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Introduction

Spinal cord stimulation(SCS) is an adjustable, non-destructive, neuromodulatory procedure which delivers therapeutic doses of electrical current to the spinal cord for the management of neuropathic pain. The most common indications include post-laminectomy syndrome, complex regional pain syndrome (CRPS), ischemic limb pain, and angina. Scattered reports regarding the treatment of intractable pain due to other causes including visceral/abdominal pain, cervical neuritis pain, spinal cord injury pain, post-herpetic neuralgia, and neurogenic thoracic outlet syndrome have also appeared in the literature. The procedures are most commonly performed by neurosurgeons or anesthesiologists specializing in pain management¹⁻³ but other specialties, such as rehabilitation medicine and orthopedic surgery, have also demonstrated interest in the procedure.

The enthusiasm with SCS began with the introduction of the gate control theory for pain control by Melzack and Wall⁴ in 1965. They noted that stimulation of large myelinated fibers of peripheral nerves resulted in paresthesias and blocked the activity in small nociceptive projections. In 1967, Shealy, inserted the first dorsal column stimulator in a human suffering from terminal metastatic cancer^{5,6}. Subsequently, electrodes have been implanted utilizing a variety of techniques: via a laminectomy in the subarachnoid space⁶, between the two layers of the dura or in the epidural space, in either dorsal or ventral to the spinal cord.⁷⁻⁹ Subsequently, less invasive percutaneous techniques were introduced.¹⁰

Great advances in technology has also driven the popularity of the field. The electrodes were initially all unipolar and bipolar arrays developed subsequently. Furthermore, the contact combinations could only be hardwired, and could not be reprogrammed after the pulse generator was implanted. In the beginning, only radio-frequency (RF) driven passive receivers were available. In the mid-seventies, the first implantable pulse generator powered by a lithium battery was introduced into the market. In 1980, the first percutaneous quadripolar electrode was produced and this could be reprogrammed non-

invasively through an external transmitter¹¹. Subsequently, implantable pulse generators (IPG) which can be both transcutaneously charged and programmed have been developed. This most recent advance is now leading a renewed interest in the utility of using special electrode arrays in the delivery of electrical stimulation to the spinal cord.

Mechanisms of Action

Although a large body of work has been published, the exact mechanisms of action of SCS remain unclear. The computer modeling work of Holsheimer, Coburn, and Strujik, have shed some light, at least theoretically, on the distribution of the electrical fields within the spinal structures¹²⁻¹⁷. It is clear that stimulation on the dorsal aspect of the epidural space creates complex electrical fields which affect a large number of structures. We do not know whether activating afferents within the peripheral nerve, dorsal columns, or supra-lemniscal pathways share equivalent mechanisms of action. Additionally, there may be antidromic action potentials passing caudally in the dorsal columns to activate spinal segmental mechanisms in the dorsal horns as well as action potentials ascending in the dorsal columns activating cells in the brainstem, which in turn might drive descending inhibition. At the chemical level, animal studies suggest that the SCS triggers the release of serotonin, substance P, and GABA within the dorsal horn.¹⁸⁻²⁰

Indications

SCS has been used for a variety of pain conditions and is particularly indicated for pain of neuropathic origin, including post-laminectomy syndrome, complex regional pain syndrome, phantom limb pain, spinal cord injury pain, and interstitial cystitis. The indications have extended to include the treatment of intractable pain due to abdominal or visceral pain, and neurogenic thoracic outlet syndrome. SCS has been successfully utilized to treat severe pain due to ischemic disease of the lower extremities and more recently, intractable angina pain. Experience suggests that, in selected patients, SCS can

produce at least 50% pain relief in 50-60% of the implanted patients. Interestingly, with the proper follow-up care, these results can be maintained over several years.

Complex Regional Pain Syndrome (CRPS)

The implementation of SCS in individuals with CRPS type I is more difficult than with any other patients groups. The possibility of aggravating the original pain or causing a new pain/allodynia at the implanted hardware site is greater than with any other diagnostic category mentioned. The pain may spread to other body parts and it is challenging to be able to cover all the affected areas with stimulation.

In 1989, Barolat et al. reported reduction of pain in ten out of thirteen patients implanted. No patients in that series were made pain free but all ten reported a definitive difference when the stimulation was stopped²¹. In 1997, Kumar et al. presented a median follow-up of 41 months on twelve patients with permanently implanted leads²². Eight patients reported near complete resolution of their symptoms and four also maintained good relief.

Kemler et al., in another series, reported 23 additional cases with 78% of the patients reporting improvement²³. In 2000, Kemler et al. published on a series of 54 patients who either underwent randomization to SCS with physical therapy or physical therapy alone²⁴. In the SCS group, 67% patients experienced significant pain relief which persisted at 6 months. A 2.4 cm decrease and improvement in VAS was noted in the SCS group compared with 0.2 cm increase in the physical therapy group. However, no functional improvement was observed in either group. In 2006, in a letter to the editor of NEJM, Kemler, recounted their five year follow-up on the patients with SCS. Their major conclusion was that the effects of SCS diminished over time for these patients. In this letter, they do not specify how reprogramming or modern devices might impact on the long term effects of SCS therapy²⁵.

Oakley and Weiner reported a prospective study of 19 patients with CRPS implanted with spinal cord stimulation systems²⁶. Of the 10 patients in whom detailed long-term

efficacy data was available, 3 reported full relief from their pain and 7 partial beneficial relief.

Three additional prospective studies without matched controls have been reported (total of 50 subjects)²⁶⁻²⁸. Two of the studies reported success rates with an 84% overall success rate. The third study by Calvillo et al²⁷, reported a significant improvement in pain scores (VAS) and a >50% reduction in narcotic use by 44% of subjects. In eight retrospective studies the overall success rate was 84% (192 patients)²⁹.

Post-laminectomy syndrome (also called Failed back surgery syndrome – FBSS)

Post-laminectomy syndrome is vaguely defined. The term has included pain localized to the center of the lower lumbar area, pain in the buttocks, persistent radicular pain, or diffuse lower extremity(s) pain. Arachnoiditis, epidural fibrosis, radiculitis, microinstability, recurrent disk herniations, infections, have been perpetrated in the etiology of this syndrome. Most published series distinguish between back and leg pain, but the details of the pain syndromes are seldom defined. SCS is accepted in the treatment of leg pain, but its widespread use for relief of pain in the lower lumbar area still remains to be defined.

