
Computer Modeling of Spinal Cord Stimulation for Low Back Pain

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Introduction

Spinal cord stimulation (SCS) is a minimally invasive and reversible therapy for many types of chronic pain. Indications include failed back syndrome (FBS), radicular pain syndrome or radiculopathies secondary to FBS or a herniated disk, post-laminectomy pain, degenerative disk disease, arachnoiditis, and complex regional pain syndrome (CRPS). The therapy is based on the “gate-control” theory for segmental pain suppression, first articulated by Melzack and Wall in 1965. According to the theory, the body can inhibit pain signals or “close the gate” by activating the large diameter afferent fibers in the dorsal column of the spinal cord. SCS delivers low-amplitude electrical stimulation to the spinal cord to block the sensation of pain.

SCS systems typically consist of three parts: 1) a series of electrodes on one or more leads, which are placed in the dorsal epidural space and deliver electrical stimulation to the spinal cord; 2) a power source, which generates the electrical stimulation; and 3) an extension, which delivers current from the power source to the electrodes. Physicians can adjust four basic system parameters (electrode polarity, pulse amplitude, pulse width, and pulse rate), as described in Table 1, to meet an individual patient’s pain control needs.

Table 1. Stimulation Parameters.

Parameter	Description
Electrode polarity	Each electrode can be programmed as an anode (+) or cathode (-), or turned off, allowing for multiple electrode configurations. There must be at least one anode and one cathode designated.
Pulse amplitude	Stimulation intensity or strength, measured in volts (V)
Pulse width	Stimulation duration, measured in microseconds (μ s)
Pulse rate	Number of times/second that a stimulation pulse is delivered, measured in pulses per second (pps) or Hertz (Hz)

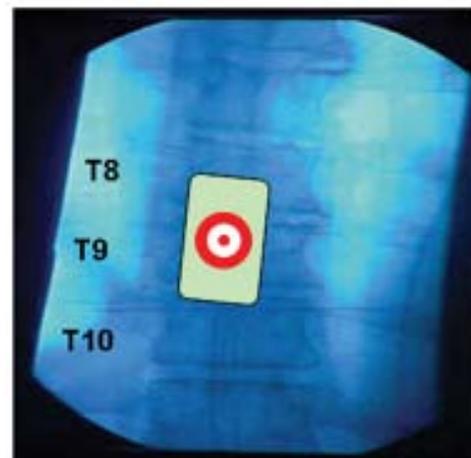
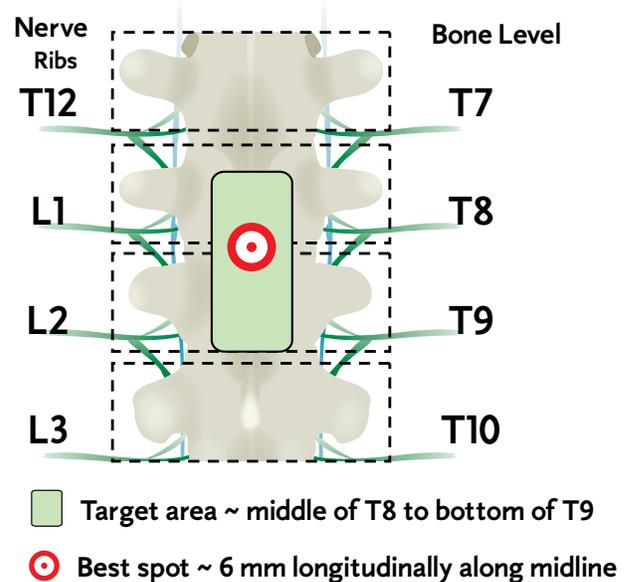
When successful, SCS creates paresthesia that completely and consistently covers the painful areas, yet does not cause uncomfortable sensations in other areas (Law, 1983). Such paresthesia can be elicited by stimulating A β fibers in the dorsal column (DC) and/or the dorsal roots (DR). DC stimulation typically causes paresthesia in a number of dermatomes at and below the level of the cathode. In contrast, DR stimulation activates fibers in a limited number of rootlets close to the cathode and causes paresthesia in only a few dermatomes. Because of

these factors, DR stimulation may not produce sufficient pain relief. Another potential drawback to DR stimulation is that the roots also contain large proprioceptive fibers which, when stimulated, can cause uncomfortable sensations and motor responses (Holsheimer, 2002). These side effects can occur at pulse amplitudes that are below the value needed for full paresthesia coverage.

Use of Spinal Cord Stimulation for Low Back Pain

While SCS has been an effective therapy in the treatment of radicular pain, its use to achieve pain relief in the axial low back has been more difficult (Barolat et al., 1993; Stojanovic and Abdi, 2002). A small, theoretical region found between the T8 and T9 vertebral level junction (i.e., corresponding to the L1 and L2 spinal nerves innervating the low back) has been identified as an optimal SCS target for low back pain (Schade, 2000; Stojanovic and Abdi in Boswell and Cole, 2006) (Figure 1).

Figure 1. SCS target for low back pain.



However, several anatomic and physiologic characteristics make it especially challenging to elicit effective stimulation in the low back area. First, at the T8 and T9 levels, the dorsal CSF layer is near its maximum thickness (Holsheimer and Barolat, 1998) (Figure 2) and the DC fibers from the lumbar back are directly adjacent to the medial side of the DR fibers. Both factors can result in preferential recruitment of DR fibers over DC fibers. Second, the L1 and L2 dermatomes are relatively thin, making precise lead placement critical to avoid T12 recruitment, which results in painful sensations in the lower rib area (Figure 3).

Figure 2. The dorsal CSF is relatively thick at the T8-T9 level (Holsheimer and Barolat, 1998).

