

needle is positioned. To solve this, we have designed special curved needles with stylets of various configurations – the sharp, oblique and blunt ones – so they can be exchanged at different stages of needle insertion (Figure 3).

The epidural dissectors – the "hockey-stick" devices and dural separators – may be used for insertion of paddle electrodes in their PNS applications, although in most cases implanters use open dissection with standard dissection instruments for establishing a plane for paddle electrode insertion [9].

PNS complications

In general, complications of neuromodulation are divided into 10 main groups [10]. Some of them occur primarily with intrathecal pumps and other means of chemical neuromodulation; some others are specific to the central nervous system and apply to the electrical stimulators of spinal and cerebral structures. Several categories, however, are applicable to PNS; these include infection, hemorrhage, injury of nervous tissue, placing device into wrong compartment, hardware migration, erosion and malfunction, including fractures and disconnections, and the general category of other issues.

Looking at the history of PNS it becomes apparent that some of the technical complications have disappeared with technological advancements, while the others remain essentially unchanged. In the early stages of PNS practice, the electrodes were custom-made. Some wrap-around electrodes had Silastic backing [3] with platinum wire facing the nerve to be stimulated. It turned out that in some circumstances such backing accumulated significant amount of fluid and this phenomenon affected the electrode impedance with subsequent loss of conductivity [3].

Later, such cuff electrodes became more biocompatible, but the main issue became a possibility of nerve injury as a result of fibrosis and possibly ischemia arising from electrode strangling the nerve within soft tissues. Multiple reports of such incidents were one of the main reasons why these devices were abandoned [11-13].

However, even with meticulous dissection and secure suturing of these cuff electrodes some of them ended up becoming displaced, and the only solution for such migration incidents was electrode revision. The migration incidence became higher with introduction of percutaneous PNS technique – here the tissue friction is minimal and the only thing that holds electrode in place is the anchor – along with so-called strain relief loop that is commonly placed next to the anchoring site. Anyone who ever revised or removed percutaneous PNS electrode would agree that these electrodes easily leave their location, and the tissue reaction around them is rather minimal. The migration is unlikely to happen in lateral (relative to the electrode axis) direction – most of the time it happens as a pullout from the original lead position (Figure 4). Sometimes, if the anchor is completely incompetent, or if the patient presents with hypermobility over the electrode path, this migration may be rather dramatic (Figure 5). In addition to this "pull-out" phenomenon, the electrode lead may also migrate "in" shifting more distally along the electrode path (Figure 6). All this, however, is easy to figure out with a simple set of radiographs – and since they have to be compared to the original images, it is important to obtain and save the radiographic image of the electrode lead position at the end of its original implantation. Incidence of migrations varies from series to series ranging from 0 to 100% [14-16].

Functioning malpositioned or migrated electrode leads are easy to re-position. A simple technique allows for such repositioning without re-opening the generator pocket [17, 18]. It is important, however, to have the generator pocket prepped and ready for exploration should the electrode lead turn out to be damaged or otherwise unsuitable for reinsertion.

Electrode leads may break at any time after the implantation. Such breakages (fractures) are usually a result of sharp kink in the electrode lead insulation. The lead insulation or the internal wires may break due to repetitive movement that involves alternating stretching and compression of the device resulting in material fatigue and eventual failure. This issue should be taken into consideration when choosing the path of electrode lead and the location of generator. Crossing large joints and traveling long distances tends to be associated with higher rate of fractures and migrations.

Both infections and hemorrhages have occurred with PNS devices – but both are quite rare. Since most of the devices are placed in superficial locations, the bleeding may be easily controlled and the hematomas are rarely symptomatic. The infections, on the other hand, may occur in both immediate and long-term periods. Surgical infections may

be a result of poor surgical technique or an insufficient dissection for the anchors and connectors when the tissue tension prevents adequate wound healing. In our series of 40 patients with PNS implants followed for longer than 30 months, there were 2 infections, and in each case, the device had to be removed. The infection was managed with systemic antibiotics that were adjusted after the microorganisms and antibiotic sensitivities were established. The PNS system may be re-implanted few months after the infection was eradicated.

Placing device into a wrong compartment is rather a theoretical concern as most of PNS electrodes are inserted in a subcutaneous epifascial plane. However, since the proximity of electrode lead to the nerve to be stimulated is extremely important in terms of getting adequate paresthesias and keeping stimulation parameters within reasonable range, various techniques have been suggested to improve the placement accuracy. Fluoroscopy is routinely used by most PNS implanters [19], but there are now multiple reports that suggest use of intraoperative ultrasound for localization of the nerve trunk and the surrounding structures [20-22].

Insertion of electrodes too deep into soft tissues tends to cause upleasant muscle spasms during stimulation [23] whereas placing them too superficially may result in lead tip erosion [24].

Overall, however, most PNS complications are minor and rarely if ever require hospitalization. Recently, we analyzed our institutional experience with PNS [24]. Among almost a hundred of PNS patients operated since April of 2000, we identified 40 patients that had their original PNS trial in our hospital and followed up for 30 months or longer. Remaining patients had either shorter follow up or their initial surgery was done in other institutions.