A great challenge, in the treatment of post-laminectomy syndrome, has been to obtain stimulation in the low back. Even with direct stimulation to the low back, the pattern of paresthesia is often replaced in time by an unpleasant segmental band of stimulation from the thoracic roots, which negates the benefits of the procedure. Previous pioneering work by Jay Law^{30,31} has shown that stimulation in the low back can be obtained only if one uses multiple arrays of closely spaced bipoles at T9-T10. North et al. has challenged the concept of the superiority of centered dual electrodes by showing that one single quadripolar electrode in midline has the ability to stimulate the axial low back³². These were acute observations, and no data exist as to the long-term behavior of single versus dual electrodes. The advent of the tripole electrodes and the ability to steer current has made it more plausible to aim for low back paresthesia. Further, flanking the cathode by lateral anodes also appears to increase the discomfort threshold theoretically³³.

Marchand et al.³⁴ conducted a prospective randomized controlled study examining patients with at least one prior surgery for chronic back pain secondary to trauma. Each patient used a SCS and acted as their own control. Although a small trial, with only eight patients pain, scores were significantly reduced with SCS compared to placebo stimulation.

The longitudinal studies by North showed that in patients with post-surgical lumbar arachnoid or epidural fibrosis without surgically remediable lesions, SCS is superior to repeated surgical interventions on the lumbar spine (for back and leg pain) and to dorsal ganglionectomy (for leg pain)³⁵. That study comprised 50 patients with a post-laminectomy syndrome who averaged 3.1 operations prior to SCS implantation. Successful outcome (at least 50% pain relief and patient satisfaction with the result) was obtained in 53% of patients at 2.2 years. Systematic review of the literature was conducted by Turner, 1995³⁶. They reviewed a total of 41 articles from 1966 to 1994 that met their criteria. It was noted that approximately 50-60% of patients with post-laminectomy greater than 50% pain relief was attained from the use of SCS. In 1996, Burchiel et al conducted a prospective multi-center study with one year follow-up and also reported 55% successful stimulation³⁷. Medication usage and work status were not changed significantly.

North et al. also conducted a prospective study randomizing patients with FBSS to either repeat back surgery or SCS surgery³⁸. Patients were allowed to crossover after six months. Ten of fifteen patients crossed over from back surgery to SCS, while only two of twelve patients crossed over from SCS to back surgery.

Studies do not routinely differentiate between axial back and leg pain. Although there is some recent data on back pain, it is still inconclusive. Most implanting physicians share the experience that SCS is far more effective for radicular pain than for axial low back pain.

Angina

The role of SCS in the management of refractory angina pectoris seems to be a very promising. There are well documented reports in the literature revealing uniformly good results in the relief of anginal pain³⁹⁻⁴³. Further, the results have been maintained in long term follow-up and have been substantiated by a reduction in the intake of nitrates as well. Interestingly, other findings have supported the evidence that SCS has effects that go beyond pain relief. The observations that there is less ST segment depression and that the exercise capacity, the time to angina and the recovery time all improve with stimulation may suggest that there is a reduction in ischemia. In a positron emission tomography study, a redistribution of myocardial flow in favor of ischemic parts of the myocardium has been demonstrated as a long term effect of spinal cord stimulation, both at rest and after pharmacologic stress induction⁴⁴.

Vulink et al. conducted a prospective study on quality of life changes in patients with refractory angina pectoris implanted with SCS. They found that both the pain and the health aspects of quality of life improved significantly after 3 months of SCS. Further, social, mental and physical aspects of quality of life were found improved after one year of SCS⁴⁵.

Hautvast et al.⁴⁶ implanted SCS in patients with stable angina pectoris and randomized them. One group's remained inactivated while the other group was instructed to use the stimulator three times per day for one hour and with any angina attack. At 6 weeks, compared with controls, the treatment group had increased exercise duration and time to angina, and decreased anginal attacks and sublingual nitrate consumption. Also, observed was a decrease in ischemic episodes on EKG, as well as a decrease in observed ST segment depressions on exercise EKG. There was an increase in perceived quality of life and decrease in pain. It was shown that a placebo effect from surgery in the treatment group was unlikely because all patients had implantation surgery at baseline.

Mannheimer et al.⁴⁷ randomized 104 patients accepted for CABG to receive either CABG (n=51) or SCS (n=53) in the ESBY study. This study demonstrated that patients

randomized to SCS showed a greater than 30% improvement in NHP scores (Nottingham Health Profile) compared with baseline, which was significant and comparable to the improvement shown by patients randomized to CABG⁴⁸. These results were consistent on follow up after 4 years. It is important to know that the 5 year mortality of 27.9% in the ESBY study was similar between those receiving SCS and those who received CABG, with no difference in the percentage of cardiac deaths. The ESBY study showed that cardiac events were similar across the groups, but that there was significantly more cerebrovascular events observed in the CABG group.

Both groups experienced a significant reduction in both the number of angina attacks and the consumption of nitrates. There was no significant intergroup difference regarding these parameters. In another prospective study of 104 patients who underwent SCS implantation for refractory angina pectoris there was a significant decrease in angina episodes at rest, angina episodes with activity, and total angina episodes⁴⁹.

DeJongste et al.⁴¹, randomized seventeen patients with angina to an active treatment group (i.e. SCS implantation) and a control group. The control group was followed for two months followed by SCS implantation. Both groups were followed for a total of 12 months. This study also revealed a significant reduction in the incidence of angina attacks and in the consumption of nitrates ($p < 0.05$).

Five additional studies are reported to be prospective but without matched controls^{45,50-53}. Each of these revealed significant benefit from spinal cord stimulation. The benefit indices ranged from reduction in angina attacks, decrease nitrate consumption, decrease in NYHA grade and improvement in NHP grade.

The concern whether stimulation can conceal an acute myocardial infarction was addressed by Andersen et al. They reported on 3 out of 45 patients treated with SCS for anginal pain who survived a myocardial infarction⁵⁴. All three patients noticed the pain to be different and unrelieved with SCS and all patients correctly guessed that the pain was due to a myocardial infarction. The authors concluded that SCS for treatment of anginal pain does not seem to conceal acute myocardial infarction. Anderson followed

this up in 1994 further concluding that neurostimulation does not conceal the pain of an acute myocardial infarction⁵⁵. Particularly, SCS reduces the severity of anginal attack but was unable to suppress the conduction and perception of cardiac pain signals which act as alarm signals of cardiac distress⁵⁶. Murray et al have shown that SCS for refractory angina is effective in preventing hospital admissions without masking the ischemic symptoms or leading to silent infarction⁵⁷.

