

THREE-COLUMN SURGICAL LEAD FOR SPINAL CORD STIMULATION OFFERS SELECTIVE DORSAL COLUMN FIBER ACTIVATION

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INTRODUCTION

Three-lead arrays for spinal cord stimulation allow anodes to be placed longitudinally and laterally with respect to a central cathode and allow for an increased therapeutic range. Three-column electrode configurations have become increasingly popular with the recent introduction of tripolar surgical leads on the market. There is much to be learned about the clinical effect of three-lead arrays; however, theoretical measures of performance can be obtained with computer modeling.

METHODS

A finite element model was used to calculate the electric field generated by electrical stimulation with a three-column surgical lead. This model consisted of an inhomogeneous volume conductor with representations for the spinal cord white and gray matter, cerebrospinal fluid (CSF), dura, epidural fat, vertebral bone, and the surgical paddle insulation and electrodes (Figure 1).

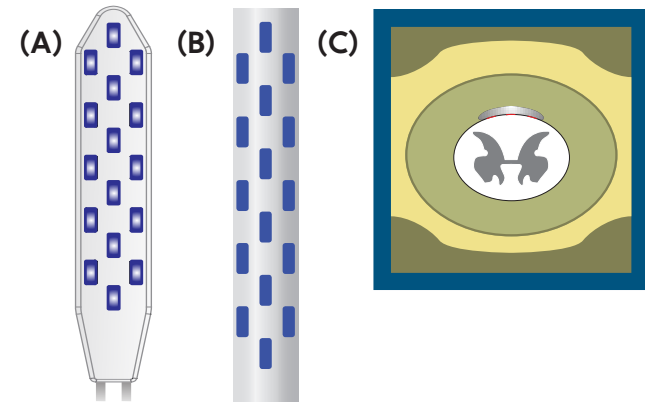


Figure 1. Model Components. (A) CAD drawing of Specify™ 5-6-5 surgical lead. (B) Modeled Specify 5-6-5 surgical lead. (C) Transverse view of spinal cord model.

The solution from the finite element model was coupled to axon models in order to compare the relative nerve fiber selectivity and energy consumption of six electrode configurations using the Specify 5-6-5 surgical lead (Figure 2). The Specify 5-6-5 surgical lead features 16 independently programmable electrodes arranged in a unique 5-6-5 pattern. Fiber selectivity was measured by the recruitment ratio, the ratio of dorsal column to dorsal root thresholds (V_{DC}/V_{DR}). Energy consumption was calculated as energy per pulse (Voltage* Current* Pulse Width) using amplitudes at discomfort threshold ($1.4*V_{DR}$).

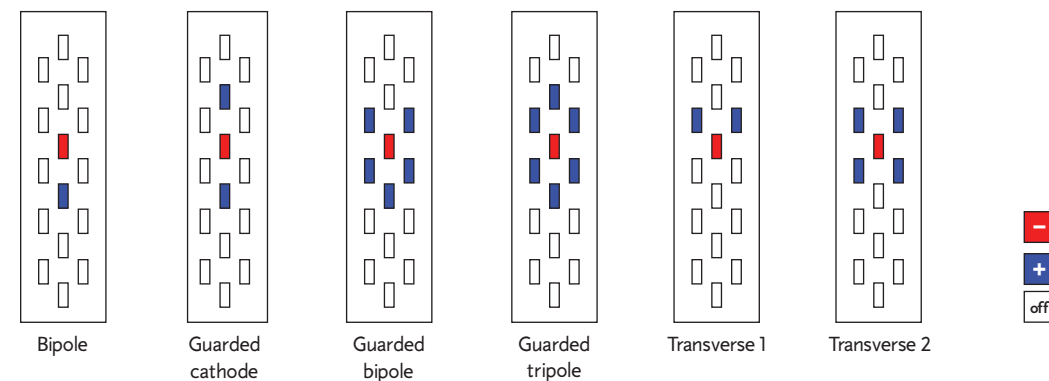


Figure 2. Modeled Specify 5-6-5 surgical lead configurations included two single-column configurations and four three-column configurations.

MODELING PERFORMANCE

Computer modeling showed improved dorsal column fiber selectivity and less dorsal root activation with three-column electrode patterns when compared to single-column configurations (Figures 3, 4). However, this benefit comes at some expense of higher energy needs (Figure 5).

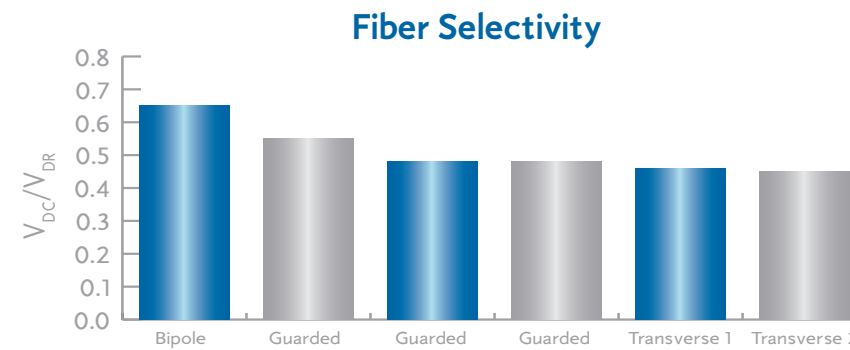


Figure 3. Recruitment ratios for modeled configurations show improved (lower) dorsal column fiber selectivity when using the three-column configurations compared to the single-column configurations.

