Sensor-Driven Position-**Adaptive Spinal Cord** Stimulation for Chronic **Pain**



Schultz, et al. (2012)



Prospective, Multicenter, Open-label, Randomized **Crossover Study Comparing Automated vs.** Conventional Manual Programming Using Medtronic RestoreSensor[™] device

Enrollment (n=79)

Implant (n=76)



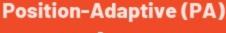


- Device recorded manual adjustments
- When on, AdaptivStim™ technology sensed body position and adjusted stimulation amplitude

- 10 U.S. centers
- 1 wk after SCS trial for chronic trunk and/or limb pain



Randomization: Week 0 (n=76)



Arm (n=36)







Conventional Manual rogramming (MP) Arm (n=40)





Crossover: Week 6



End of study: Week 12

Pain Relief & Convenience

86.5% (64/74) of patients with improved pain relief with no loss of convenience, or improved convenience with no loss of pain relief with PA vs. MP (p<0.001)

Relief, Adjustments, Change in NPRS

- 2.8% w/ worsened pain relief during PA arm
- 41% drop in avg. # of button presses for PA arm (18.2 vs. 30.7, p=0.002)
- Decreased mean NPRS in both arms (p<0.001) w/nosignificant decrease

Safety and Partcipant Experience

- 90.1% to leave PA on all/most of the time
- Improved comfort: 80.3%
- Improved activity: 69%
- Improved sleep: 47.9%
- No difference in adverse events related to uncomfortable stimulation

between arms