The mechanisms of action of SCS are unclear. There may be homogenization of myocardial blood perfusion with SCS and that this reduces myocardial ischemia^{44,58}. Another study has demonstrated that SCS improved heart muscle lactate metabolism and oxygen demand and blood flow in the coronary sinus⁵⁹. Other studies show that SCS does not effect variability in heart rates or cardiac arrhythmias^{40,60,61}. Hautvast et al.⁶² demonstrated no significant changes in heart rate variability after 6 wks concluding that heart rate variability via autonomic modulation may not be the explanatory mechanism of action.

As the relation between pain and myocardial ischemia has not been fully clarified, we do not know whether the pain relief is due to direct depression of the nociceptive signals in the spinal cord or whether there is secondary gain from a reduction in the ischemia^{63,64}. A significant amount of work by Foreman has shown that dorsal column stimulation inhibits the activity of spinothalamic tracts cells evoked by activation of the cardiac sympathetic afferents or by intracardiac bradykinin. On the other hand the effects of stimulation might be equivalent to those of a sympathectomy and may act by producing a prolonged inhibition of the hyperactive sympathetic system. Such mechanism has been shown experimentally in the rat by Linderoth et al.⁵²

The most appropriate electrode location for the treatment of angina pectoris is most likely the lower cervical and upper thoracic region, although some have reported successful higher cervical placements⁴⁷. Another consideration is continuous versus cyclical use of SCS. In practice, patients using SCS for angina pectoris often use a low intensity stimulation for several hours per day for prophylactic purposes⁶⁵. Recently, a randomized control study demonstrated improvement in functional status and symptoms

in treatment arms with conventional or sub threshold stimulation in comparison to a low output placebo treatment arm⁶⁶. This is the first “blinded study” in which stimulation below the sensory threshold for parasthesia demonstrated therapeutic efficacy eliminating the possibility of a placebo effect.

The success of the procedure ultimately will be determined by the cardiologists. Questions exist as to the actual number of patients who despite all treatment modalities (including coronary bypass) continue to have symptoms of such magnitude as to require a spinal cord stimulator. Similar to the indication for peripheral vascular disease, European physicians have demonstrated a substantially greater interest in the modality than US physicians. As with other applications, a substantial amount of data from well-controlled clinical studies will be necessary before the procedure will be fully endorsed by the medical community in the US.

Chronic critical limb ischemia (CCLI) and Pain

Cook et al. were the first to suggest in 1973 that the indications for SCS might extend beyond intractable pain control⁶⁷. They observed a group of patients with multiple sclerosis who underwent SCS to treat their chronic pain. Unexpectedly, the patients experienced not only pain relief but also an improvement in mobility as well as sensory and bladder function. Cook et al. noted apparent improvement in lower limb blood flow and subsequently used SCS in patients whose primary problem was peripheral vascular disease (PVD)⁶⁸. He demonstrated relief of rest pain, increased skin temperature, improved plethysmographic blood flow and healing of small cutaneous ulcers.

Subsequently, Meglio and Cioni in 1981 reported pain relief and ulcer healing in a patient with advanced peripheral arterial insufficiency⁶⁹. In 1988, Jacobs published clinical evidence that SCS improved the micro-circulation as measured by capillary microscopy⁷⁰.

Klomp et al.⁷¹ randomized 120 patients, with critical painful limb ischemia, to receive either best medical therapy alone or SCS in conjunction with best medical therapy. At a mean follow-up of 19 months, there was no significant difference in pain score

improvement between the two groups. Jivegard et al.⁷² also reported on a similar study where 51 patients were randomized to receive either oral medication alone or SCS with oral medication. Conversely, they reported a significant improvement in pain scores of the SCS treated group over the non-SCS group ($p < 0.01$).

Four prospective studies without matched controls (references!?) in the literature reveal an overall success rate of 78% ($n=271$). Analysis of seven retrospective studies found an overall success rate of 76% ($n=308$)²⁹. A review of the European literature demonstrates that 70-80% of patients achieved significant ($>75%$) pain relief. Many other large studies have been reported on the long term results of SCS on pain and ulcer healing⁷³⁻⁷⁸.

In a prospective randomized trial by Guarnera et al. the effectiveness of SCS compared to distal arterial reconstruction was evaluated and demonstrated a more favorable outcome in SCS (72%) compared to distal arterial reconstruction (40%)⁷⁹. In a Cochrane review looking at six studies of SCS versus conservative treatment, it was determined that limb salvage after 12 months was significantly higher in the SCS group, and significant pain relief occurred in both treatment groups, but was more prominent in the SCS group⁸⁰.

The mechanisms of action are unclear. The most likely mechanism responsible for increased blood flow in subjects with peripheral vascular disease is inhibition of the sympathetic system. This phenomenon occurs within the spinal cord at the local level and is not related to antidromic activation of afferents fibers. Supra-segmentary influence on medullary vegetative centers does not need to be invoked. The possible role of locally released vasoactive peptides is still awaiting elucidation. Whether the effects on pain and blood flow are due to the same mechanisms is unknown, although some evidence suggests that pain relief is secondary to the microcirculatory changes. Multiple mechanisms may be operating simultaneously⁸¹⁻⁸⁵.

Abdominal/Visceral Pain Syndromes

Approximately 20% of the population in United States has abdominal pain. There are many etiologies for abdominal pain including gastrointestinal, genitourinary, musuloskeletal and nervous systems. Treatment modalities have included cognitive-

behavioral, physical, and pharmacological therapies. Other more invasive therapies have extended to include celiac plexus blocks and celiac ganglia destruction. Some studies have demonstrated some localization in the spinal cord for visceral pain secondary to malignancy. Midline myelotomy through the dorsal columns at the level of T10 has shown success in eight patients with refractory pelvic cancer pain. This was also demonstrated in animal studies where dorsal column activity was observed in pelvic visceral nociception⁸⁶.

Initially there was lack of evidence for the application of spinal cord stimulation for visceral and somatic pain secondary to the belief that nociceptive pain could not be modulated via stimulation. Several initial studies have since demonstrated the benefit of SCS in abdominal visceral disease. Ceballos et al.⁸⁷ demonstrated reduction in pain scores and decrease in narcotic use in a patient treated for mesenteric ischemia. Trial stimulation was 13 days with implantation followed for 12 months with the electrode placed at T6. The patient had only two small pain recurrences in that period, one of which was when the stimulator was stopped. Krames et al.⁸⁸ described a patient treated for irritable bowel syndrome who was developing escalating pain and diarrhea. Although the pain treatment eventually required intrathecal therapy there was a significant reduction in the amount of diarrhea. The patient underwent a two week trial and subsequently had implantation at the T8 level. In the first 6 months there was a subjective decrease in pain from 9/10 to 2/10 with only two diarrhea episodes and significant reduction in pain medications. There was some return of pain after ten month follow up requiring increase in pain medications, but still remained with significant reduction in diarrhea.

