A RCT Comparing Traditional and DTMTM SCS for Chronic Back and Leg Pain: Sub-Analysis of Profound Back Pain Responders at 12 months

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Introduction: DTMTM SCS is a programming approach where electrical signals are multiplexed spatially and temporally. We report data from a RCT comparing the effectiveness of DTM SCS to traditional SCS for low back pain (LBP) relief. At the 12-month follow-up, a high number of subjects experience profound LBP relief (≥ 80%) with DTM SCS. A sub-analysis of profound LBP responders was conducted.

Methods: This prospective, multicenter, post-market, RCT compared DTM SCS to traditional SCS in patients with chronic intractable LBP (≥ 5 cm VAS) and moderate to severe leg pain. Consented subjects were randomized (1:1). Study outcomes included LBP responder rate (≥ 50% pain relief), functional disability (ODI), quality of life (PROMIS Global Health), patient satisfaction, sensory "paresthesia" experience. A sub-analysis of profound LBP responders was performed.

Results: Subjects (N = 128) were randomized. There were no statistically significant demographic differences between the treatment groups at baseline. At 12 months, DTM SCS therapy demonstrated a superior back pain responder rate (p = 0.005) compared to traditional SCS. 9.5 % of subjects treated with DTM SCS experienced paresthesia while receiving optimal pain relief at 12 months. Profound LBP responder rates were 69% and 35% for DTM SCS and traditional SCS, respectively, at 12 months. Of the subjects who were LBP profound responders in the DTM SCS arm, 83% reported minimal/moderate disability, 96% reported fair to excellent physical health, and 90% reported "satisfied" or "very satisfied" with therapy at 12 months.

Conclusion: DTM SCS therapy was demonstrated to provide superior LBP relief compared to traditional SCS. Patients who experience profound pain relief may also experience significant benefits in other clinically meaningful outcomes including functional disability, quality of life and therapy satisfaction.

An Indirect Deep Brain Stimulation Targeting Tool Using Salient Anatomical Fiducials

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Introduction: Deep Brain Stimulation (DBS) of the subthalamic nucleus (STN) is a common treatment of Parkinson's disease (PD), but its optimal therapeutic outcomes and long-term success depend on accurate targeting. STN-DBS targeting is conventionally initiated using consensus coordinates relative to the mid-commissural point (MCP) with refinement using direct imaging. In this study, we develop a machine learning (ML) model that utilizes previously validated and salient x, y, and z coordinates, known as anatomical fiducials (AFIDs), that can be placed within millimeters of accuracy on structural T1w MRI scans to predict STN center location.

Methods: AFIDs were applied on T1w images of 32 healthy participants (age: 46.2 ± 13.5 years; 12 female) acquired at Western University on a 7-T head-only scanner (Siemens Magnetom; Germany). The "ground truth" STN center was computed from the center of mass of STN segmentations derived from 7-T high-resolution T2w scans in this same dataset. X, y, and z coordinates were used as features, after principal component analysis, to predict the STN center. Linear and support vector regression (SVR, linear kernel) models were trained (n=27). Euclidean distances (EDs) between the ground truth and predicted center on testing data (n=5) allowed for combined assessment of x, y, and z models. Accuracy was compared to conventional MCP consensus coordinates (±12, -2, -4) via Wilcoxon rank-sum test ($p < 0.05$).

Results: EDs from model predictions using the left and right STN respectively are: 1) 1.07 ± 0.47 and 0.98 ± 0.63 mm (linear regression) and 2) 1.15 ± 0.55 and 1.03 ± 0.56 mm (SVR). Both model predictions were significantly more accurate than MCP consensus predictions.

Conclusions: This study demonstrates potential for a new STN-DBS indirect targeting tool, utilizing AFIDs on T1w image alone, with accuracy of approximately 1-2 millimeters (superior to MCP coordinate consensus). External validation on PD patients is ongoing.

LIN	LEFT STN				RIGHT STN			
SUBJECTS	x	y	z	ED (mm)	x	y	z	ED (mm)
Sub-1	1.99	0.00	1.55	1.88	2.74	0.05	1.08	1.97
Sub-2	0.12	0.35	0.00	0.69	0.05	0.08	0.02	0.38
Sub-3	0.14	0.04	0.76	0.97	0.55	0.49	0.08	1.06
Sub-4	0.05	0.02	0.71	0.88	0.29	0.01	0.70	1.00
Sub-5	0.01	0.25	0.57	0.91	0.12	0.08	0.03	0.48
AVERAGE				**1.07**				**0.98**
STD. DEV.				0.47				0.63
SVR	LEFT STN				RIGHT STN			
SUBJECTS	x	y	z	ED (mm)	x	y	z	ED (mm)
Sub-1	2.53	0.03	1.97	2.13	2.08	0.03	1.42	1.88
Sub-2	0.09	0.49	0.03	0.79	0.08	0.10	0.00	0.42
Sub-3	0.23	0.08	0.58	0.94	0.66	0.34	0.19	1.09
Sub-4	0.18	0.04	0.77	1.00	0.59	0.00	0.69	1.13
Sub-5	0.00	0.31	0.52	0.92	0.13	0.00	0.25	0.62
AVERAGE				**1.15**				**1.03**
STD. DEV.				0.55				0.56

Figure 1: Machine learning (ML) model prediction for the center of the left and right subthalamic nucleus (STN) with a heat map effect overlaid. The two ML models used were a linear regression (LIN, red) and support vector regression with a linear kernel (SVR, blue). Columns labelled x, y, and z on both tables represent the mean squared error, 2, for each coordinate. The last column shows Euclidean *MSEx*, z = distance, (x, y, *zpredicted* − x, y *zground truth*), from ground truth to model predicted STN center for testing subjects. *ED* = Training *MSEx* + and *MSE* applicationy + *MSEz* of the ML models were performed using the scikit-learn Python programming library.

