Functional Outcomes from the COMFORT 2 Randomized Control Trial for Peripheral Nerve Stimulation: Early Results

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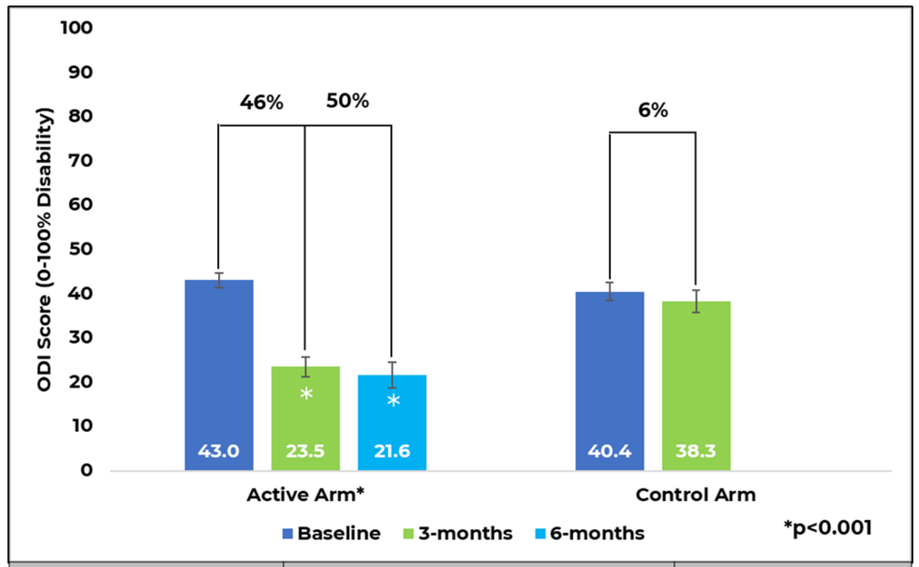
INTRODUCTION & METHODS

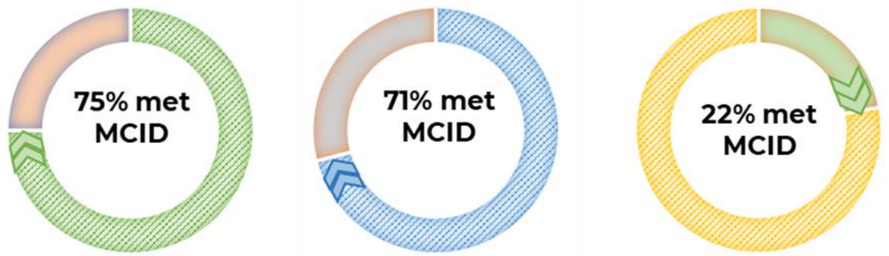
- Randomized Clinical Trial (COMFORT 2*)
- Document Efficacy and Safety of Peripheral Nerve Stimulation (PNS) over Conventional Medical Management (CMM).
- PNS delivered using battery-free system with micro-Implantable Pulse Generator (Nalu Medical, Carlsbad, CA).
- Post-market, open label, multicenter study aligned with standard of care; IRB approved.
- Chronic pain in shoulder, knee, low back and foot/ankle.
- Randomization- 2:1 Active to Control
  - Active- PNS+CMM
  - Control- CMM Only
- Successful trial ((≥ 50% pain relief from baseline) ⟶ Permanent Implant.
- 36-months follow-up
- Crossover of Control Subjects at 3-months.

RESULTS

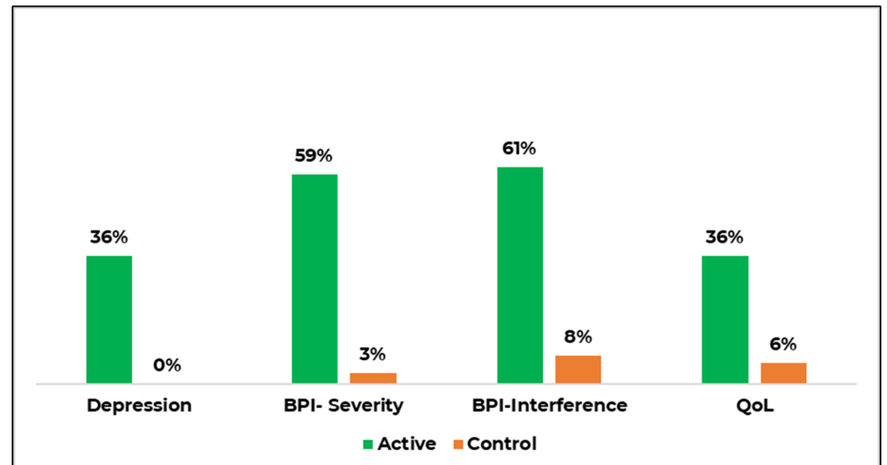
- Statistically Significant levels of Functional Improvement in Active Arm subjects compared to Control Arm.
- Majority of Active Arm subjects achieved MCID for each of the outcomes.
- Early results are consistent with results from the initial COMFORT study.



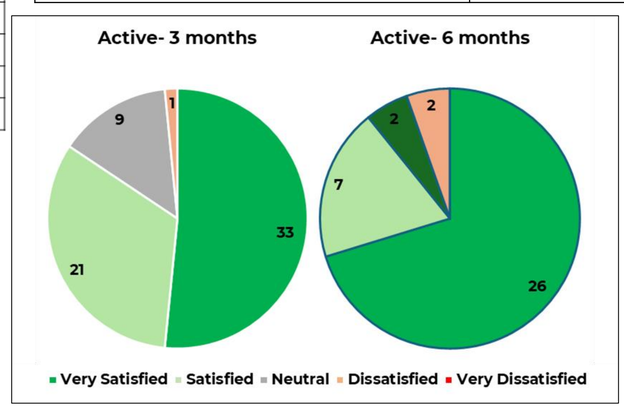
	Active Arm			Control Arm	
	Baseline	3-months	6-months	Baseline	3-months
Minimal Disability (0-20)	10%	48%	61%	12%	17%
Moderate (21-40)	31%	35%	21%	34%	39%
Severe (41-60)	49%	16%	18%	45%	37%
Crippled (61-80)	10%	2%	0%	9%	4%
Bed Bound (81-100)	0%	0%	0%	0%	2%



Oswestry Disability Index- MCID- Minimal Clinically Important Difference (≥ 10-point change[1])



Outcomes	% of subjects achieving MCID
Beck Depression Inventory	**72% (≥17.5% change from baseline[2])**
Brief Pain Inventory (Severity)	**83% (≥30% improvement in pain[2])**
Brief Pain Inventory (Interference)	**86% (1-point decrease[2])**
EQ-5D-5L- QoL	**77% (≥0.074 change in index[3])**



Figures

Above left: Oswestry Disability Index showing change from baseline to 3 and 6 months in the Active Arm and 3 months in the Control Arm. **Above Right:** Avg. percent change in Functional Outcomes from Baseline to 3-months and achieved MCID for each.

Left: Satisfaction with the PNS device at 3 and 6 months.

References:

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2. *Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials :IMMPACT recommendations. J Pain. 2008. 9:105-121.*
3. Walters SJ, Brazier JE. Comparison of the minimally important difference for two health state utility measures: EQ-5D and SF-6D. *Qual Life Res*. 2005 Aug;14(6):1523-1532. doi: 10.1007/s11136-004-7713-0. PMID: 16110932.

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