Khan et al⁸⁹ reported on the largest series with nine patients with refractory abdominal pain. Five of the nine patients had nonalcoholic pancreatitis, three had presumed abdominal wall neuromas from frequent abdominal surgery, and another had post splenectomy pain after trauma. All patients had a significant improvement in VAS scores as well as decreased narcotic use with placement of the leads at the T5-7 level at six to eight month follow up.

Tiede et al. described treatment of refractory abdominal pain in two patients. Both patients had a significant history including multiple abdominal surgeries and failed conservative measures. Each patient had an element of postprandial abdominal pain with associated nausea and vomiting. In both patients the leads were placed at the T2 level with significant improvement in pain, decreased narcotic use and increase functioning, such as return to work⁹⁰. Kapur et al.⁹¹ recently described relief of abdominal pain associated with colchicine intolerant or resistant patients with familial Mediterranean fever by placement of the electrodes at the lower thoracic levels.

More recently studies have looked at the treatment of visceral pelvic pain with reference to the dorsal columns and spinal cord stimulation. Kapural et al⁹² reported on the value of neurostimulation for chronic visceral pelvic pain in six female patients with the diagnosis of long- standing pelvic pain. These patients had a history of endometriosis, multiple surgical explorations, and dyspareunia. At an average follow up of 30 months there was a significant decrease in the VAS score with an average of more than 50% pain relief, with a decrease in opiate use.

Visceral innervation follows the embryologic origin and location of the viscera and is arranged in viscerotomes, analogous to cutaneous dermatomes⁹³. The viscera obtain their innervation via the sympathetic and parasympathetic pathways. The parasympathetics carry their afferents to anterior and posterior vagal trunks and are therefore not as amendable to spinal cord stimulation. The sympathetics carry nociceptive information from the viscera to spinal nerve roots making them a more viable target. The sympathetic afferents in the lower six thoracic and the upper three lumbar spinal segments have been shown to transmit painful impulses from the viscera⁹⁴.

Brachial Plexitis/Neurogenic Thoracic Outlet Syndrome

Spinal cord stimulation has also been described for pain secondary to either brachial plexitis or neurogenic thoracic outlet syndrome. Most of these patients complain of pain which affects the upper extremity, the shoulder, the trapezius, the axilla, and/or the anterior upper chest wall. With the currently available systems, stimulation of all areas is

often not feasible with a single electrode. Stimulation of the shoulder and the whole upper extremity requires an electrode placement in the upper cervical area. Stimulation in the axilla and upper chest wall area, instead, might be achieved only with an electrode in the lower cervical/upper thoracic area. Only occasionally an upper cervical placement will reach all of the above-mentioned areas. In the more common scenario, two electrodes are necessary in order to obtain the appropriate coverage. Further, a two channel stimulating device might be indicated, since the setting for the upper cervical region can be different from the one required to optimally stimulate the axilla and anterior chest area. One specific challenge with these patients is in the extreme hyperesthesia present in brachial plexus region as well as in the trapezius, often extending to even larger areas of the posterior thorax. Any surgical manipulations in these areas of hypersensitivity must be avoided at all cost. Tunneling of the implanted wires must be planned carefully and must be at a substantial distance from the hypersensitive area. Lack of adherence to these principles often results in excruciating pain and intolerance to the implanted system. Unfortunately, literature is relatively lacking for this indication.

Relevant Anatomy

Understanding the somatotopy of the spinal cord is paramount to knowing the technical aspects of implantation. A basic tenet of SCS is to create an overlapping of paresthesia and pain region. In order to do this, correlation of the somatotopy and the level of the spinal cord is necessary. Barolat has published extensively on the mapping of the spinal structures in man. A database was created to suggest areas of sensory response to dorsal spinal cord stimulation⁹⁵.

High cervical regions such as C2 can cover the posterior occipital region, and occasionally the lower jaw. C2-4 stimulation will provide coverage of the shoulder while stimulation in the lower cervical region such as C5-6 will provide for the entire hand. To cover the anterior chest wall or the axilla, an electrode towards C7 will be necessary.

More commonly, an implanter will seek cover the lower extremities. Lateral placement at T11-12 will cover the anterior thigh, while placement at T11-L1 can cover the posterior

thigh. Coverage off the foot as a whole can be achieved along these same areas but it becomes more difficult to cover the sole of the foot. Alternatively for coverage of the sole of the foot, a patient may require insertion on the lumbar L5 or S1 nerve roots. Low back pain is very difficult to cover because mid- thoracic stimulation can affect the chest and abdominal wall. The experience of the author had best localization with midline placement at T8-9.

Finally, most patients prefer stimulation of the dorsal column from electrodes closer to the midline. Laterally, placed thoracic electrodes are more likely to stimulate the thoracic nerve roots and result in painful stimulation.

Equipment (Electrodes and pulse generators)

The implanting physician should become familiar with the various implantable technologies existing for SCS. These include trial percutaneous electrodes, permanent percutaneous electrodes, permanent plate electrodes, totally implantable rechargeable and non-rechargeable pulse generators (IPG) and radiofrequency (RF) driven pulse generators.

Percutaneous electrodes

Percutaneous electrodes (or wire electrodes) are particularly appealing. Percutaneous electrodes can be inserted without much dissection and offers a substantial advantage when one performs a trial to assess candidacy for a permanent implant. After the trial period, the temporary percutaneous electrode can easily be removed in the implanting physician's office. During implantation, these electrodes can be advanced over several segments in the epidural space, allowing testing of several spinal cord levels to assess for optimal electrode position.

Contemporary percutaneous electrodes are slim electrodes, which are only a few millimeters in diameter and contain between 4-8 contacts with various spacings. (These are referred to as either quadripolar or octopolar electrodes.) Choosing the particular electrode entails deciding how many segments of the spinal cord are to be covered, with

larger spacing allowing broader coverage. Alternatively, closer spacing allows better steering and electric field shaping. Additionally, multiple parallel electrodes and different configuration matrices can be constructed which can create extremely focused electrical fields. The general trend is to utilize one or two quadripolar electrodes for limb pain and one or two octopolar electrodes for axial pain. Even insertion of three electrodes is being explored for better steering of current³³. These percutaneous electrodes also come in varying lengths and these differ by manufacturer. At times, extensions cables will be necessary to bridge the distance from the spinal entry point to the pocket in which will reside the battery.

The technique of percutaneous implantation.

