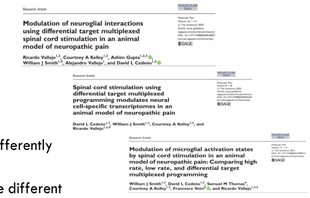
RCT Comparing Traditional and DTM SCS for Back Pain: Profound Relief, Functional and QoL Benefits.

Harold Cordner MD[1]; Michael A. Fishman MD, MBA[2]; Rafael Justiz MD[3]; David A. Provenzano MD[4]; Binit Shah MD[5]; Christopher Merrell MD[6]; Julian F. Naranjo MD[7]; Philip Kim MD[2]; Aaron Calodney MD[8]; Jonathan Carlson MD[9]; Richard H. Bundschu MD[10]; Mahendra Sanapati MD[11]; Vipul Mangal MD[12]; David L. Cedeno PhD[14]; Ricardo Vallejo MD, PhD[14]

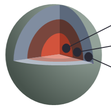
[1]. Florida Pain Management; 2. Center for Interventional Pain and Spine; 3. Oklahoma Pain Physicians; 4. Pain Diagnostics and Interventional Care; 5. Carolinas Pain Center; 6. Low Country Orthopaedics; 7. South Florida Clinical Research; 8. Precision Spine Care; 9. Hawai'i Pain and Spine; 10. Coastal Orthopedics; 11. Advanced Pain Care Clinics; 12. National Pain and Spine Centers; 14. SGX Medical

INTRODUCTION

Differential Target Multiplexed SCS



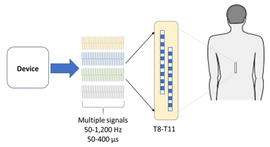
Core foundation and hypothesis of DTM SCS:



1. Beyond neurons, glial cells may be helpful
2. Glial cells respond to electrical pulses, but differently than neurons
3. Apply different signals designed to modulate different cell types in Neuron-Glial Interaction

Differential target — Different pulsed signals intended for different targets

Multiplexed — Multiple pulsed signals within the delivered stimulation



Adapted from Fishman et al. 2020, Pain Practice

METHODS

Objective:

Long-term evaluation of the effectiveness of DTM SCS programming approach in patients with chronic intractable low back pain with or without leg pain in comparison to traditional SCS programming

Design:

Multicenter (12 sites across the U.S.), prospective, post-market, open-label, randomized, controlled:
- 1:1 Randomization – Test Arm: DTM-SCS; Control Arm: Traditional SCS
- 3-months primary endpoint, 12-months follow up
- Primary outcome: Responder rate (subjects with ≥50% back pain relief)

Device:
- Same neurostimulation system in both arms (Intellis™ system)

Programming:
- For Traditional SCS: Device Manufacturer representatives
- For DTM SCS: Sponsor representatives

Populations for Analysis:

Intention to Treat (ITT): All randomized subjects (N = 67 in test arm, N = 61 in control arm)
Modified Intention to Treat (mITT): Randomized subjects who completed the Trial Phase (N = 58 in each arm)

Study Hypotheses:

Primary:
Non-inferiority for Responder Rate for back pain at primary endpoint (3-months after device activation)
Farrington-Manning binomial test with 10% margin, one-sided 0.05 alpha level

Secondary:
Superiority comparison of study arms for Responder Rate at primary endpoint for study populations

METHODS

Table 1. Key Eligibility Criteria

INCLUSION	EXCLUSION
✓ VAS back pain intensity ≥ 5.0 cm with moderate to severe chronic leg pain	❖ Contraindicated for SCS system
✓ Adult subjects (18 years of age or older)	❖ Active implanted device
✓ Stable pain medication regime	❖ Pain in other area(s) and/or medical condition requiring the regular use of significant pain medications that could interfere and/or confound evaluation of study endpoints
✓ Willing to not increase pain medications from baseline through the 3-month visit.	❖ Mechanical spine instability
	❖ Pregnancy

