Superior Efficacy of Micro-implantable Pulse Generator for Chronic Pain Management: COMFORT RCT One-Year Interim Results

Authors: M. Engle¹, J. Hatheway², A. Hersel³, G. Gutierrez⁴, V. Khemlani⁵, L. Kapural⁶, G. Moore⁷, R. Ajakwe⁸, D. Trainor⁹, JM Hah¹⁰, S. Kottalgi¹¹; MJ Desai¹²

Affiliations: ¹Institute of Precision Pain Medicine, TX; ²Northwest Pain Care, WA; ³Pain Relief & Injury Management, CA; ⁴Pain Specialists of America, TX; ⁵Columbia Pain Management, OR; ⁶Carolinas Pain Institute, NC; ⁷Pacific Sports and Spine, OR; ⁸Comprehensive Spine & Pain Physicians, CA; 9DBPS Research, LLC; 10Stanford Medicine, CA; 11Nalu Medical, Inc., Carlsbad, CA; 12International Spine, Pain & Performance Center, DC.

Link to RAPM article

INTRODUCTION & METHODS

- COMFORT Randomized Control Trial. Post-market, Open Label, Multicenter Study
- Peripheral Nerve Stimulation (PNS; Nalu Medical, CA) + Conventional Medical Management (CMM) vs CMM Only.
- Crossover of Control i.e., CMM Only at 3-months.
- Chronic Pain in low back, knee, shoulder, foot/ankle.
- Follow-up at 1, 3, 6, 9, 12, 18, 24, 30 and 36 months.

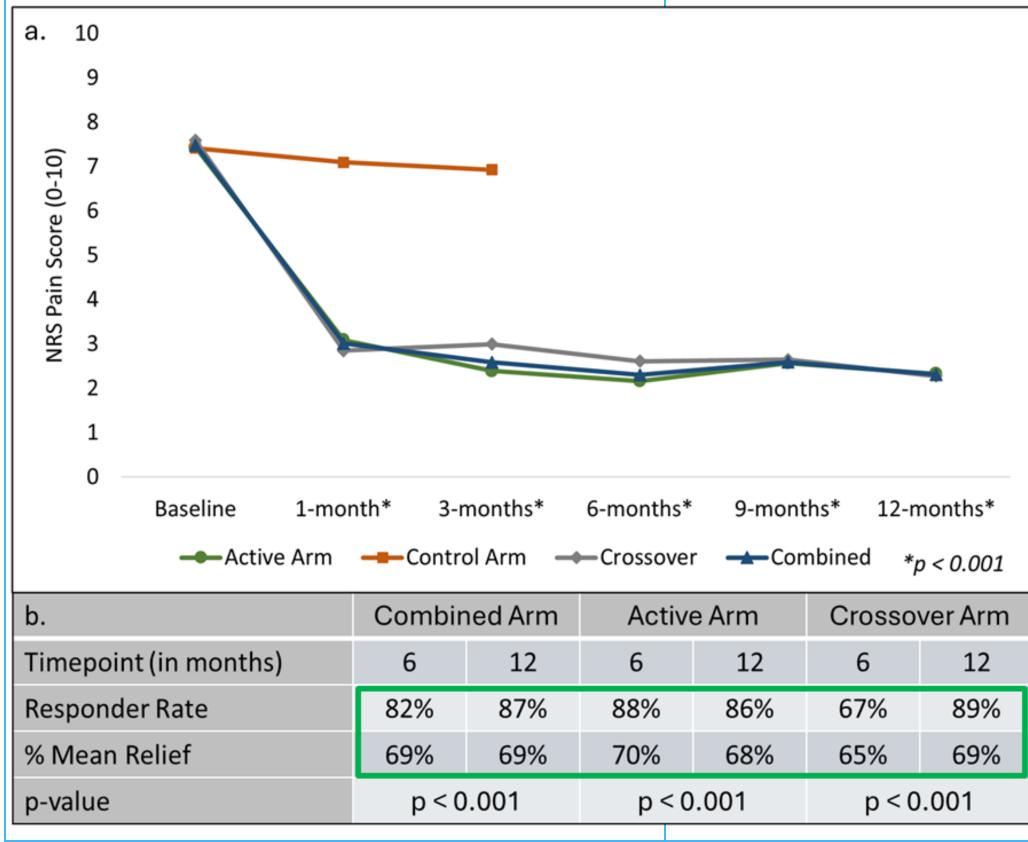
Characteristics	Mean ± Standard Deviation
Age (in years)	57.4 ± 11.8
Female	70% (54/77)
Male	30% (23/77)
Body Mass Index (BMI)	$33.0 \pm 7.8 \ kg/m^2$
Years since Diagnosis	5.0 ± 5.6
Opiates at Screening	53 % (41/77)
Morphine Milligram Equivalents (MME)	15.1 ± 22.4