The patient is positioned in a comfortable prone position on a fluoroscopy table. A pillow underneath the abdomen may create some kyphosis which might facilitate electrode insertion.

The level of electrode insertion is guided by several factors. A fundamental consideration is that several centimeters of the lead have to lie in the epidural space to assure maximal stability of the electrode and minimize unwanted migration. To assure this, insertion must take place at least two spine segments below the desired target. For cervical placement, one must be aware of the cervical cord enlargement and when possible, electrode insertion should be performed below the T1-2 level. Some surgeons advocate upper thoracic placement of percutaneous electrodes through a limited spinous process removal, in order to minimize the potential risk of spinal cord damage. For practical purposes, implantation for low back problems necessitates electrode insertion at T12-L1 or L1-2 while implantation for an upper extremity target requires insertion at T2-3 or T3-4.

The fluoroscopy equipment must be ready to function in both the antero-lateral and lateral planes at the time of needle insertion. The Touhy needle is inserted with as shallow an angle as possible. While in the thoracic area this can be accomplished with

either a midline or paramedian approach, in the upper lumbar area a paramedian approach is required. A steep angle increases the risk of electrode fracture.

Several methods are available to identify the epidural space. The tactile feedback is important but cannot be solely relied upon. The most common method is the loss of resistance using a low-friction glass syringe. We prefer to inject a small amount of air. Fluid injected in the epidural space may later be aspirated through the needle and give the false impression of being in the subarachnoid space. After multiple passes at one spine level have been performed, the loss of resistance method may lose its reliability. Inserting a Seldinger wire through the needle can provide invaluable information as to the degree of penetration into the spinal canal. If the needle tip is in the interspinous ligament and has not penetrated the ligamentum flavum, the wire cannot be advanced. The wire can be advanced only if the needle tip is in the paraspinal muscles or within the spinal canal. The pattern of advancement and the location of the wire under fluoroscopic imaging can further clarify its position.

Once the electrode is in the spinal canal, one has to be certain that it is positioned in the epidural space and not within the subarachnoid space. Even though this may seem obvious and easily recognizable, this may become a very difficult task and require multiple attempts at needle placement. This is particularly true if the arachnoid has been previously pierced and CSF has escaped and pooled in the dorsal epidural space. In the subarachnoid space, much less resistance is encountered when moving the electrode, particularly for lateral movements. The wire seems almost to be "floating" and undergoes large shifts of direction, where in the epidural space, movements are more discrete and obtained only with specific manipulations. The same type of wire/electrode movement can however be experienced epidurally if the dural sac has significantly collapsed secondary to CSF loss. Electrical stimulation will clarify the position, as a subarachnoid placement can elicit motor or sensory responses at much lower thresholds than epidural placement.

When the epidural space is satisfactorily identified, the electrode is gently inserted under fluoroscopic guidance in the antero-posterior view. Removal of the electrode once it has

been inserted through the tip of the needle has to be accomplished without insulation with the electrical contacts. If the electrode does not slide without minimal resistance, the needle and the electrode should be removed together. Every time the electrode is withdrawn through the needle, it should be inspected for minute breaks in the insulation, which would necessitate its disposal. Alternatively, a sleeve can be inserted over the guide wire in the epidural space. The guide wire is then removed and the electrode is inserted through the sleeve. This obviates the risk of shearing the electrode during manipulation. The electrode is then steered in the epidural space to the desired location. Should the targeted location prove to be less than two spinal segments from the electrode insertion, the electrode should be withdrawn and repositioned at a more caudal level.

Frequently, the electrode curves around the dural sac and ends in the ventral epidural space. In the antero-posterior projection this might be indistinguishable from a proper midline dorsal location. A gentle lateral curve of the electrode shortly after its entry in the epidural space should arise the suspicion that it is directing ventrally around the dural sac. Absolute confirmation of the ventral location arises from the stimulation generating violent motor contractions or observation in the lateral plane which would readily disclose the anterior position of the electrode tip. If more than one electrode is inserted, it is wise to insert the other needles before inserting the electrodes. Needle insertion might shear an already implanted electrode. Besides, it is often possible to insert two electrodes simultaneously and advance them synchronously in the epidural space while maintaining their relative position and spacing.

Once in place, the electrode must be secured to the interspinous ligament to minimize dislodgment. An X-ray is obtained to document electrode level and position. We have found that securing loops at the electrode insertion site serves to relieve the strain and reduces migration during bending. Frequently, anchors are used to secure the electrode and the implanter should remember that anchoring is a two step process: 1. Securing the anchor to the electrode. 2. Securing the anchor to the fascia. At present, there is only one anchor available which has the ability to be detected on radiographs, the TITAN anchor (Medtronic, Inc, Minneapolis, MN) (Figure 1)

A major disadvantage that has been cited with percutaneous electrodes is their tendency to migrate. This is related to their inherent flexibility, which is necessary for their insertion through a Touhy needle, and to their cylindrical shape, which does not prevent migration even months after implantation. Some percutaneous electrodes require a stiffening stylet for introduction. Also, percutaneous electrodes are less energy efficient than plate electrodes. The electrical current is distributed circumferentially around the electrode and is expected to result in greater shunting of current. Patients with percutaneous leads also describe a greater positional variance in their paresthesia.

Recently ANS (ANS – A St. Jude company, Plano, TX) has introduced a slim-line plate type electrode, which can be inserted percutaneously. The broader electrode base provides a surface where fibrosis should lessen the risk of caudal electrode migration. The slimmer profile of the electrode might also have advantages in the cervical spine where spinal cord compression might be an issue. Finally, the design emulates that of a mini-plate lead as the contacts are on one side with the other side being insulated. This will definitely be more energy efficient than a percutaneous lead which would allow delivery of current circumferentially. (Figure 2)

Plate electrodes

Plate-type electrodes (or ribbon electrodes, paddle electrodes, or laminotomy electrodes) require a surgical procedure, laminotomy, and implantation under direct vision⁽²⁸⁾. Implantation under direct vision may be safer in the upper thoracic and cervical areas, where there is a risk of damaging the spinal cord with the large bore Touhy needle. Most implants can be done through a skin incision between 2.5 – 4 cm long, depending on the size of the patient and spinal anatomy. The amount of bony removal is usually minimal

Multiple arrays or different electrode configurations can be also constructed with plate electrodes. The main advantage of plate electrodes resides in their more inherent stability in the dorsal epidural space and lesser propensity to migrate. Some preliminary data by North also suggest a broader stimulation pattern and lower stimulation requirements with plate electrodes⁹⁶. Plate electrodes are more energy efficient in delivering electrical

stimulation. We advocate plate electrodes as the only option in the case of previous spine surgery at the implant levels.