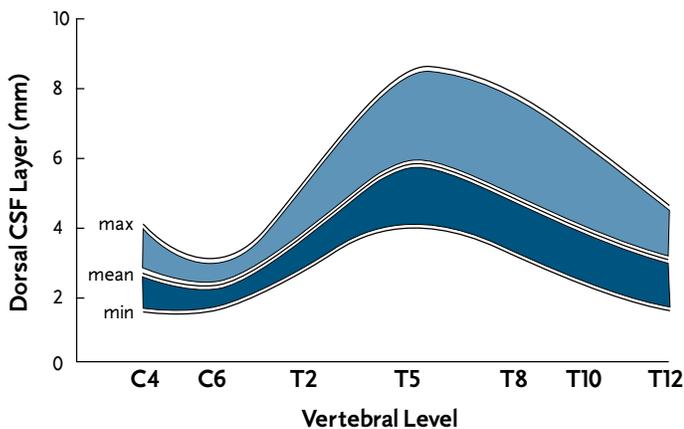
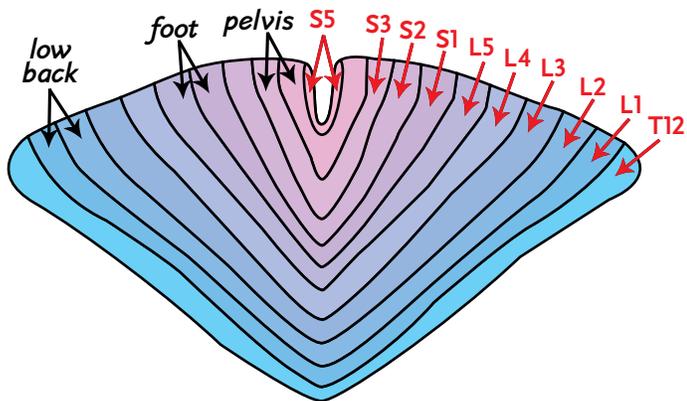


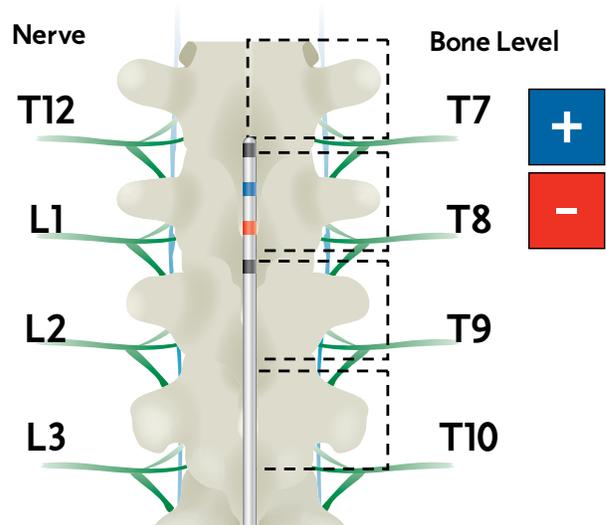
Figure 3. L1 and L2 dermatomes are thin and close to T12 (Feirabend et al., 2002).



Physicians have tried a number of different SCS configurations in their efforts to achieve effective paresthesia for the treatment of low back pain. Some use one percutaneous quadripolar lead on the physiologic midline (Law, 1983; North et al., 2005) and postulate that patients can tolerate higher amplitudes with this configuration, since electrodes are relatively far from the DR fibers. If the cathode is placed at the T8 level, the anode is typically

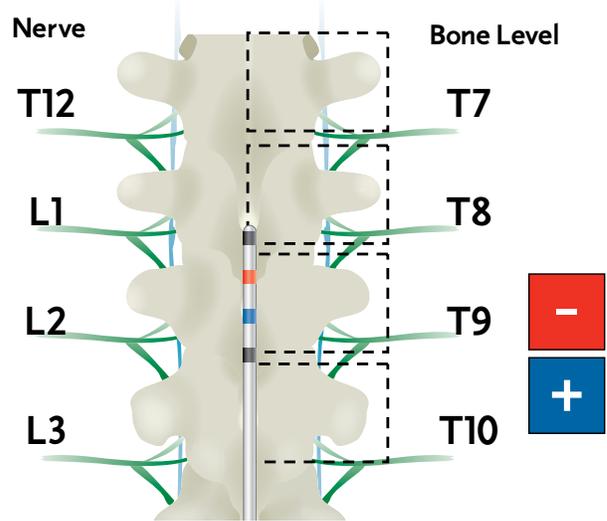
placed above it to shield T12 spinal nerves and avoid rib pain (Figure 4).

Figure 4. One quadripolar lead on the physiologic midline with anode above cathode to shield T12 stimulation (North, 1991, 2005).



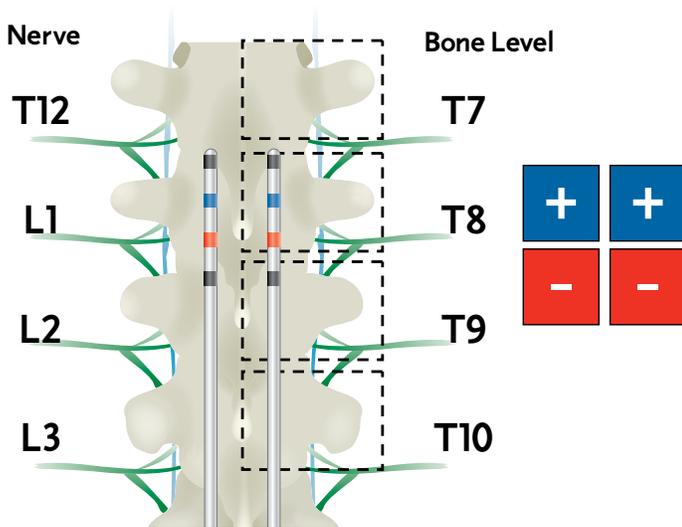
If the cathode is placed at the T9 level, the anode is typically placed below it, resulting in a wider therapeutic range (i.e., the ratio of discomfort threshold to paresthesia perception threshold) (Law, 1983) (Figure 5).

