

DIFFERENTIAL EFFECTS OF SPINAL CORD STIMULATION ARE ACHIEVED WITH THREE-LEAD PATTERNS

Gabriela Miyazawa, MS; Jordan Greenberg, Phd; Gary King, Phd
Medtronic Neuromodulation, Minneapolis, MN, USA

INTRODUCTION

Implantable neurostimulation systems drive up to 16 contacts and can support multiple columns of electrodes for spinal cord stimulation (SCS). A wide array of percutaneous leads are currently available that provide varying degrees of longitudinal coverage along the spinal cord. Three-column patterns with different electrode spacings can be studied using computer models by determining the effect of a particular electrode configuration on fiber selectivity and energy consumption.

METHODS

Using a finite element program, the electric field was generated for three three-lead configurations (Figure 1) with a midline cathode: "X" pattern, "Y" pattern, and "+" pattern. Three one-lead configurations were additionally modeled for comparison: guarded cathode (GC), dual guarded cathodes with the same amplitude (DC), and dual guarded cathodes with different amplitudes (DC-imbal) (Figure 2).

Three variations were modeled with two standard-spaced (9 mm center-center) leads flanking: (1) a standard (9 mm center-center), (2) a compact (7 mm center-center), or (3) a subcompact (4.5 mm center-center) eight-electrode lead.

Axon models were used to calculate dorsal column (V_{DC}) and dorsal root (V_{DR}) fiber activation thresholds. The energy per pulse ($V \cdot I \cdot PW$) and the area within the dorsal columns activated by the stimulation was determined using these models. Models were compared to single-column configurations.

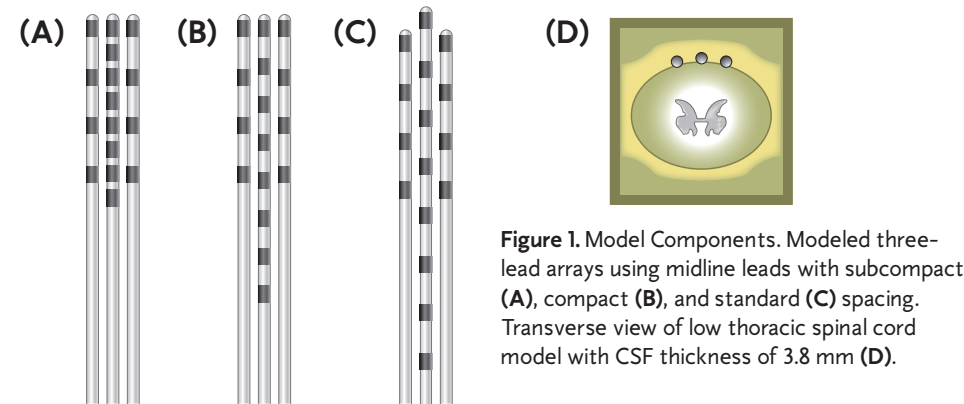


Figure 1. Model Components. Modeled three-lead arrays using midline leads with subcompact (A), compact (B), and standard (C) spacing. Transverse view of low thoracic spinal cord model with CSF thickness of 3.8 mm (D).

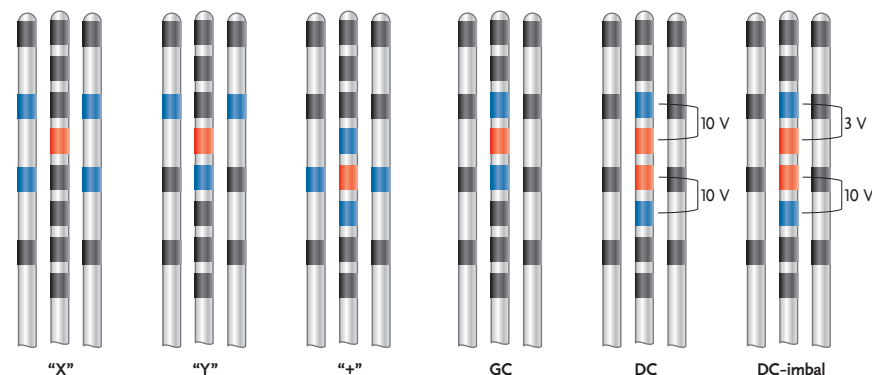


Figure 2. Modeled three-lead and one-lead configurations shown with a subcompact lead in the middle. Cathodes = red, anodes = blue. Applied stimulation voltages are shown for the DC configurations.

MODELING PERFORMANCE

Computer modeling showed improved dorsal column fiber selectivity (lower recruitment ratio, V_{DC}/V_{DR}) with the "+" pattern and with subcompact leads on the midline (Figure 3). However, this benefit came at the expense of higher energy needs (Figure 4). Neuron activation areas revealed slight differences with each modeled configuration (Figure 5).

Fiber Selectivity

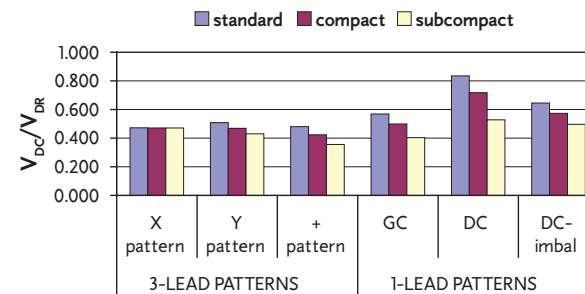


Figure 3. Three-lead patterns: When only one cathode in the midline was used ("X" pattern), there was a negligible effect on DC fiber selectivity using any electrode spacing. For the "Y" and "+" patterns, the lead with the smaller electrode center-center spacing resulted in the greatest selectivity of DC versus DR fibers. One-lead patterns: The GC resulted in the lower V_{DC}/V_{DR} than dual cathodes on the midline with or without different amplitudes.