Plate electrodes come in many sizes, shapes, spacing, and configurations. There are single column and dual column electrodes. As with percutaneous leads, there are varying lengths, and shapes – such as curved leads and hinged leads, all designed to help facilitate insertion and tailor the electrode selection to the patient.

There is some literature describing the advantages of plate leads. North et al have published on comparison between plate and percutaneous electrodes⁹⁶. Laminectomy electrode placement, although more invasive than percutaneous placement, yielded significantly better clinical results in patients with failed back surgery syndrome at up to 3 year follow up. Clinical success was defined as at least 50% pain relief and patient satisfaction with treatment. Secondary outcome measures were ability to perform various activities of daily living, neurological function, and analgesic use. There is some theoretical evidence that shaping of the electrical field is possible with even more complex electrode arrays. Holsheimer et al⁹⁷ concluded that the transverse tripolar system enabled finer control of paresthesia. Electrical field steering could change the paresthesia area completely. When the transverse tripolar configurations are used, the threshold for stimulation of dorsal roots is higher, compared with the dorsal column threshold. This results in a wider therapeutic range, wider paresthesia coverage, and a greater probability to fully cover the painful area with paresthesia.

One must bear in mind, that with the increasing number of contacts, there is a significant increase in power consumption and the complexity of programming rises in even a greater magnitude. With two contacts, the total number of configurations possible are eight, with four contacts, sixty-four; and with eight and with sixteen contacts, it increases exponentially to reach a number in the millions.

Two basic positions can be utilized: prone or semi-lateral. The prone position allows a more intuitive understanding of the spatial relations and is one that more surgeons are

familiar with. In this position, it can be difficult to obtain adequate sedation for the surgical exposure and maintain the airway. In the semi-lateral position, the patient lies comfortably in a park bench type position, allowing access to the spine as well as the flank, abdomen, or buttock for the implant of the pulse generator. The patient is asked to place him/herself in the most comfortable position. If the pain is predominantly on one side, the patient is asked to lie on the less affected side. In this position, airway management is safer than in the prone position and the anesthesiologist is more comfortable in keeping the patient deeply sedated. Given the variable degree of rotation of the body, it can be difficult for the surgeon to determine the location of the midline. This might constitute a significant problem in the cervical area.

Strategies at different spine levels

The planned level is localized either with fluoroscopy or with a plain X-ray with metallic markers placed on the skin at the level of the planned incision. In a thin individual the incision is about one inch in length; even in large individuals, the incision seldom needs to be more than two inches long. Different considerations apply if one is implanting through a previously operated on level.

For cervical placement, the patient is placed in the semi-lateral position with the neck slightly flexed. Even with a short skin incision one can reach 3-4 levels by extending the incision and stretching the skin edges with a Gelpi retractor. The neck should be flexed but not excessively rotated laterally. Even though some neck rotation is inevitable, extreme rotation substantially increases the level of difficulty.

Subperiosteal dissection is usually limited to the upper half of the spinous process inferior to the addressed ligamentum flavum and to the whole spinous process superior to it. Parts of the superior spinous process are incrementally removed until the ligamentum flavum is exposed. In the lower thoracic/upper lumbar area this usually resulted in removal of inferior 1/3rd of the spinous process. In the mid-thoracic area, due to the acute angle and significant overlapping of the spinous processes, the whole spinous process must be removed. Following removal of the ligamentum flavum, the electrode(s)

is inserted in the dorsal epidural space; the electrode position is then confirmed with fluoroscopy and testing is performed with either motor stimulation or with the patient awakened and, when mentally lucid.

Alternatively, the electrode can be placed with the patient fully in the prone position. Fluoroscopy should be used to identify the same level where the active contacts were placed during the trial. A laminotomy is performed approximately one level below this point as allow the plate electrode to reach up to the intended level. After placing the electrode, intra-operative stimulation with electromyographic correlation will be able to detect stimulation in the extremity and lateralization of the electrode. We stimulate the electrode with 5 Hz stimulation at greater than 310 us pulse width and ramp up the amplitude until EMG signal changes are detected. Bilateral extremity stimulation suggests midline placement and early root onset implies too lateral a placement. We have had instances in which the physiological midline differed from the anatomic midline and we will be more apt to rely on the intra-operative physiology in those instances. When treating, axial symptomatology, the lead is placed to straddle the midline. For patients with unilateral pain, the lead is placed so that one array is on the side of the pain and the other is on the midline.

Rechargeable and non-rechargeable Pulse Generators and Radio-Frequency Receivers (Figure 3)

Electrical stimulation consists of rectangular pulses delivered to the epidural space through implanted electrode via a power source. Two basic types of systems are currently available: an Internal Pulse Generator (IPG; also called the battery.) or a radiofrequency (RF) coupled pulse generator with an implantable receiver. The later has largely fallen out of favor due to the inconveniences of having an external power source. However, the advent of the totally implantable, rechargeable pulse generator has surmounted the power requirement issues, which were previously, the real RF advantage.

The totally implantable pulse generator contains a lithium battery. Activation and control occur through an external transcutaneous telemetry device. The IPG can be turned on and off through a small controller which the patient can carry. The controller also allows some control over the stimulation parameters. More extensive control of the unit can be achieved through a small portable unit which can be programmed by the physician. Life span of the battery varies with usage and with the utilized parameters (voltage, rate, pulse width, etc.). Most patients can expect, under average usage, that the battery last between 2.5 to 4.5 years. Available lithium powered pulse generators allow stimulation with fine resolution increments of 0.05 V and with varying rates and pulse widths. Replacement of the battery requires a surgical procedure which is usually performed on an outpatient basis.

