Pain Outcomes from the COMFORT 2 Randomized Control Trial for Peripheral Nerve Stimulation- Early Results

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Scan for detailed information about the COMFORT study

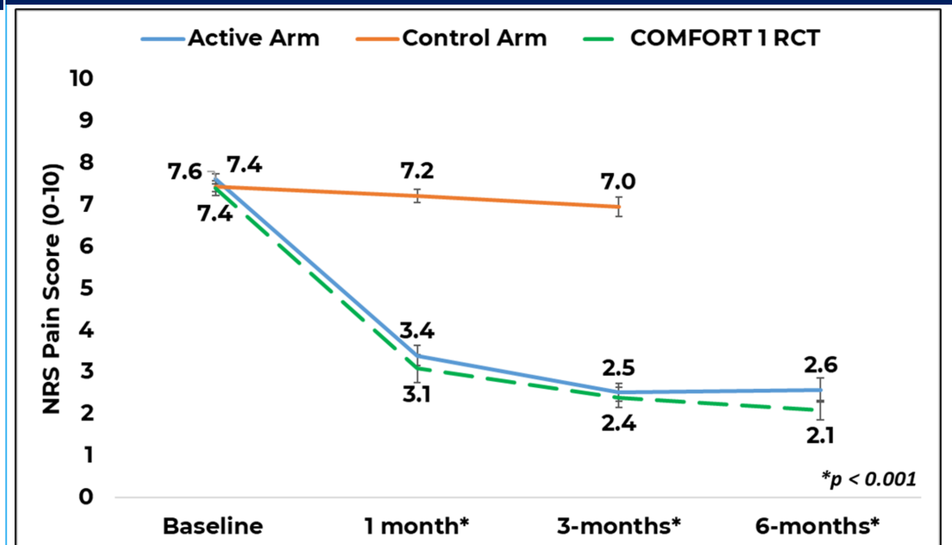
INTRODUCTION & METHODS

- 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.

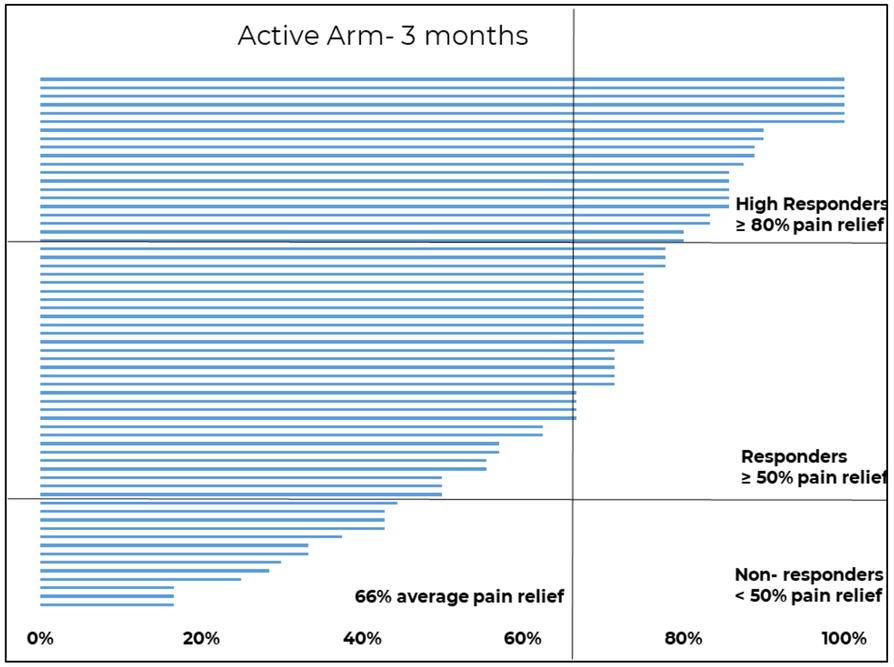
CONCLUSIONS

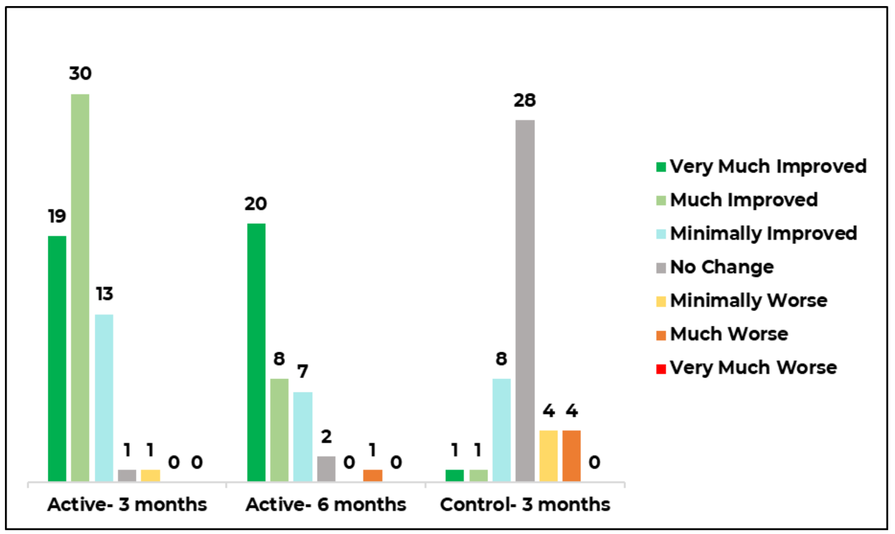
- Statistically significant pain relief in PNS+CMM compared to CMM only.
- Overall improvement in activity, mood, and QoL (PGIC).
- No reports of pocket pain and no serious adverse device effects.
- Early results from COMFORT 2 are consistent to outcomes from COMFORT 1 RCT[1].

RESULTS



Baseline	1 month*	3-months*	6-months*
Active Arm*	**n= 80**	**n= 64**	**n= 38**
Responder Rate (≥ 50%)	**70%**	**78%**	**82%**
% Pain Relief	**55%**	**66%**	**64%**
Control Arm	**n= 58**	**n= 46**	***p<0.001**
Responder Rate (≥ 50%)	**0%**	**7%**	
% Pain Relief	**2%**	**6%**	





Figures:
Above- NRS pain scores in Active (3 and 6 months) and Control Arms (3-months) with Responder rates and average pain relief. PNS+CMM statistically superior to CMM only.
Above Right: Percent pain relief in individual subjects in the Active Arm at 3 months. 78% subjects were Responders and 31% of subjects were High-Responders. Average Pain Relief was 66% which was statistically significant compared to baseline and CMM only.
Right: Patient Global Impression of change in Active (3 and 6 months) and Control(3-months). 97% of subjects showed improvement in PGIC at 3-months in the Active Arm compared to just 22% in the Control Arm. 92% subjects reported improvements in PGIC at 6-months.

*Registered on www.clinicaltrials.gov; NCT05870124.

1. Hatheway J, Hersel A, Song J, et al. Clinical study of a micro-implantable pulse generator for the treatment of peripheral neuropathic pain: 3-month and 6-month results from the COMFORT-randomized controlled trial. Reg Anesth Pain Med 2024;0:1-7. Doi:10.1136/rapm-2023-105264.

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