Figure 5. One quadripolar lead on the physiologic midline with cathode above anode (Law, 1983).



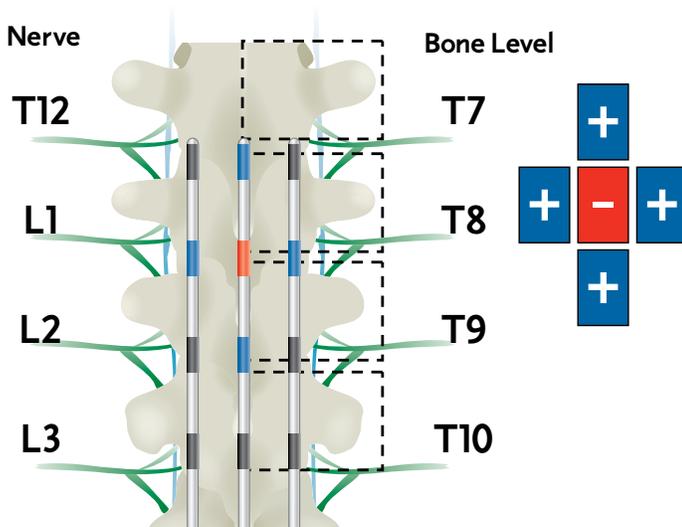
Others (e.g., Barolat et al., 1993) use two percutaneous quadripolar leads flanking the midline, which may create paresthesia in both the back and lower limbs, resulting in better coverage (Figure 6). Two leads allow independent, optimized amplitudes on each side (Schade, 2000; Stojanovic and Abdi in Boswell and Cole, 2006).

Figure 6. Two quadripolar leads flanking the physiologic midline (Schade, 2000).



A third configuration employs three percutaneous leads. For example, Prager and Chang (2000) reported on a system consisting of three percutaneous, quadripolar leads with the outer two connected in parallel (Figure 7). This allowed anodes to be placed longitudinally and laterally with respect to the cathode (a “guarded cathode” configuration) and increased the therapeutic range. That is, it permitted high amplitude stimulation without the negative sensory and motor effects observed with single or dual quadripolar leads.

Figure 7. Three quadripolar leads with a laterally and longitudinally guarded cathode (plus-sign) configuration.



To date, physicians have typically determined electrode combinations and geometries for a given patient by trial and error. This task becomes increasingly complex as the potential number of leads and electrodes per lead increases (see Enhanced Programming Capabilities, p. 7). To better understand possible differences in current density, neuron activation patterns, fiber selectivity, and energy requirements among various electrode configurations on three leads, Medtronic uses two computational models, one developed at the University of Twente, and an analogous model developed within Medtronic using commercially available software.

Computer modeling was based upon Medtronic’s unique models of four- and eight-electrode leads, each of which has a different inter-electrode spacing (Table 2) that provides varying degrees of longitudinal coverage along the spinal cord.

Table 2. Lead Specifications.

Lead	Electrode Length (mm)	Edge-to-Edge Spacing (mm)	Center-to-Center Spacing (mm)
Standard 1x8 Model 3777	3.0	6.0	9.0
Compact 1x8 Model 3778	3.0	4.0	7.0
Subcompact 1x8 Model 3776	3.0	1.5	4.5
Pisces-Quad® (1x4) Model 3487a	3.0	6.0	9.0

Three-lead arrays can be used to generate new patterns of electrode configurations using two standard-spaced, four-electrode leads (model 3487A) flanking one eight-electrode lead (Figure 8).

Figure 8. Three-lead arrays with one octad lead (variable electrode spacing) in the middle flanked by two standard-spaced leads.

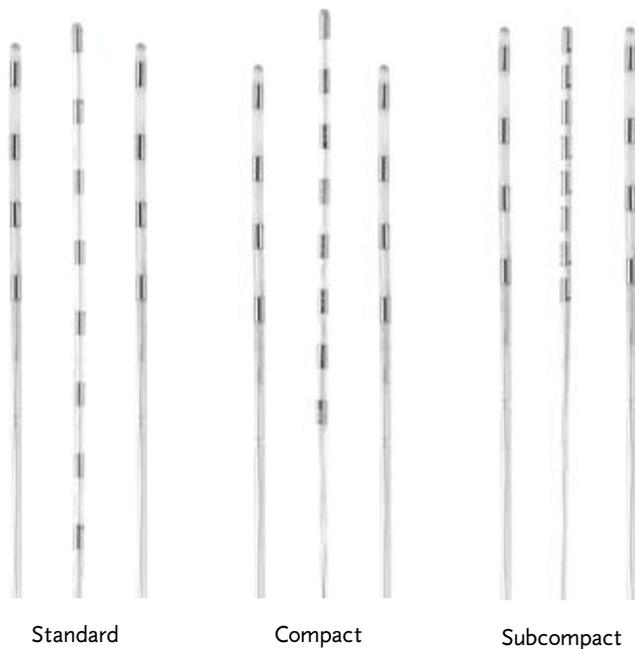
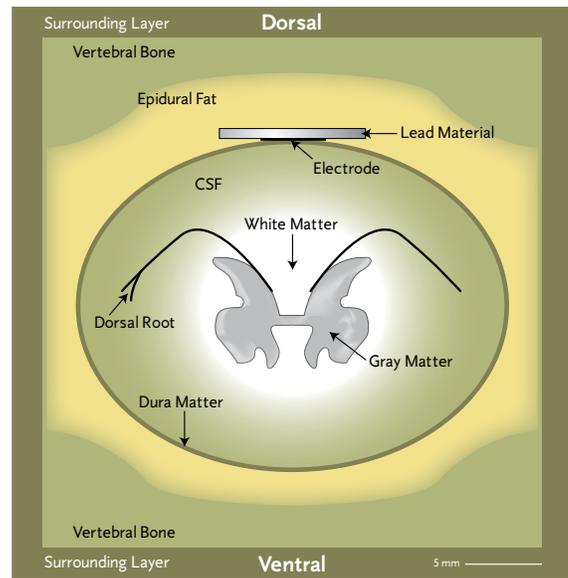


Figure 9. Transverse view of the cervical volume conductor model (Holsheimer, 1997b).