A particular IPG is selected based on many variables. From a practical standpoint, the first and foremost reason might be the size of the patient. Although larger batteries will have longer life, the site of insertion of the IPG (either the buttock, abdomen, or the subclavicular region) is often the source of significant patient complain. (We prefer to implant the IPG in the buttock because of the ease associated in tunneling from the electrode insertion. Further, with a patient placed prone for electrode insertion, there is no repositioning required to reach the buttock region. We identify boney prominences including the posterior superior iliac crest, the greater trochanter of the femur, and the apex of the iliac crest and implant the IPG in the lateral aspect of this triangle. (Figure 4)

Radio frequency (RF) driven systems, consist of a passive receiver, implanted subcutaneously, and a transmitter which is worn externally. An antenna applied to the skin in correspondence of the receiver is connected to the transmitter ,which sends the stimulation signals transcutaneously. In order for the system to function, the transmitter has to contain charged alkaline batteries and the antenna must make adequate contact with the receiver. This requires the patient to wear the external system in order to receive the stimulation. RF driven systems can deliver stimulation with rates up to 1,400 Hz, and can be customized to deliver high power levels. RF systems have the inconvenience of having to wear the antenna and the radio-receiver. The problem might go beyond pure inconvenience in individuals who have handicapped motor function in the upper

extremities and cannot properly go through all the steps required to make the external unit function properly. Other patients, particularly individuals who have reflex sympathetic dystrophy (RSD), may not tolerate the antenna taped to the skin. Obtaining adequate contact of the receiver with the skin may be difficult secondary to swelling at the site. The equipment cannot be worn while swimming or showering, and severe perspiration, as with exercise and physical therapy, might make proper contact of the antenna problematic. Furthermore, the patient has to replace batteries on a regular basis and make sure that proper coupling exists between the antenna and the receiver at all times. However, what one loses in convenience, however, is gained in power and flexibility. Currently only RF systems can provide a stimulation rate up to 1,400 Hz. This might be beneficial in some patients with neuropathic chronic pain syndromes⁹⁸, as well as in patients with extrapyramidal motor disorders .

Rechargeable systems have now become available. Medtronic's device, known as the Restore Rechargeable Neurostimulation System, uses a battery with an estimated nine-year total life span. It takes about six hours to fully recharge the batteries. The Advanced Neuromodulation Systems' Eon device has a battery life that is currently estimated at seven years. Boston Scientific's Precision device has a battery life estimated at five years. A detailed comparison of the features of the rechargeable batteries are seen in Table 1.

Complications

With the proper expertise, permanent complications are rare⁷⁰. The most serious complication, which is shared with any type of spine surgery, is paralysis or any severe neurological deficits. This can occur during spinal cord stimulation procedures, both with percutaneous and plate electrodes. Infection of the implanted hardware has occurred with a 3-5% rate. Persistent pain at the implant site has been seen in about 5% of patients. Recalcitrant cerebrospinal fluid leakage has been encountered in a few patients, requiring multiple surgical revisions. Breakage or malfunction of the implanted hardware, particularly the electrodes and the subcutaneous extension cables has been encountered in

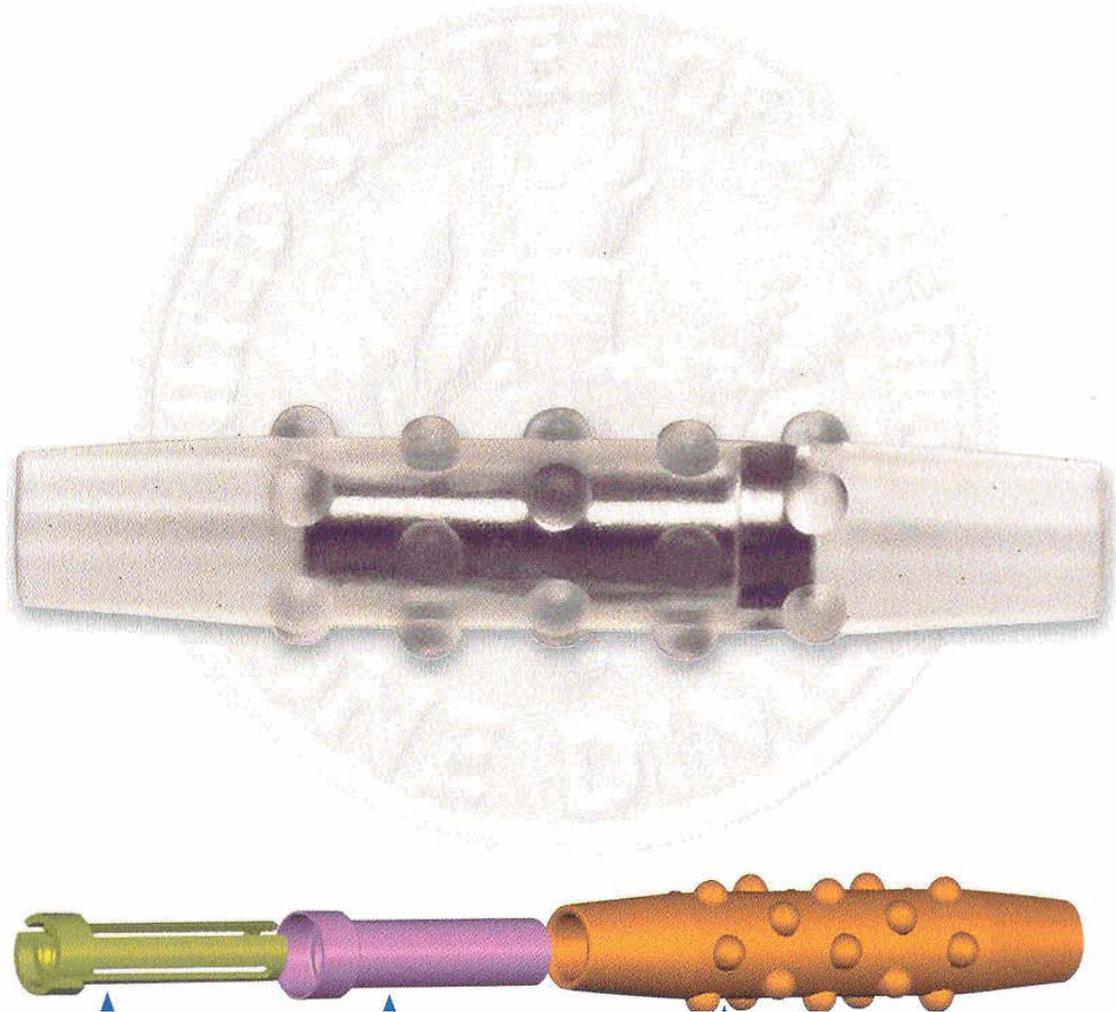
about 10% of the implanted systems. Painful stimulation, necessitating either repositioning or removal of the electrode, has also been reported in a number of cases.

Conclusions

The treatment of chronic pain remains challenging. Spinal cord stimulation has been performed for over 30 years, and slow but steady progress with this technology has been made. As the equipment and stimulation parameters are improved, selection criteria has been better defined and is slowly being expanded. More importantly, experience in the technique and the equipment has made SCS a much more reliable and safe modality. Like all the modalities performed for chronic pain management, its results are favorable. It is important to remember that the goal of neurostimulation is to reduce pain, rather than to eliminate pain. It has been shown to have a 50% improvement in pain relief. Very few other invasive modalities can claim this success rate with a few years of follow-up

Careful follow-up of the patients is necessary for successful long-term satisfaction. Equipment related problems can arise at any time after implantation, such as discomfort at the pulse generator/radio receiver site, electrode(s) breakage or migration, infection, etc., and an open dialogue with the patients is vital for the continuing successful implementation of the modality. Spinal cord stimulation has earned a well established and firm role in contemporary chronic pain management.

