A Novel Finite Element Analysis-based Current Steering Algorithm for Intuitive and Targeted Spinal Cord Stimulation

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INTRODUCTION

Targeted stimulation that activates specific anatomical locations has the potential to improve pain relief while minimizing undesired stimulation side-effects. The Nalu Neurostimulation micro-implantable pulse generator (micro-IPG) includes multiple independent current sources (Figure 1) that can be used to shape the electric field (Figure 2) to maximize the current density in a desired location while minimizing the current in other tissue.

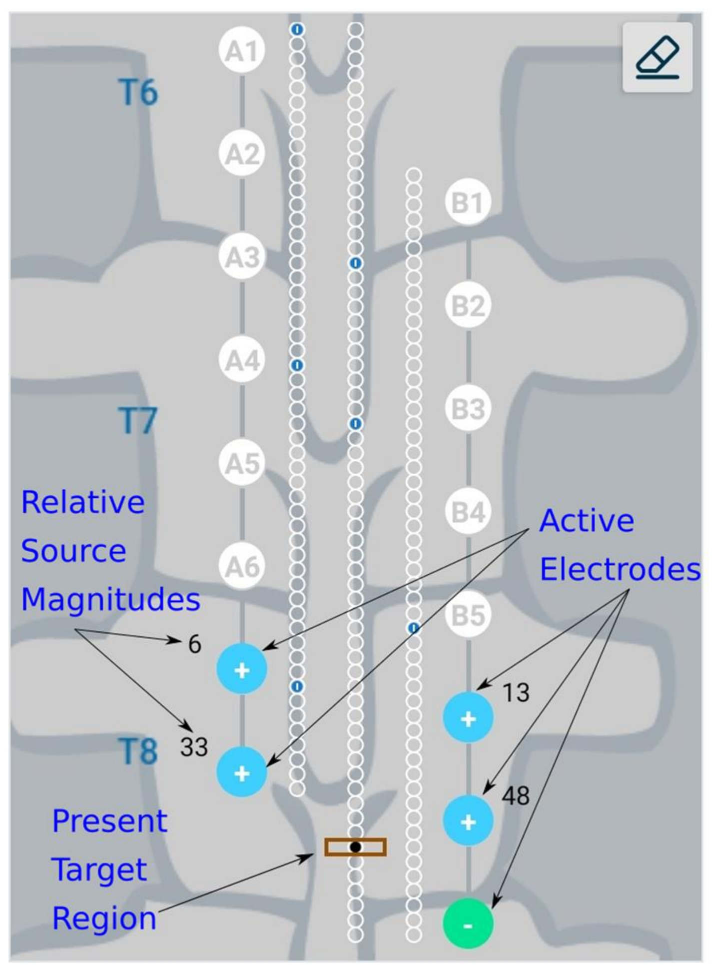

Figure 1 - Schematic representation of user interface showing multiple independent current sources. Green, filled circles indicate current sinks and blue filled circles indicate current sources. The number near the electrodes represent the relative percentage of current sourced/sunk through the electrodes. Small blue circles with a dash inside them represent target locations which have already been checked by the clinician.