Computer Modeling of Spinal Cord Stimulation

The model developed by the University of Twente simulates the effect of SCS on DC and DR fibers in the spinal cord (Holsheimer et al., 1995). It consists of two parts: 1) a three-dimensional volume conductor model of the anatomical and electrical properties of the spinal area, and 2) a model of the electrical behavior of myelinated nerve fibers in the same area. First, the volume conductor model is used to calculate the electrical field produced by anodal and cathodal electrodes at given potentials and specific positions. This field is then applied to the nerve fiber model to determine the extent to which DC and DR fibers are stimulated. Many subsequent publications have relied on this model (e.g., Holsheimer and Wesselink, 1997a; Holsheimer and Wesselink, 1997b; Struijk and Holsheimer, 1996).

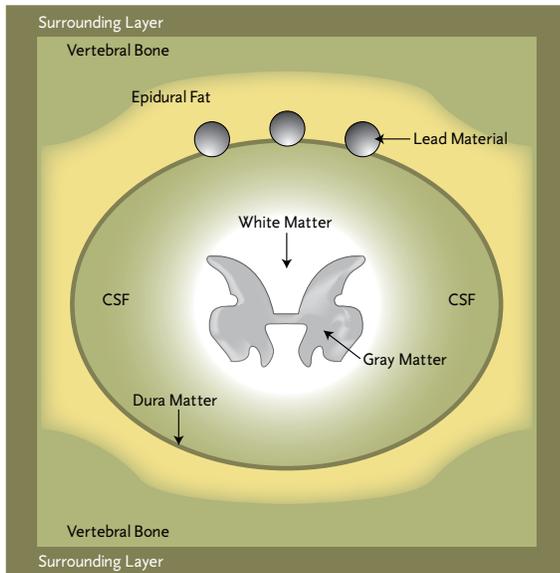
Included in the volume conductor model are geometries and electrical conductivities of the white and gray matter of the spinal cord, the dura mater, the cerebrospinal fluid (CSF), epidural fat, electrode insulation, and vertebral bone (Figure 9). The model measures approximately 24 mm x 25 mm x 60 mm. Based on magnetic resonance images from 26 normal human subjects, dorsal CSF thickness approximates the mean values for the mid-cervical, mid-thoracic, and low-thoracic spinal cord (Holsheimer et al., 1994).

Two-dimensional anodal and cathodal electrodes are placed in the dorsal epidural space next to the dura. These electrodes are set at different, constant voltages; and, in monopolar stimulation, the boundary of the model serves as the distant anode. "A finite difference method is applied to discretize the governing Laplace equation. The resulting set of linear equations is solved using a Red-Black Gauss-Seidel iteration with variable over-relaxation" (Holsheimer and Wesselink, 1997b), and the electric field is calculated. Excitation thresholds are determined for DC and DR fibers using a nerve fiber model based on a cable model extended with collaterals (McNeal, 1976). The stimulus threshold for a particular fiber is determined by increasing the potential difference between the active electrodes until excitation of the fiber model occurs.

Medtronic's analogous model uses commercially available finite element software (Ansoft Maxwell[®] 3D; Ansoft, Pittsburgh, PA) to calculate the electrical field in the three-dimensional volume conductor (Figure 10). Representations for white and gray matter of the spinal cord, dura mater, CSF, epidural fat, and vertebral bone are based on the geometries of the University of Twente low-thoracic model (Enschede, The Netherlands). Voltage boundary conditions were used in the model to calculate the electrical field generated by a particular electrode configuration (combination of anodes and cathodes). A neuron simulation program (Neuron v. 5.8) is used to calculate the response and thresholds of DC and DR fibers, which have the properties of mammalian myelinated fibers (McIntyre, 2002). The DC fiber is 12.8 μm in diameter

with a 10-node collateral $5.7 \mu\text{m}$ in diameter. The DR fiber is $15 \mu\text{m}$ in diameter and is attached to a 31-node $12.8 \mu\text{m}$ longitudinal fiber in the lateral dorsal columns. A monophasic, rectangular stimulus pulse of $210 \mu\text{s}$ is used.