Figure 1: Titan Anchor – (Medtronic Inc. Minneapolis, MN)



3-PART DESIGN

- Titanium insert
- Soft silicone outer body
- Silicone sleeve

Figure 2: Slim-line Electrode – (ANS – A St. Jude Company, Plano, Tx)

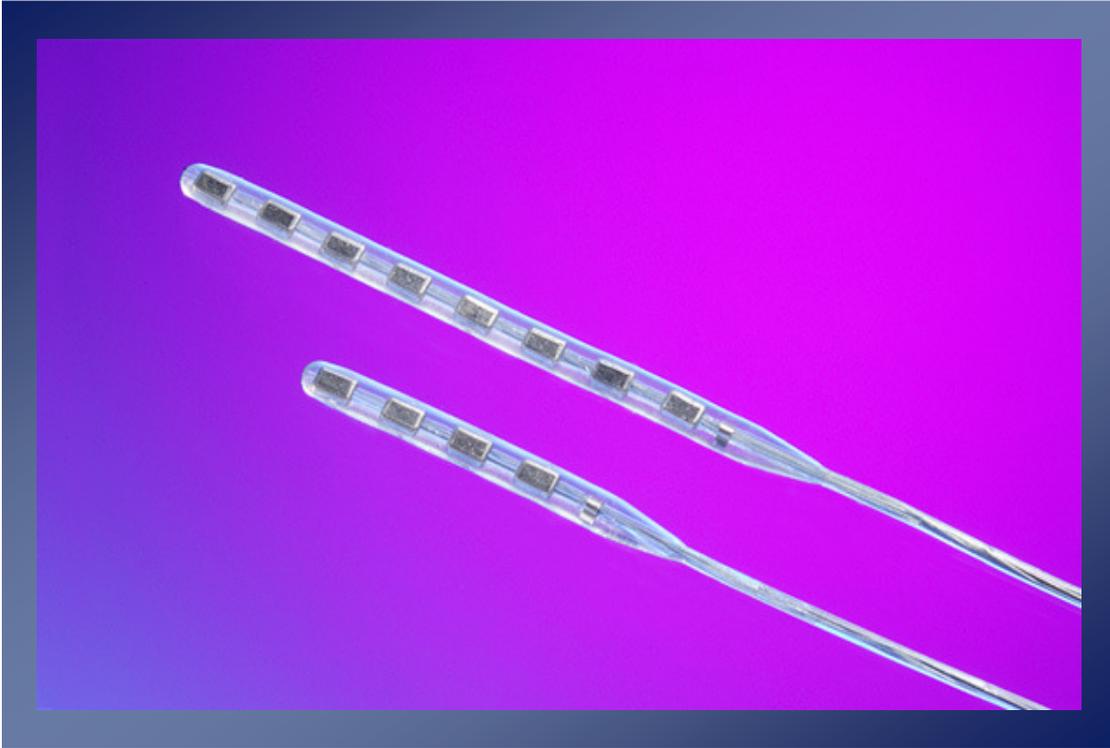


Figure 3: Rechargeable batteries.



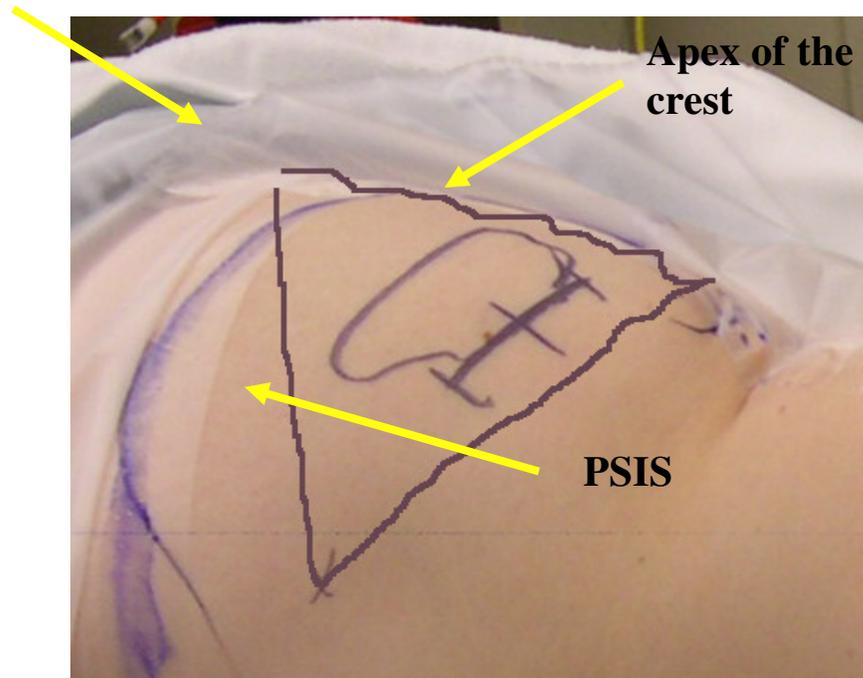
Table 1: Comparison on Rechargeable Batteries

	Precision Plus	Restore Advanced	Eon
Volume (cc)	22	39	42
Dimensions	55 x 45 x 11	65 x 49 x 15	59 x 58 x 16
Weight (g)	36	72	75
Stimulation output	Multiple current sources	Constant voltage	Constant current
Amplitude	0 - 20 mA	0 - 10.5V	0 - 25.5 MA
Frequency	2 - 1200 Hz	2 - 130 Hz	2 - 1200 Hz
Pulse Width	20 - 1000 us	60 - 450 us	50 - 500 us
Battery Capacity	200 mA hr	300 mA hr	325 mA hr
Rechargeable	Cordless	Cordless	Connect to Outlet
Wireless communication	up to 30 inches	up to 4 inches	N/A
Maximum Recharge Depth	2 cm	1 cm	2.5cm

Figure 4: Battery Placement

The following is our described technique for the placement of the battery in the buttock region. The boney prominences are marked: the greater trochanter/lateral femur, the apex of of the iliac crest, and the posterior superior iliac spine (PSIS). A triangle is created and the battery incision is made parallele to the top rung of the triangle.

Lateral Femur



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