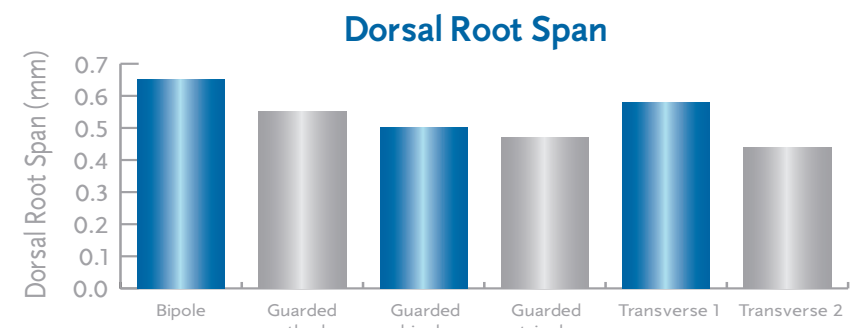


Figure 4. In general, the dorsal root span is larger with single-column electrode patterns compared to the three-column configurations. A shorter dorsal root span is obtained with three-column guarded configurations.

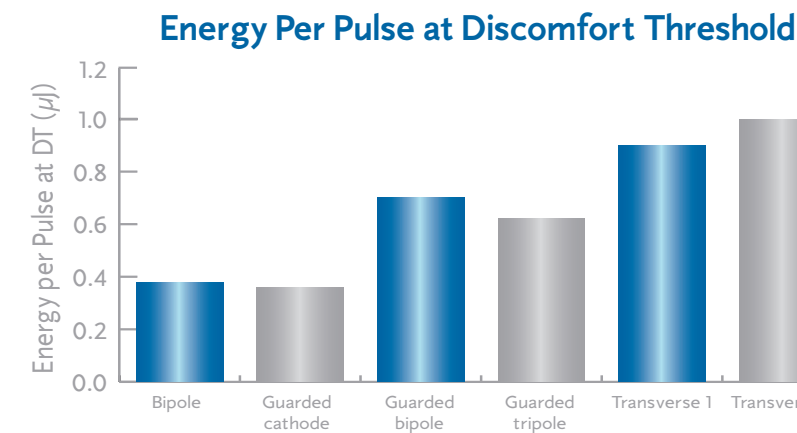


Figure 5. The energy per pulse for single-column configurations was lower than the three-column configurations.

TECHNICAL HIGHLIGHTS

In addition to the novel three-column electrode patterns, the Specify 5-6-5 surgical lead offers several technical features (Figures 6, 7, 8).

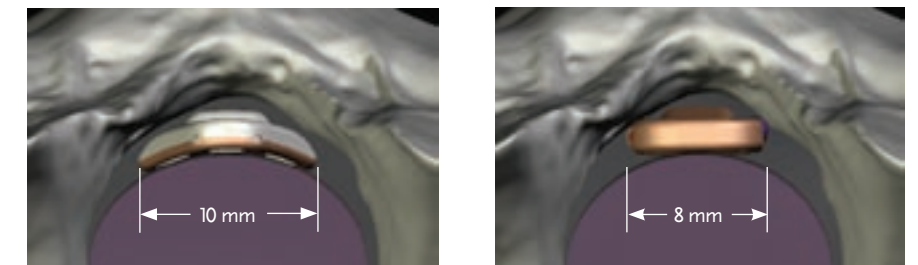


Figure 6. The Specify 5-6-5 surgical lead (left) is designed for an improved anatomical fit within the epidural space in order to provide more consistent electrode contact with the dura, compared to the Specify™ surgical lead, model 3998 (right).

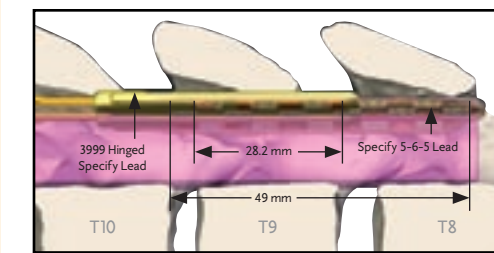


Figure 7. The paddle has an electrode span of 49 mm (center column) providing an additional range of programming options for stimulation and improved coverage in the event of stimulation target migration over time (compared to the 3999 Hinged Specify™ surgical lead electrode span of 28.2 mm).

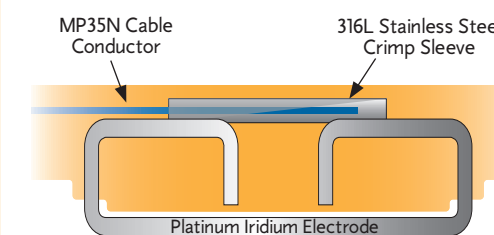


Figure 8. The paddle also offers a unique electrode design that locks electrodes in place known as DuraLoc™ electrode technology and a cable conductor routing method that minimizes stresses on the conductors.

CONCLUSIONS

Modeling Performance

The three-column configurations had lower recruitment ratios than the single-column configurations modeled, suggesting improved dorsal column fiber selectivity with the three-column patterns. This benefit comes at some expense of higher energy needs, which could lead to more frequent recharge intervals for rechargeable devices.

Technical Highlights

- Paddle designed with anatomical curvature to provide consistent electrode contact with dura.
- Paddle electrode span allows for increased programming options and the ability to address migrating pain patterns.
- Electrode design and cable routing method that provide a robust and reliable design.

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.