Significant and Sustained Pain Relief: COMFORT PNS RCT at 1-year

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Introduction

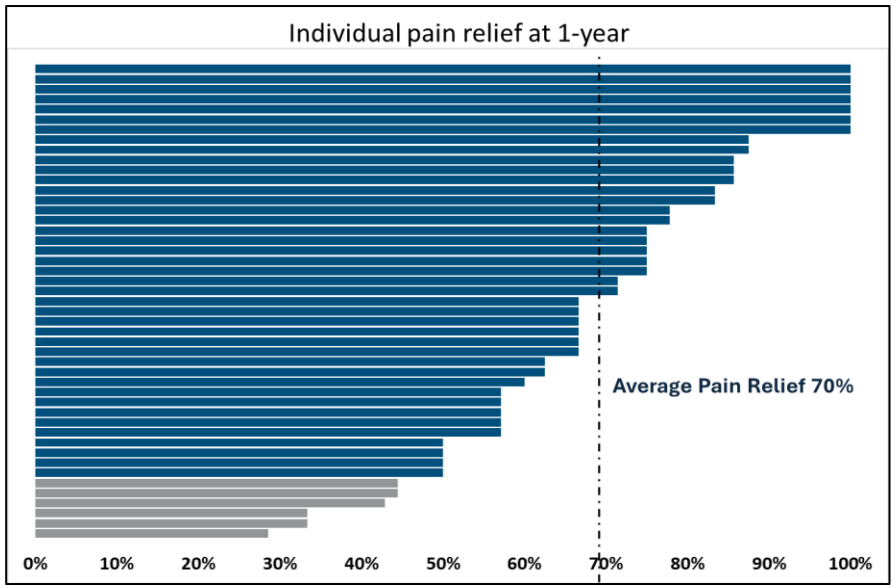
We are reporting 1 year data from the COMFORT randomized clinical trial (for details see QR code) involving a micro-implantable pulse generator (micro-IPG) system (Nalu Medical Inc., Carlsbad, CA).

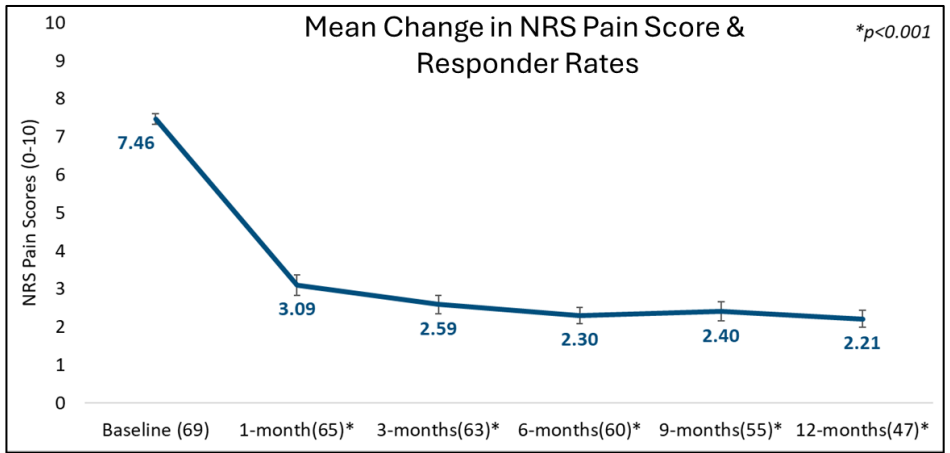
Methods

Subjects in the COMFORT study were randomized to either the Active arm (PNS with conventional medical management (CMM) or the Control Arm (CMM alone). Control Arm subjects could cross over to Active at 3-months. Subjects needed to have a successful trial (≥ 50% pain relief from baseline) lasting 7-10 days to receive the permanent implant. Subjects will be followed out to 36 months at various timepoints. 47 subjects completed 1-year follow-up and the results are reported here.

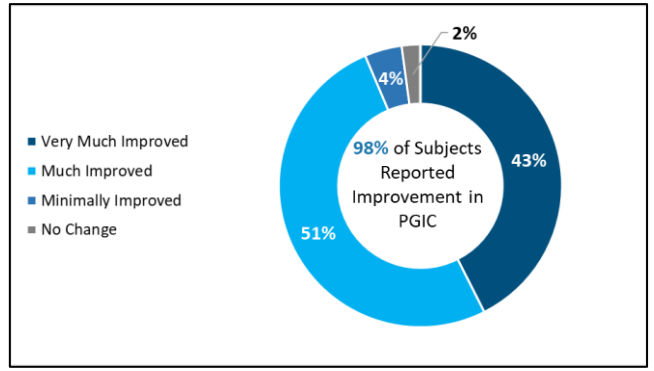
Results

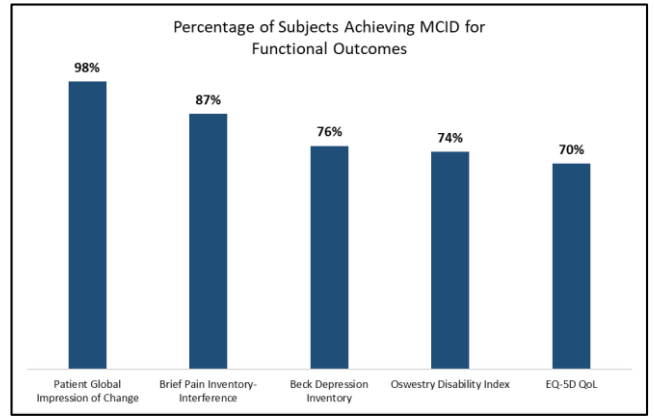
- PNS with CMM was superior to CMM alone, meeting the primary endpoint.
  - At 3-months the Active Arm had an 81% responder rate compared to 3% for the Control Arm ($p<0.001$).[1]
  - At 1 year the responder rate was 87% with an 70% average pain reduction.
- The trial success rate of 91% accurately predicted responders with low rate of false positives, demonstrating no need for protracted trial periods.
- A majority of subjects achieved Minimal Clinically Important Difference (MCID) for the various functional outcomes. [2,3]
- Majority of subjects were programmed with specific complex programming delivered by the micro-IPG including multi-area, multi-contact, high pulse width and high frequency programs and scheduled programs.[4]





Timepoint	1-month	3-months	6-months	9-months	12-months
Mean Pain Relief (%)	58%	65%	69%	67%	70%
Responder Rate (≥ 50%)	74%	81%	82%	75%	87%





References
1. Hatheway J, Hersel A, Song J, et al. Reg Anesth Pain Med Epub 2024;0:1-7. doi:10.1136/rapm-2023-105264.
2. Ostelo RW, de Vet HC. Best Pract Res Clin Rheumatol. 2005. 19:593–607.
3. 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 Feb;9(2):105-121.
4. M. Engle et al. Complex programming yields beneficial outcomes in COMFORT PNS RCT. ePoster ASPN 2024

Scan for detailed information about the COMFORT study

Conclusions

- **Significant and sustained pain relief out to 1-year**
- **No serious adverse device effects or reports of pocket pain**
- **MCID for functional outcomes achieved by majority of subjects.**