



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 ± 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

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**.

