Advanced Peripheral Nerve Stimulator Delivers Consistent Pain Relief Across Various Neuropathic Etiologies: COMFORT RCT Findings

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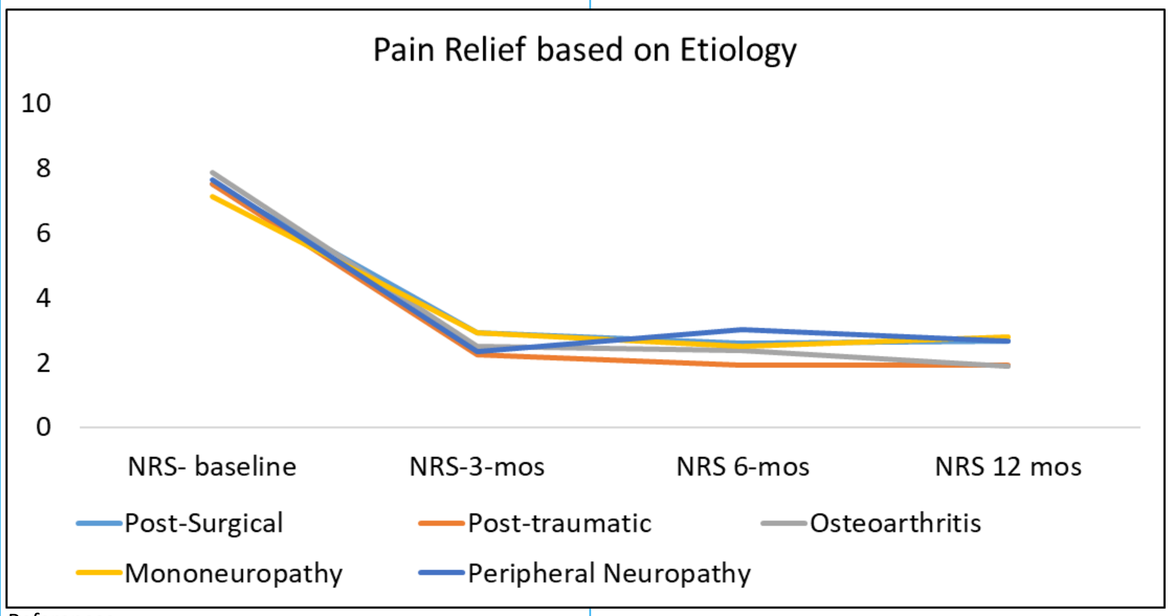
INTRODUCTION

- Peripheral Neuropathic Pain (PNP) may require interventional treatment beyond conservative methods; Peripheral Nerve Stimulation (PNS) is an option.
- The COMFORT study enrolled subjects with various chronic pain etiologies and diagnoses:
  - Post- traumatic
  - Post-surgical
  - Mononeuropathy
  - Osteoarthritis (OA)
  - Peripheral neuropathy

METHODS

- Eligible subjects had one of the mentioned etiologies in the knee, low back, shoulder and foot/ankle.
- Subjects randomized to
  - PNS + Conventional Medical Management (CMM), or
  - CMM alone
- PNS delivered using a battery-free micro-Implantable Pulse Generator (IPG) with complex programming capabilities.



Diagnosis at Enrollment	Post-traumatic	Post-surgical	Mononeuropathy	OA	Peripheral Neuropathy
6-Month Outcomes (n=60)					
	n=23	n=13	n=14	n=8	n=2
Baseline	7.52	7.53	7.12	7.88	7.66
Average Pain score (NRS)	1.91	2.61	2.50	2.37	3.00
Responder Rate	91%	69%	79%	88%	50%
Avg Pain Relief	73%	64%	67%	69%	56%
12-Month Outcomes (n=61)					
	n=23	n=12	n=15	n=8	n=3
Average Pain score (NRS)	1.91	2.67	2.8	1.88	2.67
Responder Rate	91%	92%	73%	88%	100%
Avg Pain Relief	73%	65%	60%	77%	65%

Figure- Left, shows consistent pain relief across etiologies at 3, 6 and 12 months, irrespective of pain etiology.

Table- above, outlines the outcomes at 6 and 12 months based on diagnosis at enrollment and randomization.

CONCLUSIONS

- Significant and sustained pain relief across various peripheral chronic pain conditions with PNS.
- Patients experienced high responder rates and pain reductions, sustained at both 6 and 12 months, irrespective of etiology of pain.
- Broad applicability and long-term effectiveness of PNS, establishing the micro-IPG as a versatile tool for managing diverse pain types.

References:
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2. Hatheway J, Hersel A, Engle M, et al. *Reg Anesth Pain Med Epub 2024* doi: 10.1136/rapm-2024-106099.

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