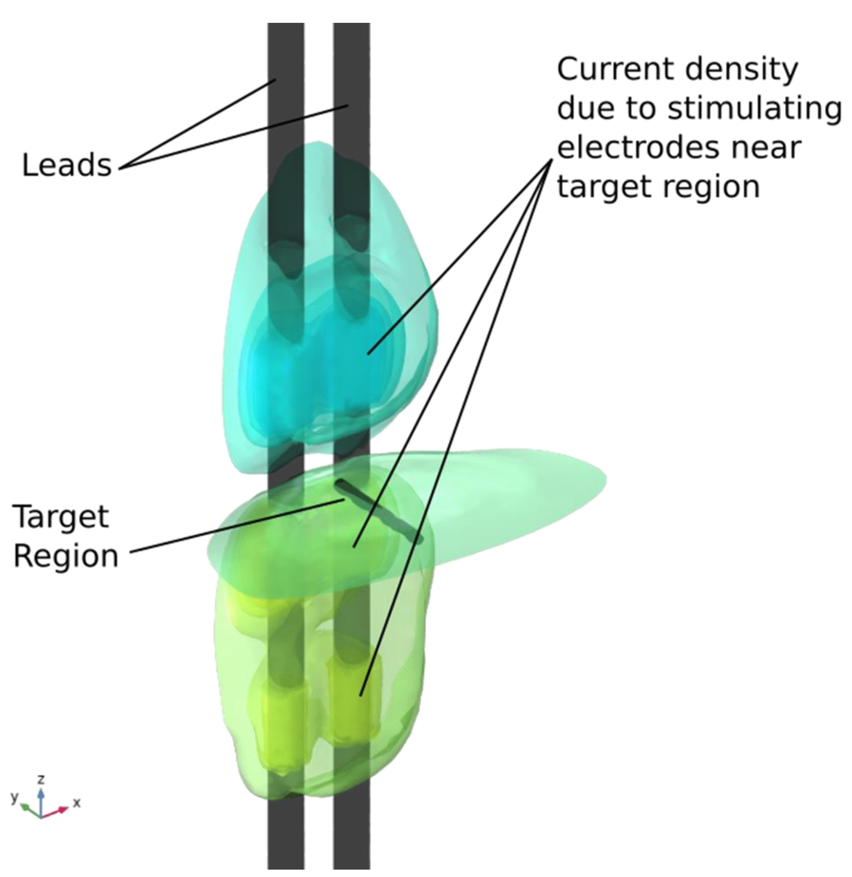

Figure 2 - Current density near the target region, indicating shaping of the electric field. The electrodes in the immediate vicinity of the target region are active.

METHODS

A novel optimization problem has been formulated that uses a solution of the Poisson equation:

$$\nabla \cdot (\sigma \nabla u) = 0 \in \Omega$$

evaluated using Finite Element Analysis (FEA) over a geometric model of the spinal cord and the embedded leads (Figure 3).

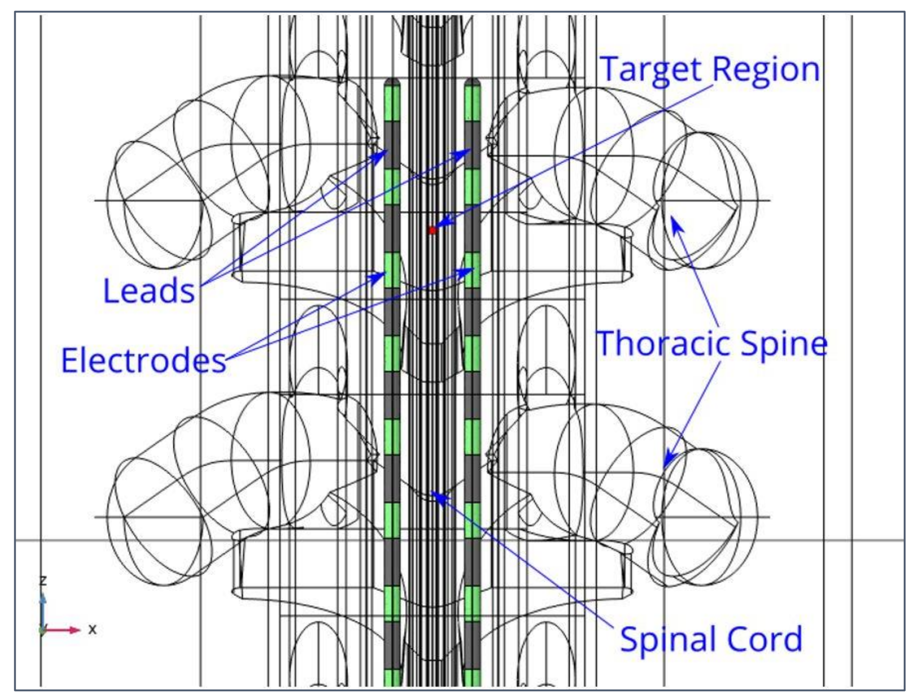

Figure 3 - Stimulation leads and target region. The leads are shown in grey color and the electrodes are shown in green color. The target region shown in red color, is placed within the white and grey matter domains.