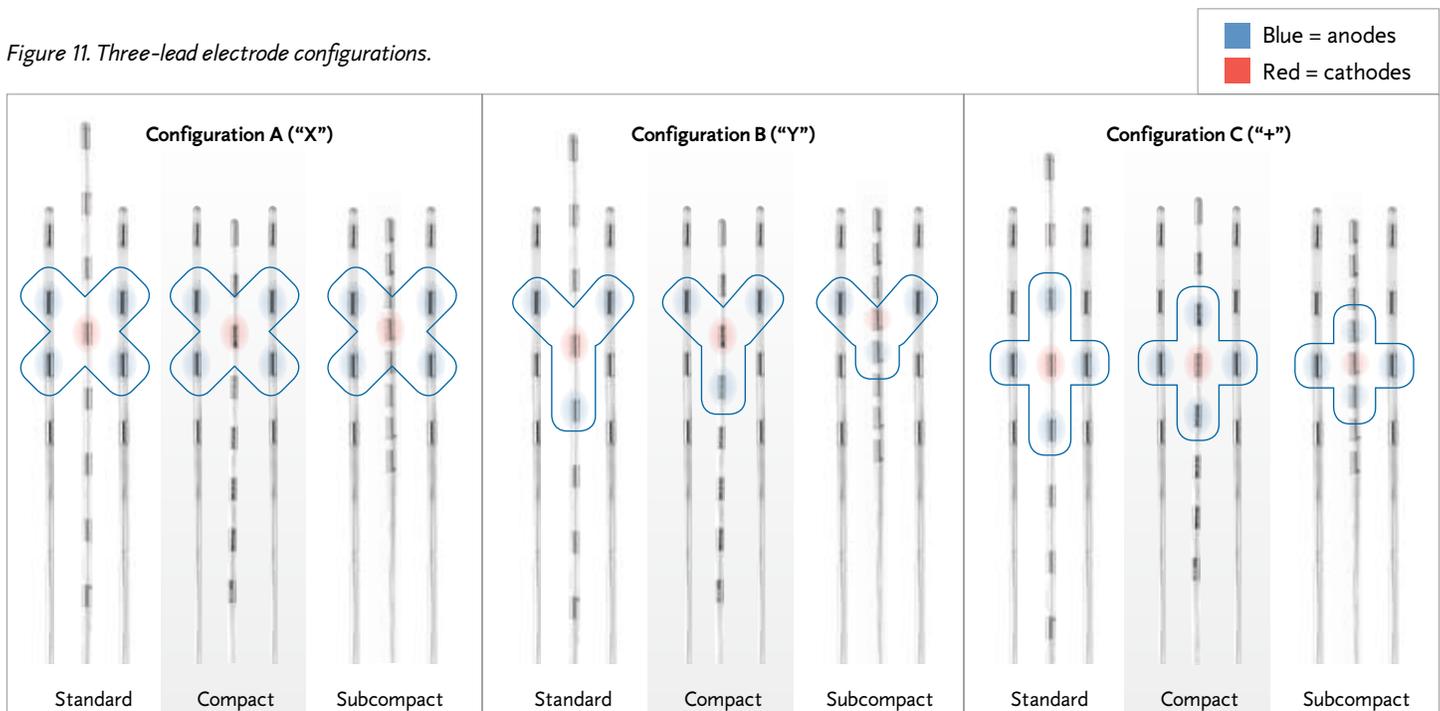
Figure 10. Transverse view of the low-thoracic volume conductor model.



Analysis of Electrode and Lead Configurations

Using the computational tools described above, Medtronic analyzed the current density, patterns of neuron activation, recruitment ratios, and energy requirements for three different electrode configurations (Figure 11):

Figure 11. Three-lead electrode configurations.



- a “X” configuration (Configuration A),
- a “Y” configuration (Configuration B), and
- a “guarded cathode” or plus sign (+) shaped configuration (Configuration C).

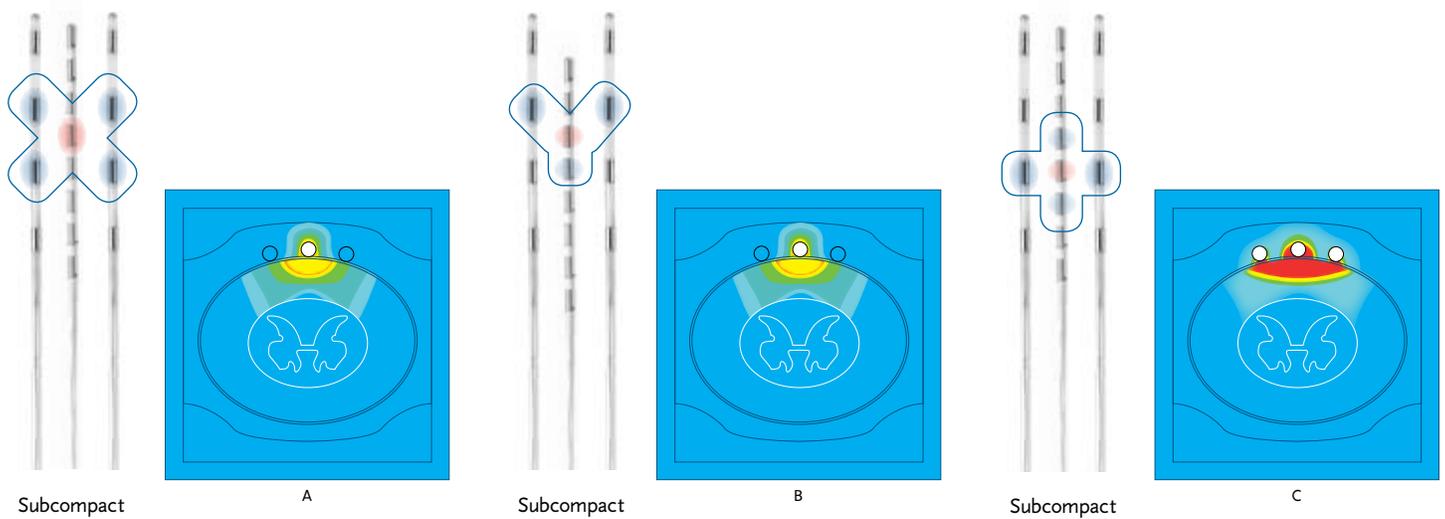
Each configuration consisted of three leads and required use of Medtronic model 37082 Stretch-Coil™ bifurcated extension to create a “4-8-4” configuration. Within each configuration, Medtronic analyzed three different variations, each of which consisted of two four-electrode leads (Medtronic model 3487 standard spaced Pisces-Quad® leads) flanking a standard, compact, or subcompact eight-electrode lead on the midline (see Table 2 for specifications). All three-lead configurations assume a 2-mm lateral interlead spacing and a 3.8-mm low-thoracic CSF thickness.

