Early 6-month Pain Outcomes from the COMFORT 2 Randomized Controlled Trial

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Introduction

Early results are presented from a second study in a series of landmark randomized clinical trials (for details see QR code) involving a micro-implantable (micro-IPG) system (Nalu Medical Inc., Carlsbad, CA).

Methods

- **Active Arm:** Peripheral Nerve Stimulation (PNS) + Conventional Management (CMM); **Control Arm:** CMM alone.
- **Chronic pain** in low back, shoulder, knee and foot/ankle.
- **Cross over option** for control subjects at 3 months.

Results:

Twenty-six (26) subjects in the Active Arm have completed 6-months of device use.

6-month Responder Rate (≥50% pain reduction) of 88%

Mean pain reduction baseline to 6-months of 67% (p<0.001; Figure 1).

Patient Global Impression of Change (PGIC) data shows that 92% of these subjects reported improvement in PGIC (Figure 2). There have been no serious adverse device effects and no reports of pocket pain.

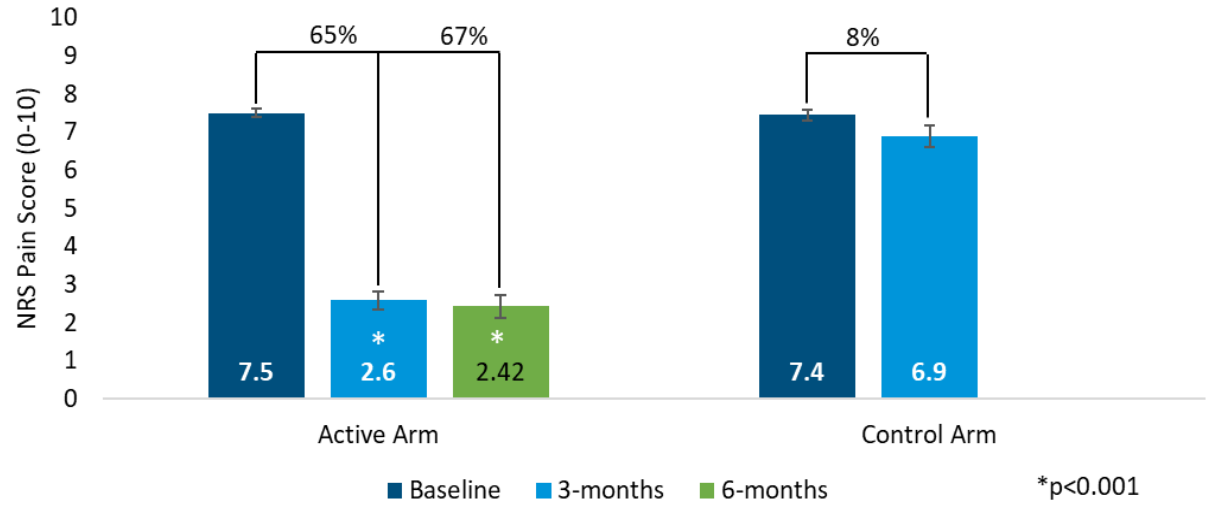

Figure 1: *Active vs Control- Pain Relief at 3 and 6 months compared to baseline. At 3-months, the Active Arm showed an average 65% improvement in pain score compared to 8% in the control arm (p<0.001). At 6-months, subjects showed an average 67% improvement in pain.*

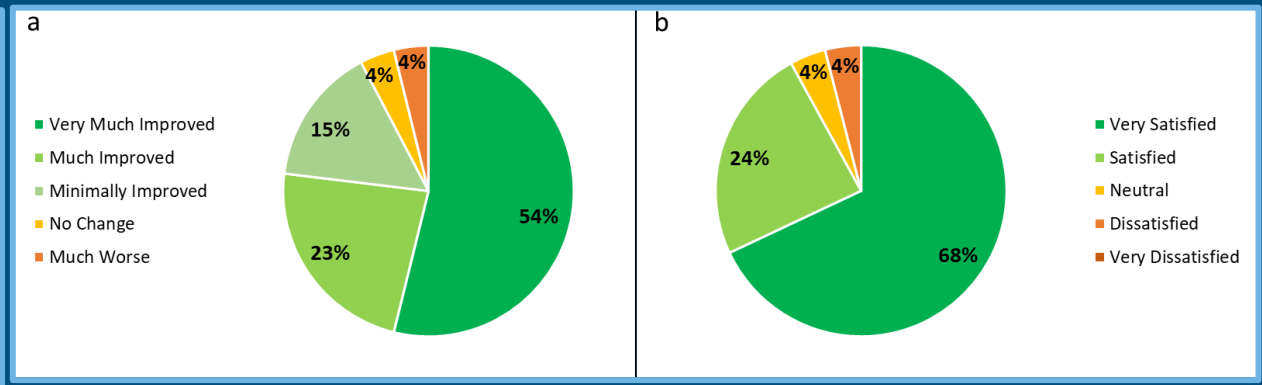

Figure 2: ***a.*** *Patient Global Impression of Change at 6-months. 92% (24/26) of subjects showed improvement from baseline to 6-months in activity limitations, symptoms, emotions and overall quality of life related to pain condition.* ***b.*** *92% (23/25) subjects reported overall satisfaction with the system at 6-months.*

Conclusions:

- **PNS+CMM is better than CMM alone (p<0.001) at 3-months**
- **Statistically significant pain reduction at 6-months**
- **Majority of subject reporting improvement in PGIC and system satisfaction**
- **No serious adverse device effects or reports of pocket pain**

Reference:

1. Registered on www.clinicaltrials.gov; NCT05870124.

Scan for detailed information about the COMFORT study