The solution to the optimization problem determines the optimal current sourced through a set of electrodes to achieve a targeted stimulation location. The algorithm inputs include the relative offset and stagger between the two implanted leads (Figure 4) and can also work around any electrodes that may need to be excluded from the solution (Figure 5).

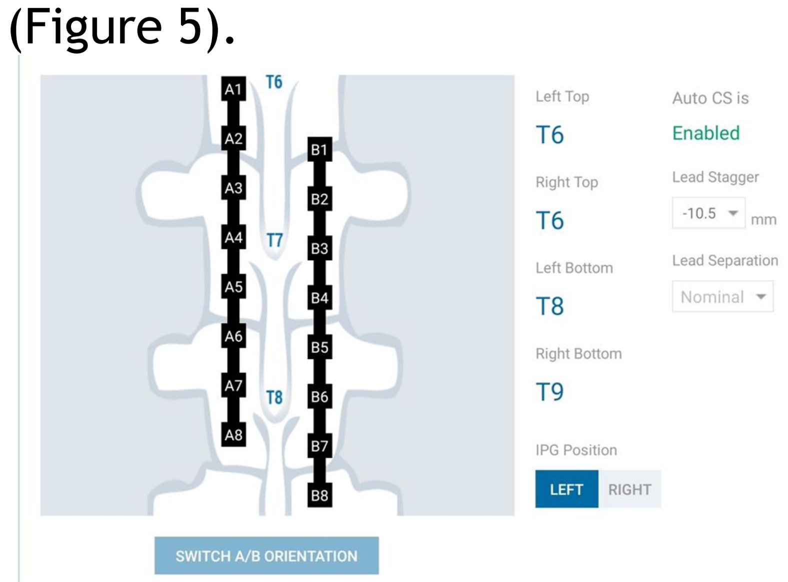

Figure 4 - Schematic representation of the lead configuration in terms of relative offset and stagger between the leads. The lead configuration is provided as inputs to the current steering algorithm.

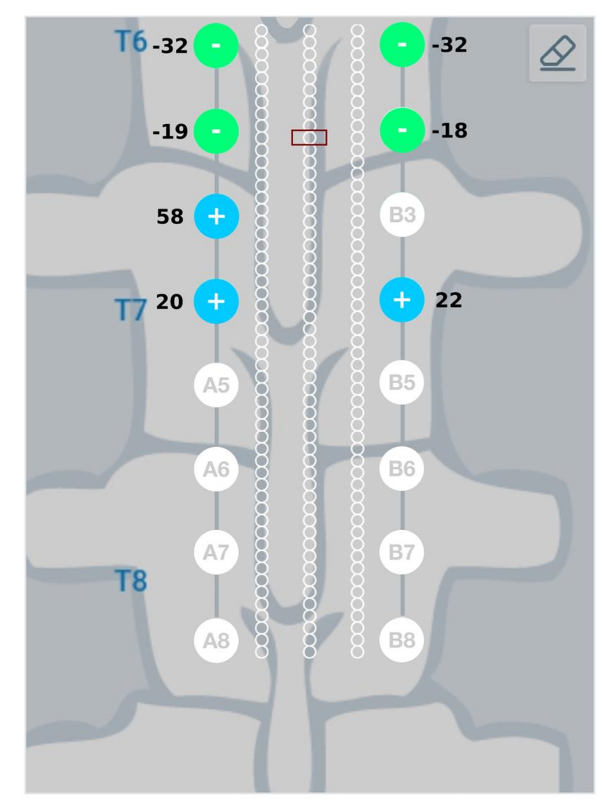

Figure 5 - Schematic representation of Current steering results graphically represented on the user interface. The current steering results are shown with electrode B3 assumed to be disconnected. The current steering solution gives the optimum electrode excitation pattern without using B3 as an active electrode..

RESULTS

The result of the algorithm is a set of anodes and cathodes as well as the percentage current to be sourced from each anode (Figure 6). The Clinician Programmer calculates and stores the FEA results to allow the clinician to intuitively select target locations and rapidly test various SCS configurations and parameters while receiving feedback from the patient on therapeutic outcomes.