RESULTS

Table 2. Baseline Demographics

	DTM SCS	Traditional SCS
Subjects Randomized (N)	67	61
Female/Male	34/33	34/27
Mean age (SD)	61.3 (12.2)	60.7 (11.8)
Years of pain onset (SD)	12.6 (13.0)	12.9 (11.2)
Mean number of prior surgeries (SD)	1.49 (1.33)	1.41 (1.13)
VAS (cm) Back Pain (SD)	7.25 (1.49)	7.35 (1.26)
VAS (cm) Leg Pain (SD)	6.20 (2.58)	6.58 (2.06)

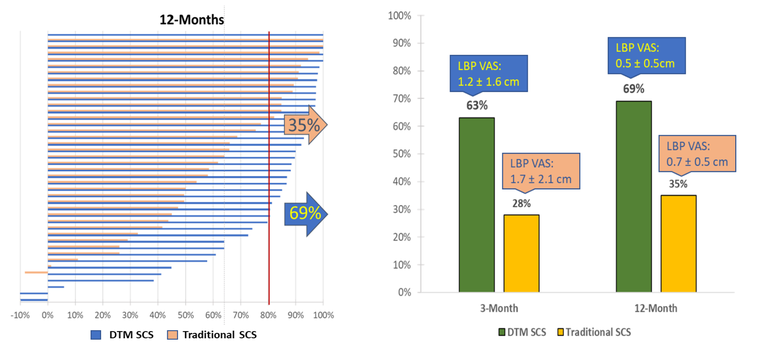


Figure 1. Left: Tornado plot showing % relief at 12 months and the profound responder rate (≥80% relief). Right: Bar graphs showing sustained profound response and mean low back pain VAS of profound responders at 3 and 12 months.

RESULTS

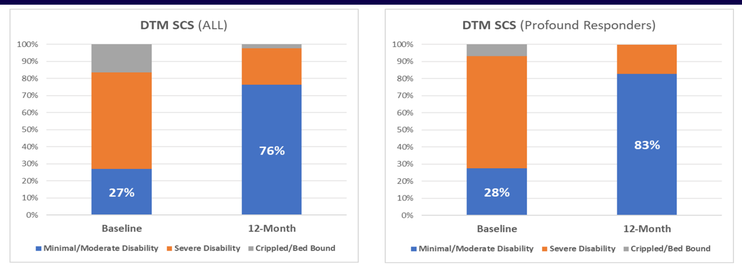


Figure 2. Bar graphs showing that DTM SCS improved disability for most subjects, with 76% of all subjects and 83% of profound responders reporting minimal/moderate disability at 12-months.

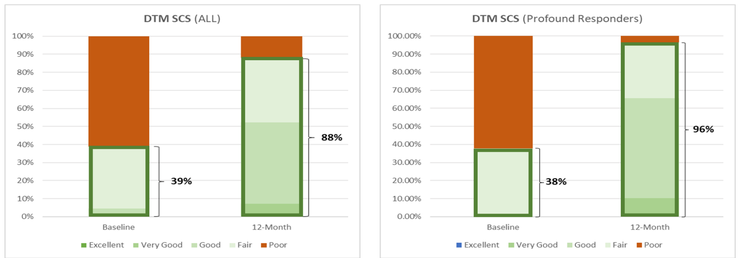


Figure 3. Bar graphs showing that DTM SCS improved quality of life for most subjects, with 88% of subjects and 96% of profound responders reporting very good to fair global health at 12-months.

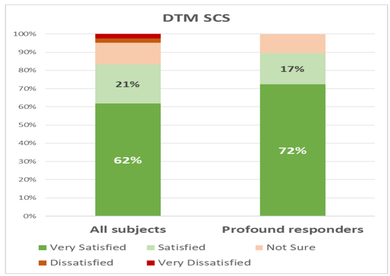


Figure 4. Bar graph showing that 83% of all subjects and 89% of profound responders treated with DTM SCS were very satisfied and satisfied. Furthermore, 62% of all subjects and 72% of profound responders treated with DTM SCS were very satisfied.

CONCLUSIONS

- DTM SCS achieved sustained superior responder rate for relief of chronic low back pain relative to traditional SCS
- DTM SCS provided sustained profound relief of low back pain, with 69% of subjects experiencing ≥ 80% improvement
- DTM SCS provided strong improvements in the extent of disability and global physical health
- Most subjects, particularly profound responders, were very satisfied after 12-months of DTM SCS therapy

UC202308505EN