Complex Programming Yields Beneficial Outcomes in COMFORT PNS RCT

Authors: M. Engle[1], J. Hatheway[2], A. Hersel[3], G. Gutierrez[4], V. Khemlani[5], L. Kapural[6], G. Moore[7], R. Ajakwe[8], D. Trainor[9], JM Hah[10], J. Ruais[11]; S. Kottalgi[11]; MJ Desai[12]
Affiliations: [1]Institute of Precision Pain Medicine, TX; [2]Northwest Pain Care, WA; [3]Pain Relief & Injury Management, CA; [4]Pain Specialists of America, TX; [5]Columbia Pain Management, OR; [6]Carolinas Pain Institute, NC; [7]Pacific Sports and Spine, OR; [8]Comprehensive Spine & Pain Physicians, CA; [9]DBPS Research, LLC; [10]Stanford Medicine, CA; [11]Nalu Medical, Inc., Carlsbad, CA; [12]International Spine, Pain & Performance Center, DC.

Introduction

Peripheral nerve stimulation (PNS) is a well-established method for the treatment of chronic intractable pain. The COMFORT RCT is an ongoing study to document the efficacy of PNS with Conventional Medical Management (CMM) compared to CMM only. A battery-free micro-implantable pulse generator (mIPG; Nalu Medical, Carlsbad, CA) utilized for PNS in the study, can deliver complex programming to stimulate peripheral nerves. The study results show significantly different outcomes at **12-months compared to other PNS systems**[1-4]. One hypothesized reason for this difference may be that the mIPG has **broader and more complex programming capabilities than other PNS systems**, similar to the capabilities of existing SCS systems. The COMFORT study is funded by the manufacturer and approved by an Institutional Review Board.

Methods

To investigate the effect of the programming and preferred programs on the pain outcomes, data from **subjects with both programming and 12-months** of device use was evaluated. Subjects were provided up to 8 different programs (which can be utilized independently or rotated based on a personalized schedule), utilizing different therapy options. Subjects identified their **preferred, most frequently used programs at 1-year**.

References

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2. Gilmore CA, et al. Reg Anesth Pain Med. 2019 Nov 17: rapm-2019-100937. doi: 10.1136/rapm-2019-100937.
3. Wilson RD, et al. Am J Phys Med Rehabil. 2014 Jan;93(1):17-28. doi: 10.1097/PHM.0000000000000011.
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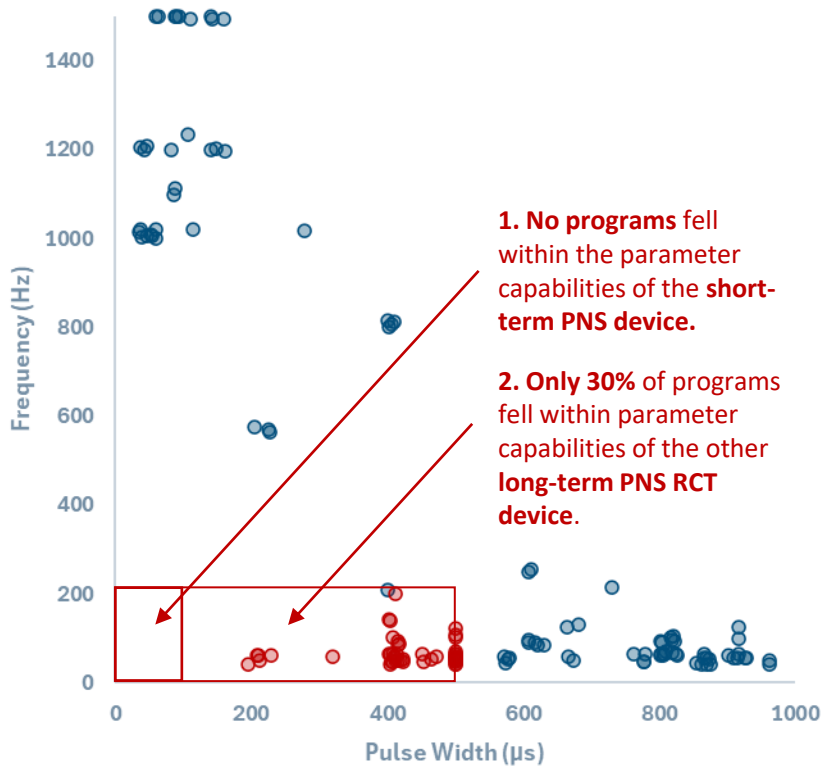
Results & Discussion

Pulse Width and Frequency Combinations
Favorite COMFORT Programs at 12-months
(n=97 programs, avg 3.6 prog/pt)



n=27 patients

Results at 1-year

- **87% were responders** (≥50% pain relief)
- **30% were high responders** (≥80% pain relief).
- **70%** overall average pain relief

Favorite Programs at 1-year

- **All subjects (100%) utilized "complex programming"** (capabilities typically only seen in the mIPG and existing SCS systems)
- Percentage of programs with **complex programming**:
  - **67%** - multi-contact (>2 contacts)
  - **59%** - multi-area
  - **48%** - high pulse width (≥500 µs)
  - **52%** - high frequency (≥500 Hz)
  - **30%** - scheduled (multi-program)

Circle colors indicate # of programs

Conclusions

The **high utilization of complex programming** is associated with strong, durable outcomes and **may explain why the COMFORT study results are demonstrating significantly better outcomes than other technologies**.