Energy Per Pulse at Discomfort Threshold

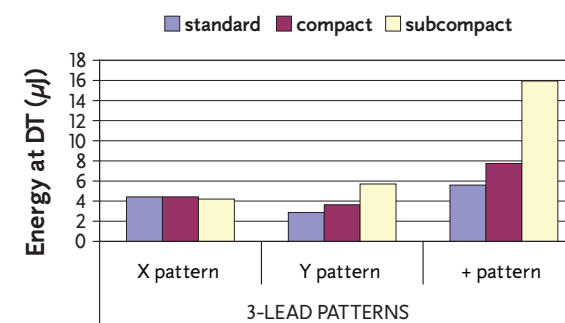


Figure 4. For the three-lead patterns, the cost of improved recruitment ratios is a higher energy demand per pulse.

Areas Activated by Stimulation

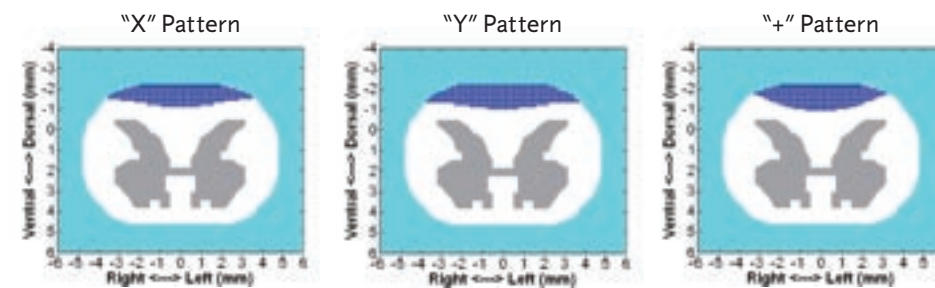


Figure 5. Different electrode configurations can create subtle differences in patterns of neuron activation (subcompact lead in the midline).

TECHNICAL CONSIDERATIONS

- In the past, one limitation to the use of three percutaneous leads has been higher energy requirements. However, the availability of rechargeable neurostimulators on the market has addressed this limitation.
- The Stretch-Coil™ bifurcated extension can be used with a 1x8 extension to connect three percutaneous leads (Figure 6).

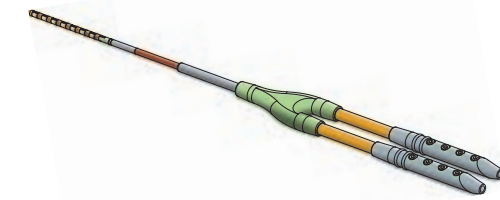


Figure 6. The Stretch-Coil™ bifurcated extension can be used to connect two 1x8 leads in order to create the unique 4-8-4 pattern.

- Programming algorithms have been developed in order to reduce programming complexity of three-lead arrays (Figure 7).

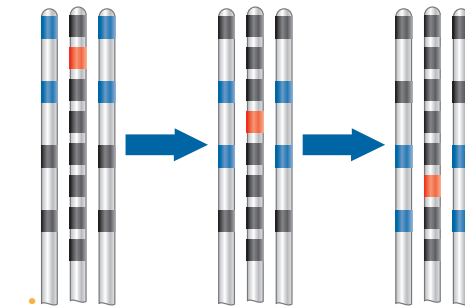


Figure 7. The TARGETSTIM® algorithm aids in the rapid identification of the optimal location of stimulation and allows for shifting of stimulation fields in longitudinal or transverse directions (longitudinal field shifting shown).

CONCLUSIONS

Multiple three-lead configurations for SCS can be created using a bifurcated extension that offers flexibility and new patterns for paresthesia coverage.

- Decreasing the electrode center-center spacing results in a lower recruitment ratio, suggesting increased DC versus DR selectivity.
- In general, three-lead patterns resulted in lower V_{DC}/V_{DR} than one-lead patterns for all electrode spacings modeled.
- One cathode on the midline (GC) is more selective for DC fibers compared to two cathodes on the midline (DC, DC-imbal).
- In the three-lead patterns, using smaller electrode spacings also results in higher energy at discomfort threshold, which could lead to shorter recharge intervals.
- The electrode spacing when only one cathode is activated on the midline has no impact on fiber selectivity or energy consumption, and therefore the middle lead can be positioned to give the desired pattern of stimulation (in this case, an "X" pattern).
- Guarding the cathode longitudinally and laterally ("+" pattern) improves dorsal column selectivity.

NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

Brief Summary: Product Technical Manuals and Programming Guides must be reviewed prior to use for detailed disclosure.

Indication for Use – Chronic, intractable pain of the trunk and/or limbs—including unilateral or bilateral pain. **Contraindications:** Diathermy. **Warnings:** Defibrillation, diathermy, electrocautery, MRI, RF ablation, & therapeutic ultrasound can result in unexpected changes in stimulation, serious patient injury or death. Rupture/piercing of neurostimulator can result in severe burns. 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, pregnancy, unborn fetus, or delivery. Follow programming guidelines & precautions in product manuals. Avoid activities that stress the implanted neurostimulation system. EMI, postural changes, & other activities may cause shocking/jolting. **Adverse Events:** Undesirable change in stimulation; 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, & surgical risks.

For full prescribing information, please call Medtronic at 1-800-328-0810 and/or consult Medtronic's website at www.medtronic.com. **Rx Only.** November, 2007.