Out of 40 patients, 8 did not sufficiently improve during the trial and 32 proceeded with permanent implantation. In a long-term follow up series of these 32 patients, there were a total of 27 subsequent operations (including 12 battery replacements) but in only one case of infection a hospital admission was required. Out of 15 re-operations, there were 6 revisions (one for electrode erosion 4 weeks after implantation, 4 for electrode migration at 1, 3, 5 and 9 months after original implantation, and one for device disconnection) and 9 device removals (2 due to infections at 1 and 49

months, 3 due to a loss of effectiveness at 9, 10 and 25 months, and 4 – due to improvement of symptoms at 13, 17, 21 and 56 months after original implantation). This experience illustrates the well known observation about relatively high rate of complications but, at the same time, very minor morbidity associated with the entire PNS approach [14, 15].

Conclusions

Although commonly used in clinical practice, peripheral nerve stimulation (PNS) for treatment of chronic pain is performed mainly with devices developed and marketed for spinal cord stimulation applications. This may be one of the reasons why PNS approach is marked by a very high complication rate, as the anatomy of peripheral nerves and the surrounding soft tissues is quite different from epidural spinal space for which the current devices are designed.

Based on the literature data and the analysis of the author's experience with PNS procedures it appears that although the rate of complications is relatively high, the morbidity associated with PNS approach is very minor and most problems may be resolved with simple re-operations, usually on outpatient basis. The reduction in complication rate is expected to occur when the hardware used in PNS procedures is appropriately adapted for PNS applications.

Table 1. Commonly used paddle and percutaneous electrodes (electrodes used for PNS are in bold, model numbers are in parentheses)

Percutaneous electrodes

Medtronic: 4 contacts (frequently referred to as Quad) Pisces Standard (3487A) Pisces Plus (3888) Pisces Compact (3887) Verify (temporary) (3862) 8 contacts (frequently referred to as Octad) 1x8 Standard (3777, 3898) 1x8 Compact (3778) 1x8 Subcompact (3776)

St. Jude Medical: 4 contacts Quattrode 7 mm (3141, 3143, 3146, 3149) Quattrode 10 mm (3151, 3153, 3156, 3159) Ouattrode 7 mm trial (3046) **Quattrode wide spaced** (3161, 3163, 3166, 3169) Quattrode wide spaced trial (3066) Axxess Ouad 3/4 (4143, 4146) Axxess Quad 3/6 (4153, 4156) Axxess Ouad 3/4 trial (4044) Axxess Quad 3/6 trial (4054) 8 contacts **Octrode** (3181, 3183, 3186, 3189) Octrode trial (3086)

Boston Scientific

8 contacts Linear (2108) Linear ST (2208, 2218) Linear Phase III (2138, 2158) Linear 3-4 (2352) Linear 3-6 (2366) Paddle electrodes Medtronic: 4 contacts **Resume II** (3587A) Resume TL (3986A) **On-Point** (3987A) Resume (3986, out of production) Symmix (3982, out of production) 8 contacts Specify (3988, 3998) 2 x 4 Hinged Specify (3999) 16 contacts Specify 2 x 8 (39286) Specify 5-6-5 (39565) St. Jude Medical 4 contacts Lamitrode 22 (3222) Lamitrode 4 (3240, 3254, 3255) Lamitrode S4 (3243, 3246, 3266, 3267) 8 contacts Lamitrode 44 (3244, 3262, 3263) Lamitrode 44C (3245, 3264, 3265) Lamitrode 8 (3280) Lamitrode S8 (3268, 3269, 3283, 3286) Lamitrode Tripole 8 (3210) Lamitrode Tripole 8C (3208) Exclaim (3224, 3225) 16 contacts Lamitrode 88 (3288) Lamitrode 88C (3289) Lamitrode Tripole 16 (3219) Lamitrode Tripole 16C (3214) Penta (3228) **Boston Scientific** 16 contacts **Artesan** (8116) Artesan (slotted contact) (8120)

Table 2. Commonly used implantable pulse generators (IPG) and radiofrequency (RF) receivers (model numbers are in parentheses)

Primary cell IPG	Rechargeable IPG	RF receivers
Medtronic:	Medtronic:	Medtronic:
4 contacts Itrel (out of production) Itrel II (7424 – out of production) ITREL 3 (7425) 8 contacts Synergy (7427) Synergy Versitrel (7427V)	<i>16 contacts</i> Restore (37711) RestoreAdvanced (37713) RestoreUltra (37712)	4 contacts X-trel (3470 – out of production) 8 contacts Mattrix (3271/3272)
<i>16 contacts</i> Prime (37701) PrimeAdvanced (37702)		
St. Jude Medical:	St. Jude Medical:	St. Jude Medical:
8 contacts Genesis (3608, 3643) Genesis XP (3609, 3644)	8 contacts Genesis RC (3708, 3744) 16 contacts	8 contacts Renew (3408) 16 contacts
16 contacts Eon C (3688)	Eon (3716) Eon Mini (3788)	Renew (3416)
	Boston Scientific:	
	16 contacts Precision (1110)	