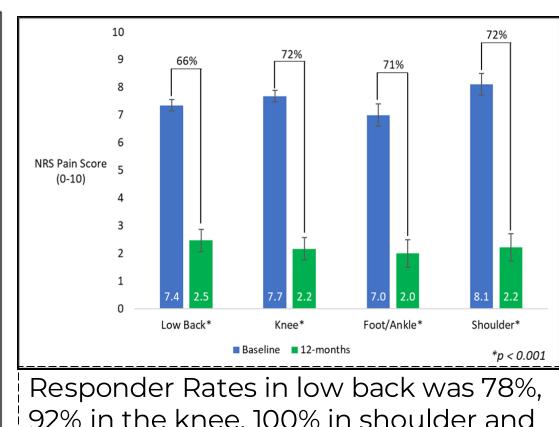
	Shoulder (Suprascapular & Axillary Nerves)
	Low Back (Superior Cluneal Nerve) 49%
	Knee (Genicular, Peroneal, Sciatic) 21%
	Foot/Ankle (Sciatic, Tibial, Sural, Peroneal) 17%
Target Areas of Pain in the COMFORT RCT	

RESULTS- SUMMARY

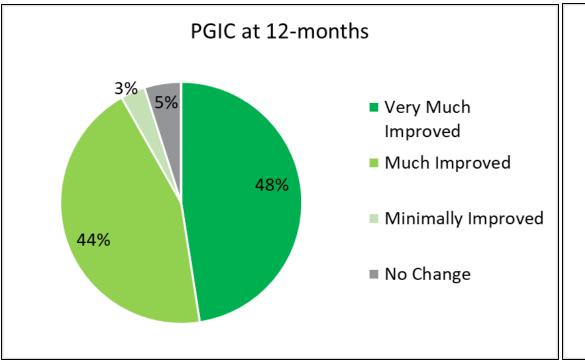
- **Long-term** results from this landmark study are consistent with previously reported 6-month outcomes.
- Statistically significant reduction in pain and improvements in functional outcomes, showing **superiority** of PNS system over CMM.
- **No** Serious Adverse Device Effects and no reports of pocket pain.
- Outcomes provide basis for long-term clinical evidence to support **patient** access to PNS therapy.

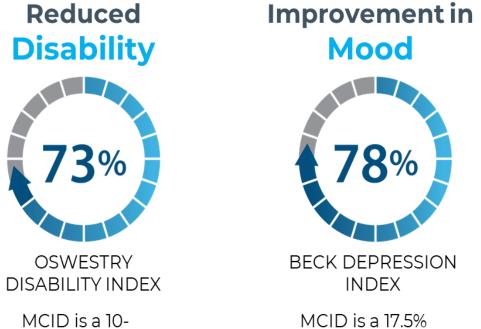
Reduced





92% in the knee, 100% in shoulder and foot/ankle areas.





MCID is a 10improvement from baseline. improvement from baseline.

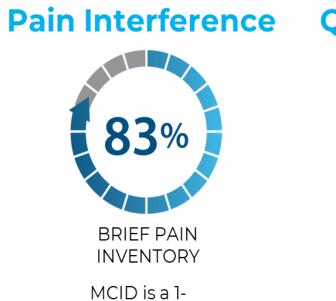
Satisfaction at 12-months

Very Satisfied

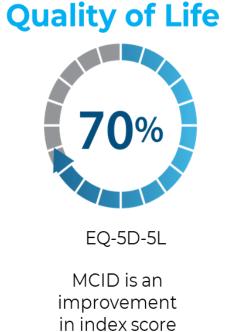
Satisfied

Neutral

Dissatisfied



MCID is a 1point decrease from baseline



by ≥0.074

from

baseline.

Very

Uncomfortable

Improvement in

System Comfort at 12-months 3% 2% ■ Very Comfortable Comfortable Neutral Uncomfortable



NANS2025 ANNUAL MEETING