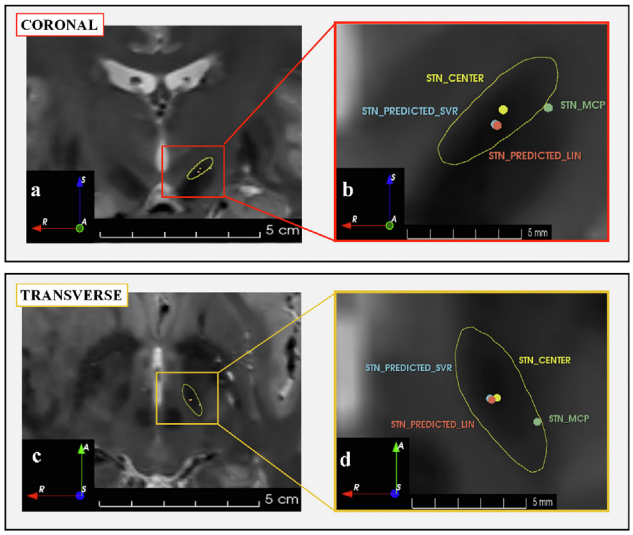

Figure 2: 3D Slicer visualization showing the ground truth location of left subthalamic nucleus (STN) center, in yellow, on a T2-weighted MRI scan with STN segmentation outline for one of the test subjects (Sub-3). Linear regression (LIN), and support vector regression (SVR) STN center predictions after training (n = 27) are shown in red and blue, respectively. Meanwhile, mid-commissural point coordinate consensus (MCP, 12, -2, -4) prediction is shown in green. a) shows a coronal view of these predictions and b) corresponds to a magnified view. Similarly, c) shows a transverse view and d) corresponds to a magnified view. All model predictions were significantly more accurate than MCP consensus coordinate predictions (Wilcoxon rank-sum test, $p < 0.05$). All fiducials were snapped to visible surface on the transverse view to allow for visualization on the same slice.

Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation for Chronic Refractory Neuropathic Pain - A Successful Series of 5 Challenging Cases

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Introduction: Percutaneous peripheral nerve stimulation (PNS) has progressed significantly over the last decade. From the proof of concept that ultrasound-guided (USG), percutaneous implantation was possible to advances in waveforms, and development of several definitive and temporary implantation systems, the field has been rapidly evolving. In this clinical series, we document 5 of the most challenging cases treated at the Department of Pain Medicine at Mayo Clinic (Florida) in 2021.

Methods: Five patients presenting with longstanding, chronic, moderate-to-severe, previously refractory pain syndromes were treated with USG percutaneous implantation of a definitive PNS system (Bioness StimRouter, Valencia, California, United States of America). Detailed information on the pain syndrome of each patient, etiology, target nerve for stimulation, and technical USG approach can be found in Table 1. Final lead position under US for each case can be seen in Figure 1.

Results: At the 3-month post-procedural scheduled follow-up, all the patients demonstrated 50% or greater reduction in the numerical rating scale (NRS) score for pain as compared to baseline. There were no peri-procedural complications and/or adverse effects, namely local infection, lead migration, lead fracture, or loss of sensory stimulation coverage.

Conclusions: The development of USG as a viable method of image guidance for percutaneous PNS has led to an exponential growth in the field. This series demonstrates that lead placement is both feasible and an appropriate treatment modality even in the most challenging refractory pain syndromes, after multiple failed conservative and invasive treatment options.

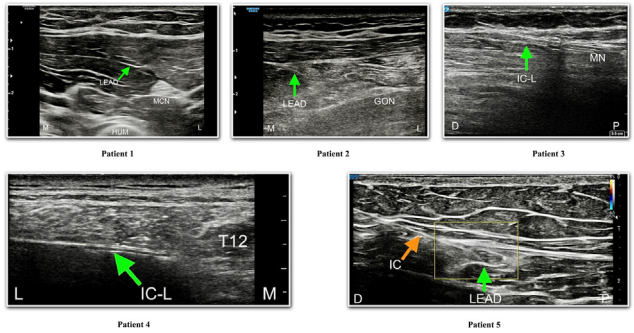

Figure 1: Post-procedural ultrasound pictures of the lead placement in the target nerves for the 5 cases reported. In cases of bilateral stimulation only one lead (one side) is shown. Legend - GON: greater occipital nerve; HUM: hum erus; IC: introducer cannula; IC-L: introducer cannula withlead; M: medial; MCM: misculocutaneous nerve; L: lateral; T12 - 12th rib.