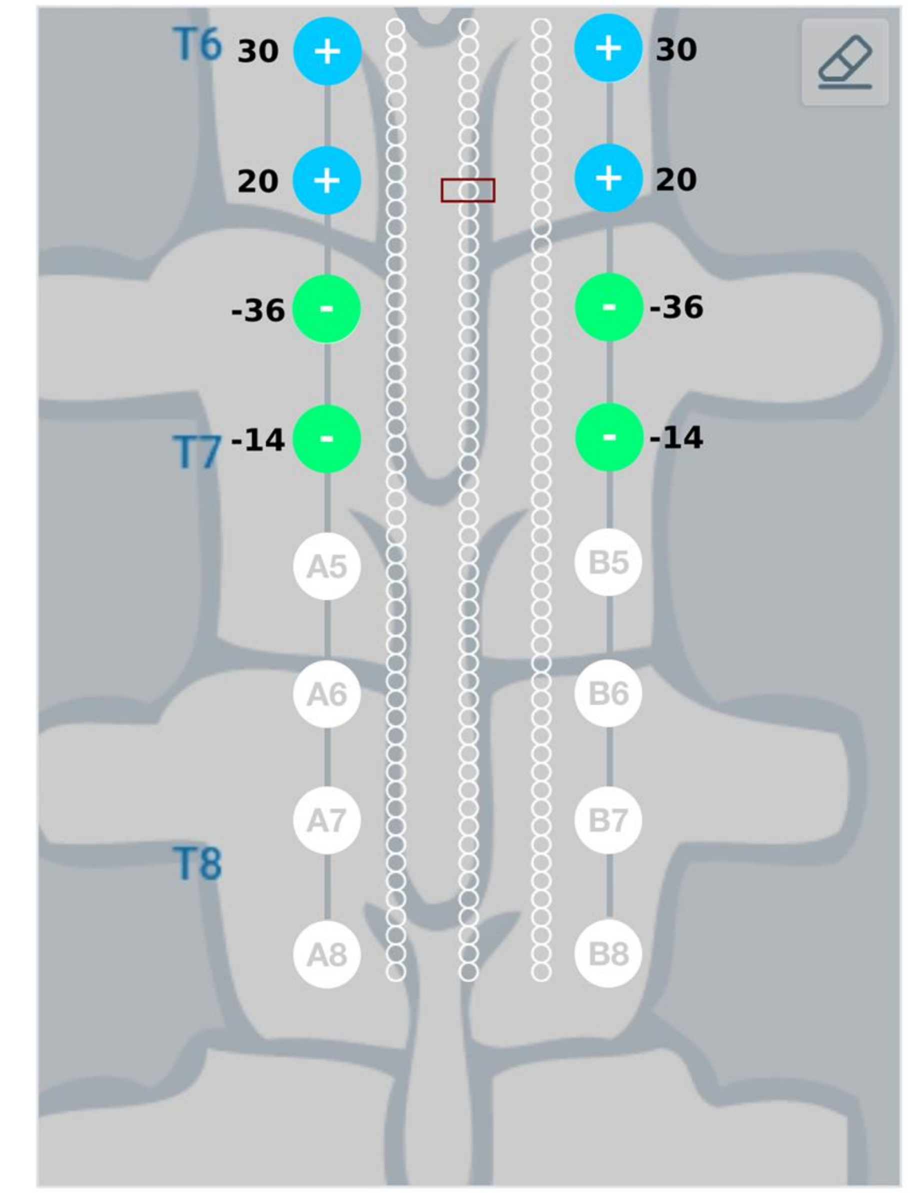

Figure 6 - Schematic representation of current steering results graphically represented on the user interface. The current steering results are obtained in the form of optimum electrode excitation pattern - shown on the parallel leads in this figure. Green, filled circles indicate current sinks, and blue, filled circles indicate current sources. The numbers near the electrodes represent the relative percentage of current sourced/sunk through the electrodes.

CONCLUSION

Highly-capable implantable pulse generators provide a plethora of stimulation options for clinicians to better target spinal cord anatomy for complex pain patterns. We propose a novel finite element analysis-based current steering algorithm to calculate complex SCS configurations and parameters based on intuitive clinician inputs for targeted spinal cord stimulation. Further research necessary to refine the models and algorithm as additional clinical experience is gathered.