

Method for Smoothly Shifting Electric Stimulation Field along a Lead Using Interleaved Pulses

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INTRODUCTION

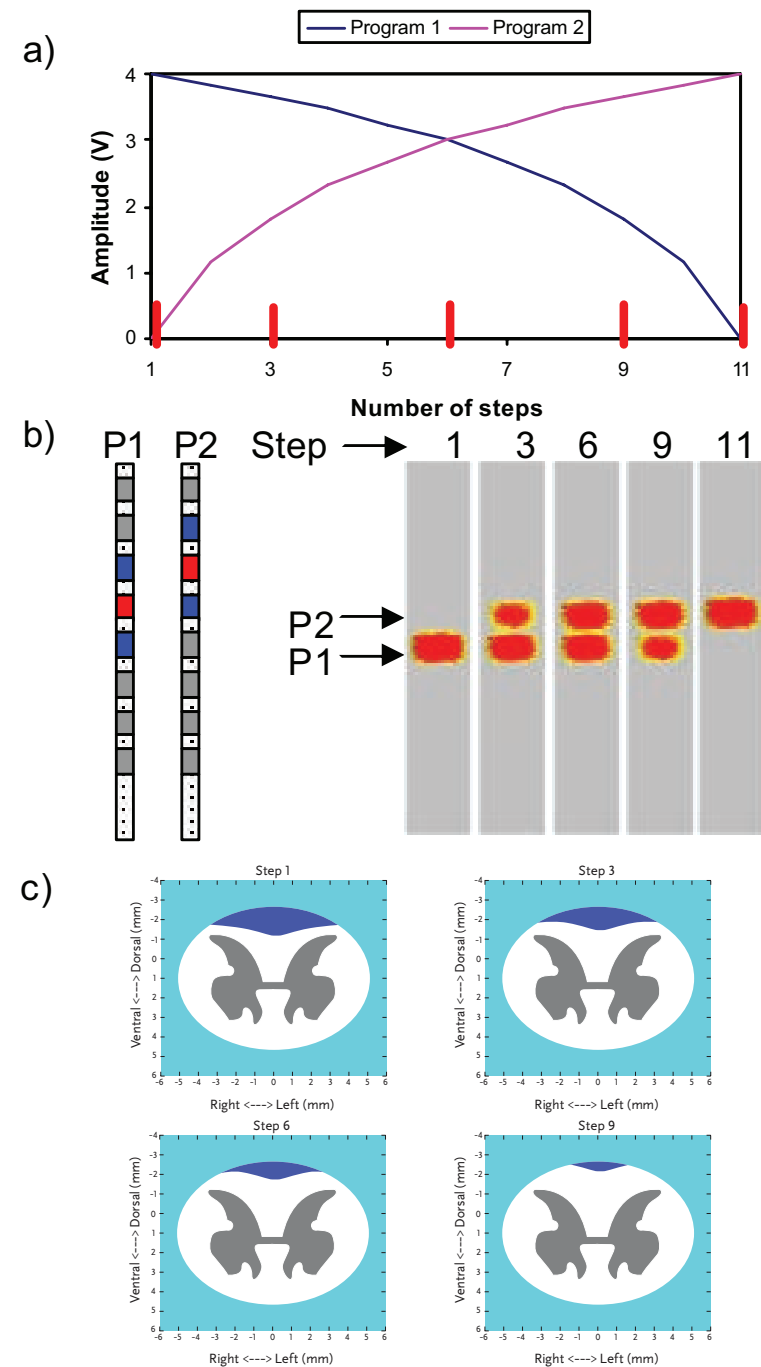
The identification of optimal parameters for spinal cord stimulation (SCS) can be a time-consuming, circuitous process. A method for quickly finding optimal active electrode locations on stimulation leads without causing patient discomfort is required for programming efficiency. A novel method of shifting an arbitrary electrode configuration along a lead using interleaved stimulation pulses in a manner that provides consistently comfortable paresthesia is described and clinical data are presented.

METHODS

A multi-center, open-label, prospective study was performed on 22 patients previously implanted with at least one octad percutaneous lead for the treatment of chronic leg and/or low back pain. Using an investigational system, the amplitudes of interleaved pulses were gradually adjusted allowing therapy to shift along the stimulation lead. Quantitative in-clinic time data were captured as were qualitative data on the patients' comfort levels and pain coverage.

Finite-element models of the stimulation field during application of the system supplemented the investigation data. A guarded cathode (longitudinal tripole) configuration was used as an example. Activation functions were calculated in the direction of the dorsal column fibers (longitudinally along the cord) and were used to qualitatively show the magnitude and location of depolarized sites. Quantitative measures of stimulus spread were calculated using a distribution of activated dorsal column fibers for each program by coupling the results from the electric field model to a neuron simulation program.

MODELING RESULTS

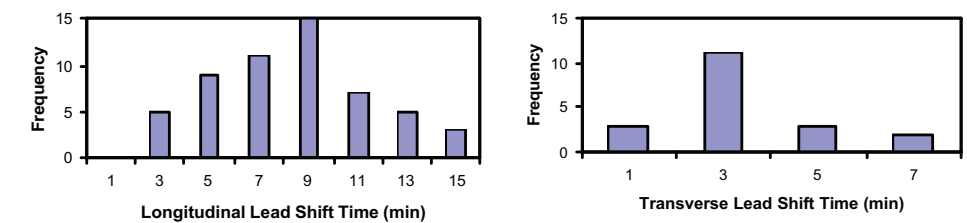


(a) Example of algorithm using two interleaved programs with a target amplitude of 4V; (b) Positive activation function plotted on surface of dorsal spinal cord for programs 1 and 2 (P1 and P2); (c) Area of activation within dorsal columns for steps 1, 3, 6, and 9 for P1.

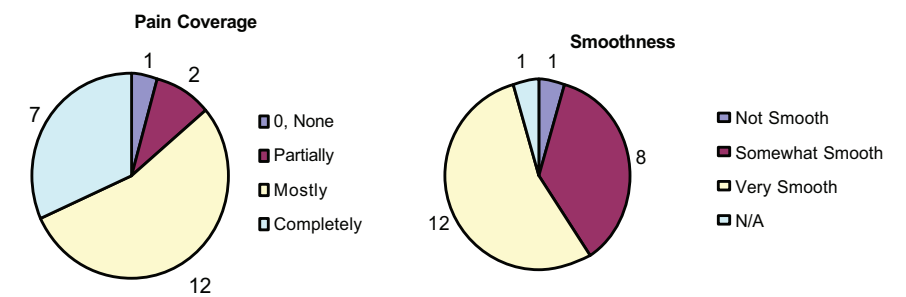
CLINICAL RESULTS

The results of this clinical study show that this method of shifting electrode configurations resulted in time-efficient, smooth transitions while maintaining a good level of pain coverage.

The average time to shift an electrode configuration longitudinally along the entire lead was 7 minutes and 22 seconds. The average time to shift an electrode configuration transversely across leads was 2 minutes and 21 seconds.



The median score for paresthesia coverage was 2 on a scale from 0-3 (mean = 2.1), with 3 indicating complete coverage of painful areas. The median rating for the sensation of programming changes was 2 (mean = 1.5), on a scale from 0-2 with 2 being "very smooth."



CONCLUSIONS

A method using interleaved pulses has been developed that provides quick, smooth shifting of contact configurations within and across leads. This novel therapy optimization approach is capable of efficiently and effectively shifting paresthesia towards the goal of covering areas of pain. Computer modeling demonstrates dorsal column fiber activation as the process shifts stimulation fields along a lead.

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.

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