Current density

Electrical stimulation of excitable tissue, such as neuronal tissue, involves the passage of current through the tissue. Current density plots show the distribution of current within the volume conductor model. As articulated by Wesslink (1998), the current density at the spinal cord will be only a small fraction (i.e., 5-10%) of the current density at the electrodes, because most of the current will be shunted in directions lateral, rostral, and caudal to the cord within the highly conductive CSF (Wesslink, Holsheimer, and Boom, 1998).

For Configurations A, B, and C, there is negligible difference in current density whether the eight-electrode lead on the midline had standard, compact, or subcompact electrode spacing. Figure 12 shows current density

Figure 12. Current density.



for each of the three configurations using subcompact lead spacing.

Patterns of neuron activation

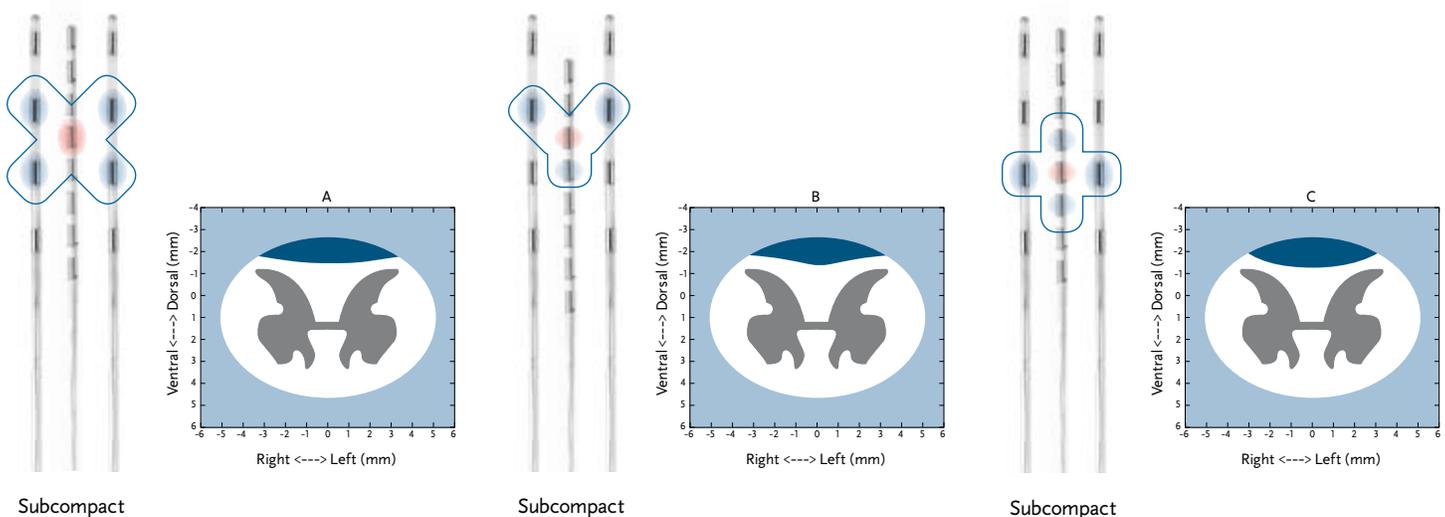
The effect of stimulation on neuron activation is represented in the transverse plane, since DC fibers are oriented longitudinally along the dorsal spinal cord. The neuron activation pattern has been generated by calculating whether a DC fiber is activated at the discomfort threshold (1.4 times the dorsal root threshold). Figure 13 shows neuron activation patterns for each of the three configurations using subcompact lead spacing.

Recruitment ratio

According to Holsheimer and Wesselink's modeling work, both DC and DR fibers can give paresthetic sensations and probably therapeutic effects, although care must be taken to avoid stimulation of large-diameter muscle afferents, which may lead to undesirable motor effects (Holsheimer and Wesselink, 1997). The recruitment ratio used in Medtronic's modeling is the ratio of dorsal column stimulation threshold to dorsal root stimulation threshold (V_{DC}/V_{DR}). Lower recruitment ratios indicate a lead and electrode combination that preferentially activates dorsal column fibers over dorsal root fibers.

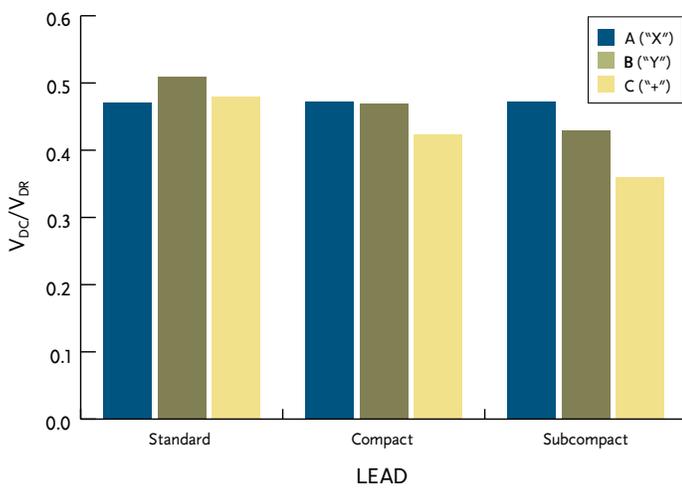
For Configuration A, there is negligible difference in recruitment ratio whether the eight-electrode lead on the midline has standard, compact, or subcompact electrode

Figure 13. Neuron activation patterns.



spacing. The electrode spacing has no impact on Configuration A because a single electrode (cathode) is active on the midline lead. Therefore, the lead can be repositioned so that the cathode is aligned to provide the desired "X" configuration. This is not the case for Configurations B and C where more than one active electrode is programmed on the midline lead. Thus electrode spacing does impact recruitment and energy requirements for these two configurations. However, for Configurations B and C, the recruitment ratio decreases as electrode spacing on the eight-electrode lead decreases. The recruitment ratio is lowest for Configuration C. Figure 14 shows recruitment ratios for the three configurations.