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Figure 1. Erosion of occipital nerve stimulation electrode lead

Figure 2. Erosion of supraorbital nerve stimulation electrode lead

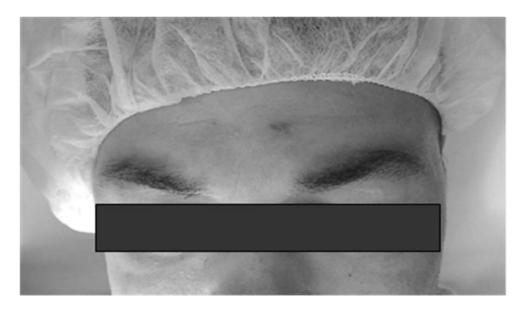
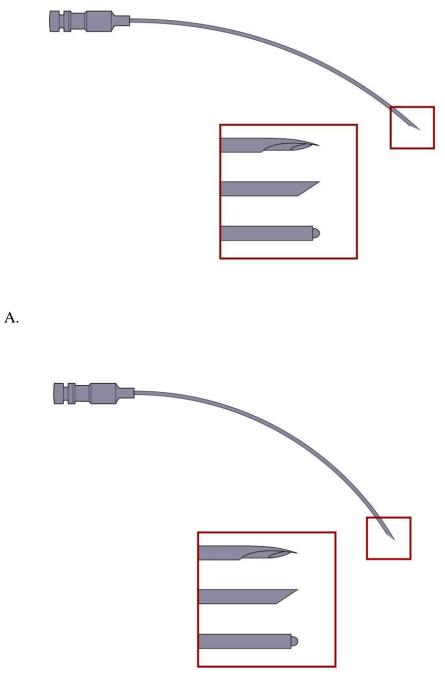


Figure 3. Curved design of the insertion needle for PNS applications. A. Needle / stylet assembly with 45° curve and three tip styles (inset). B. Needle / stylet assembly with 60° curve and three tip styles (inset)



В.

Figure 4. Migration of occipital nerve stimulation electrode leads – both left and right electrode leads have migrated away from their original position. A. Anteroposterior radiograph. B. Lateral radiograph

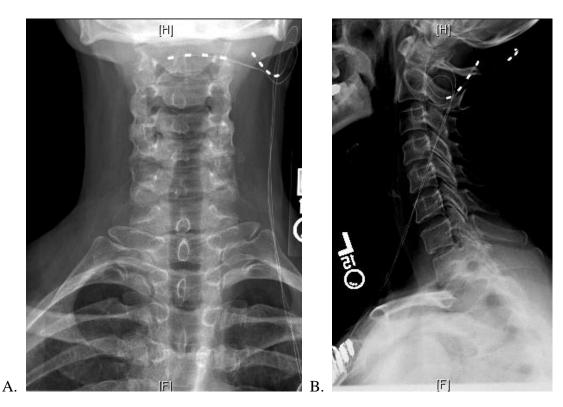


Figure 5. "Extreme" migration of occipital nerve stimulation electrode lead – the electrode lead has migrated all the way toward the generator pocket

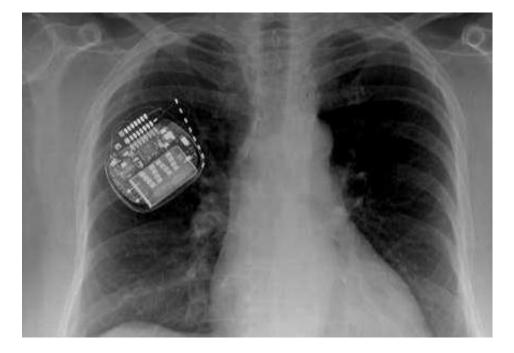
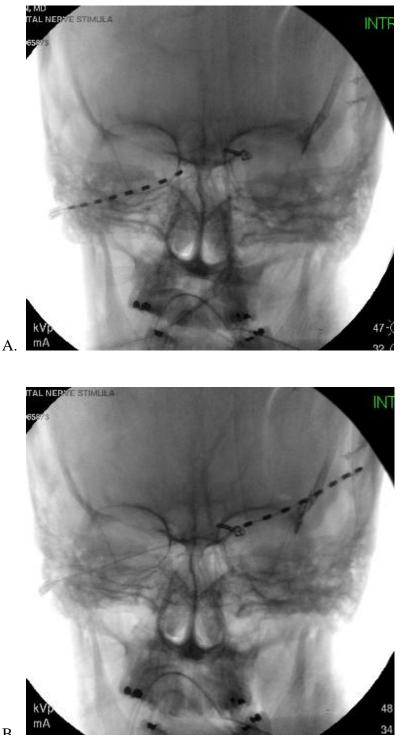


Figure 6. "In" migration of the occipital nerve stimulation electrode lead. A. Original electrode lead position. B. Electrode position 8 month after insertion with "in" migration to the contralateral side of the neck



B.