Figure 14. Recruitment ratios.



Energy requirements

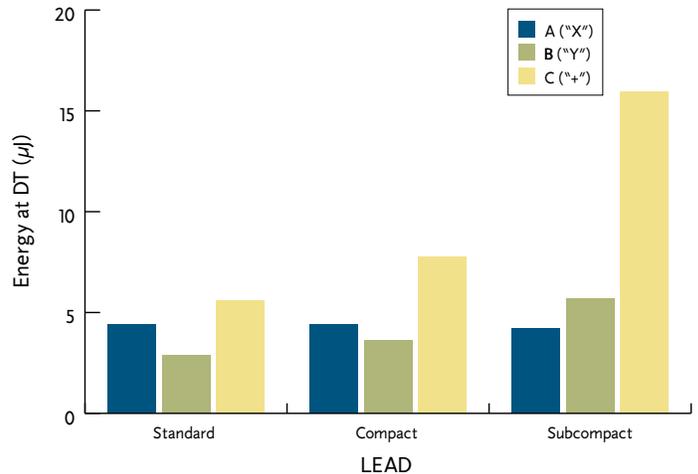
The energy per pulse at discomfort threshold (DT) has been calculated for each of the three configurations using the following equation:

$$Energy = \frac{V * V * PW}{Z}$$

where V is the voltage at DT, PW is the pulse width, and Z is the tissue impedance.

For Configuration A, there is negligible difference in energy requirements whether the eight-electrode lead on the midline has standard, compact, or subcompact electrode spacing. For Configurations B and C, energy requirements increase as electrode spacing on the eight-column lead decrease. Energy requirements are highest for Configuration C. Note that, for Configuration C, the cost of a lower recruitment ratio (Figure 14) is a higher energy requirement. Figure 15 shows energy requirements for each of the three configurations.

Figure 15. Energy at DT for each model.



Medtronic RESTOREADVANCED® Neurostimulation System

In the past, one limitation to the use of three percutaneous leads has been high energy requirements (Holsheimer, 1997). Medtronic's recently released RESTOREADVANCED neurostimulation system overcomes this limitation. The system is rechargeable and has two-ports, 16 electrodes, and a Stretch-Coil™ bifurcated extension, which can connect three percutaneous leads to a 16-electrode compatible neurostimulator (Figure 16).* The extension attaches to one port and connects to two four-electrode leads and an eight-electrode lead.

Figure 16. RESTOREADVANCED rechargeable neurostimulator, Model 37082 Stretch-Coil bifurcated extension, and trialing system for a three-lead array: ENS, myStim® patient programmer, and snap-lid screening cable.



Enhanced Programming Capabilities

Medtronic recognizes the complexity of programming three-lead arrays. RESTOREADVANCED and PRIMEADVANCED® neurostimulation systems have unique capabilities to facilitate patient programming

* The Restore® family of neurostimulators also has a primary cell that can accommodate three percutaneous leads for patients for whom a rechargeable neurostimulator would not be appropriate.

and minimize this complexity. **TARGETSTIM™** aids rapid identification of the best location to focus stimulation and permits shaping or steering of stimulation either longitudinally or transversely with any electrode configuration to easily optimize paresthesia coverage. Developed based on modeling and customer input, the **OPTIMIZER™** feature generates 20 algorithm-based electrode combinations to refine the stimulation parameters, which may reduce programming time. Using the **AUTOFILL™** capability, clinicians are able to quickly generate related program groups that permit the patient to make further refinements at home without jeopardizing their basic program or returning to the clinic for minor adjustments. Thus apprehension about the potential for three-lead arrays to introduce greater complexity into the programming process need not be a concern.

Figure 17. Medtronic Model 8840 N'Vision® programmer.



higher energy needs, which could lead to more frequent recharge intervals. Only Medtronic offers a rechargeable neurostimulator with a nine-year battery life and enhanced programming options, a Stretch-Coil bifurcated extension, and a full complement of clinical percutaneous leads. The flexibility of this advanced technology permits physicians to select from a full range of one-, two-, or three-lead configurations to provide optimal therapy based on an individual patient's needs, potentially offering greater control over pain coverage than that provided by conventional lead systems. Although no clinical evidence exists yet to support the results presented in this discussion, modeling data indicate that a three-lead configuration with strategic placement of anodes around a single cathode may facilitate a higher degree of control over the electrical fields produced during SCS therapy for low back pain. Other investigators have published similar findings (Prager et al., 2006; Wesselink and North, 2006; Caraway et al., 2006).

Summary

Multiple three-lead configurations can be created using the Medtronic Stretch-Coil™ bifurcated extension that offer flexibility and new patterns for paresthesia coverage. Modeling demonstrates that lead configurations have similar activation patterns, regardless of which lead is used as the center lead on the midline (subcompact, compact, or standard). For electrode configurations that have more than one active electrode on the middle lead, a lead with the smaller center-to-center spacing may result in a better (i.e., lower) recruitment ratio of DC to DR fibers. However, this benefit comes at the expense of

References

- ¹ Barolat G, Massaro F, He J, Zeme S, Ketcik B. Mapping of sensory responses to epidural stimulation of the intraspinal neural structures in man. *J Neurosurg*. February 1993;78(2):233-239.
- ² Caraway D, Miyazawa G, Greenberg J, King G. [Abstract] A midline single cathode offers preferential dorsal column recruitment with spinal cord stimulation. *Anesthesiology*. 2006;105:A712.
- ³ Feirabend HK, Choufoer H, Ploeger S, Holsheimer J, van Gool JD. Morphometry of human superficial dorsal and dorsolateral column fibres: significance to spinal cord stimulation. *Brain*. May 2002;125(Pt 5):1137-1149.
- ⁴ Holsheimer J. Which neuronal elements are activated directly by spinal cord stimulation. *Neuromodulation*. 2002;5(1):25-31.
- ⁵ Holsheimer J, Barolat G. Spinal geometry and paresthesia coverage in spinal cord stimulation. *Neuromodulation*. 1998;1(1):129-136.
- ⁶ Holsheimer J, den Boer JA, Struijk JJ, Rozeboom AR. MR assessment of the normal position of the spinal cord in the spinal canal. *Am J Neuroradiol*. May 1994;15(15):951-959.
- ⁷ Holsheimer J, Struijk JJ, Tas NR. Effects of electrode geometry and combination on nerve fibre selectivity in spinal cord stimulation. *Med Biol Eng Comput*. 1995;33(5):676-682.
- ⁸ Holsheimer J, Wesselink WA. Effect of anode-cathode configuration on paresthesia coverage in spinal cord stimulation. *Neurosurgery*. September 1997a;41(3):654-659; discussion 659-660.
- ⁹ Holsheimer J, Wesselink WA. Optimum electrode geometry for spinal cord stimulation: the narrow bipole and tripole. *Med Biol Eng Comput*. September 1997b;35(5):493-497.
- ¹⁰ Law JD. Spinal stimulation: statistical superiority of monophasic stimulation of narrowly separated, longitudinal bipoles having rostral cathodes. *Applied Neurophysiology*. 1983;46(1-4):129-137.
- ¹¹ McIntyre CC, Richardson AG, Grill WM. Modeling the excitability of mammalian nerve fibers: influence of afterpotentials on the recovery cycle. *J Neurophysiol*. February 2002;87(2):995-1006.
- ¹² McNeal DR. Analysis of a model for excitation of myelinated nerve. *IEEE Trans Biomed Eng*. July 1976;23(4):329-337.
- ¹³ Melzack R, Wall PD. Pain mechanisms: a new theory. *Science*. November 1965;150(699):971-979.
- ¹⁴ North RB, Kidd DH, Olin J, et al. Spinal cord stimulation for axial low back pain: a prospective, controlled trial comparing dual with single percutaneous electrodes. *Spine*. 2005;30(12):1412-1418.
- ¹⁵ Prager JP, Chang JH. Transverse tripole spinal cord stimulation produced by a percutaneously placed triple lead system. *Paper presented at the Worldwide Pain Conference, Meeting of the International Neuromodulation Society, July 15-21, 2000*.
- ¹⁶ Prager JP, Ross EL, Wesselink WA. [Abstract] Spinal cord stimulation using a midline cathode has a better dorsal column recruitment ratio. *Anesthesiology*. 2006;105:A709.
- ¹⁷ Schade CM. Active electrode screening for low back pain. *Paper presented at: Worldwide Pain Conference, Meeting of the International Neuromodulation Society, July 15-21, 2000*.
- ¹⁸ Stojanovic MP, Abdi S. Spinal cord stimulation. *Pain Physician*. April 2002;5(2):156-166.
- ¹⁹ Stojanovic MP, Abdi S. Spinal cord stimulation. In: Boswell MV, Cole BE, eds. *Weiner's Pain Management: A Practical Guide for Clinicians*. 7th ed. New York, NY: CRC Taylor & Francis; 2006.
- ²⁰ Struijk JJ, Holsheimer J. Transverse tripolar spinal cord stimulation: theoretical performance of a dual channel system. *Med Biol Eng Comput*. July 1996;34(4):273-279.
- ²¹ Wesselink WA, Holsheimer J, Boom HB. Analysis of current density and related parameters in spinal cord stimulation. *IEEE Trans Rehabil Eng*. 1998;6(2):200-207.
- ²² Wesselink W, North RB. Three column contact patterns for spinal cord stimulation offer selective dorsal column fiber activation. *Neurosurgery*. 2006;59(2):470-471.

NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

Brief Summary: Product manuals must be reviewed prior to use for detailed disclosure.

Indications

Implantable neurostimulation systems - A Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) system as an aid in the management of chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain associated with the following conditions:

- Failed Back Syndrome (FBS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia

Contraindications

Diathermy - Do not use shortwave diathermy, microwave or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the locations of the implanted electrodes, resulting in severe injury or death.

Warnings

Sources of strong electromagnetic interference (eg, defibrillation, diathermy, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the neurostimulation system, resulting in serious patient injury or death. These and other sources of EMI can also result in system damage, operational changes to the neurostimulator or unexpected changes in stimulation. Rupture or piercing of the neurostimulator can result in severe burns. An implanted cardiac device (eg, pacemaker, defibrillator) may damage a neurostimulator, and the electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device.

Precautions

The safety and effectiveness of this therapy has not been established for pediatric use (patients under the age of 18), pregnancy, unborn fetus, or delivery. Patients should be detoxified from narcotics prior to lead placement. Clinicians and patients should follow programming guidelines and precautions provided in product manuals. Patients should avoid activities that may put undue stress on the implanted neurostimulation system components. Patients should not scuba dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmosphere absolute (ATA). Electromagnetic interference, postural changes, and other activities may cause shocking or jolting.

Adverse Events

Adverse events may include: undesirable change in stimulation described by some patients as uncomfortable, jolting or shocking; hematoma, epidural hemorrhage, paralysis, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, chest wall stimulation, and surgical risks.

For further information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com.

Rx Only.

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