Spinal cord stimulation (HF-SCS) at 10 kHz for the treatment of chronic focal neuropathic post-surgical pain

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Introduction

Chronic post-surgical pain (CPSP) is one of the largest sub-groups of focal mononeuropathies. Incidence of chronic pain from iatrogenic peripheral nerve injuries resulting from surgeries like mastectomy, thoracotomy and amputation vary from 5-85%[1]. The focal nature of the pain may warrant targeting a neural structure like dorsal root ganglion (DRG) to elicit pain relief. However, early pre-clinical evidence from high frequency SCS (HF-SCS) at 10 kHz demonstrated an inhibitory effect on projection interneurons in the superficial layers of dorsal horn. Thus, we hypothesized that HF-SCS at 10 kHz may provide effective pain relief in focal CPSP conditions.

Methods

- Major inclusion criteria
  - Subjects with chronic, intractable pain of ≥5 cm (on a 0-10 cm visual analog scale [VAS]) of the trunk, upper or the lower limb from CPSP
  - A score of ≥4 in the Douleur Neuropathique 4 (DN4) questionnaire
- Major exclusion criteria: Significant spinal stenosis, epidural scarring or symptoms of myelopathy
- Subjects enrolled following Institutional Review Board approval
- Each subject implanted with two epidural leads spanning appropriate vertebral bodies as determined by the location of pain
- Senza system (Nevro Corp., Redwood City, CA) implanted in subjects with successful trial stimulation (≥40% pain relief)
- Safety and effectiveness endpoints captured up to 12 months post-implant
- Interim three month results presented (mean ± standard error) in the permanent implant population

Figure 1 (Left). Lead location for a subject with neuropathic groin pain post-hernia repair. The subject's baseline pain was 8.2 cm on VAS. The lead placement was anatomically guided and there was no intra-operative paresthesia mapping involved.

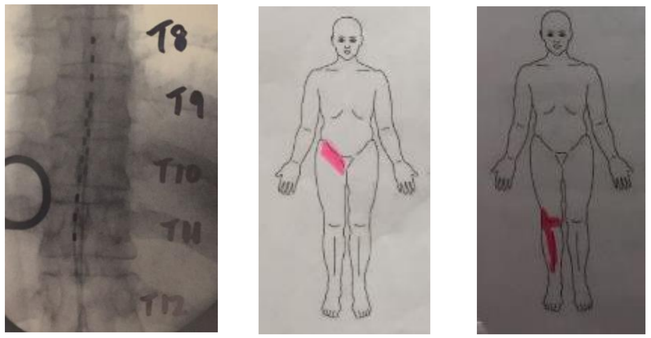
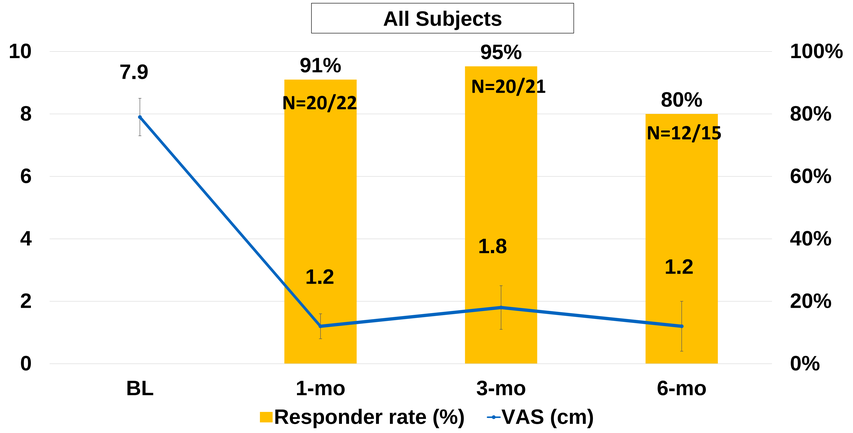


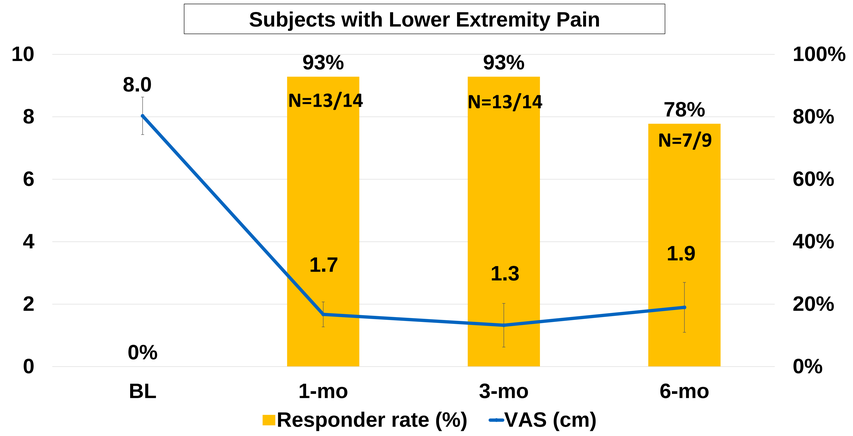
Figure 2. Representative pain maps in a subject with pain post-hernia repair (middle) and pain post-knee surgery (right).

Results: Trial Success

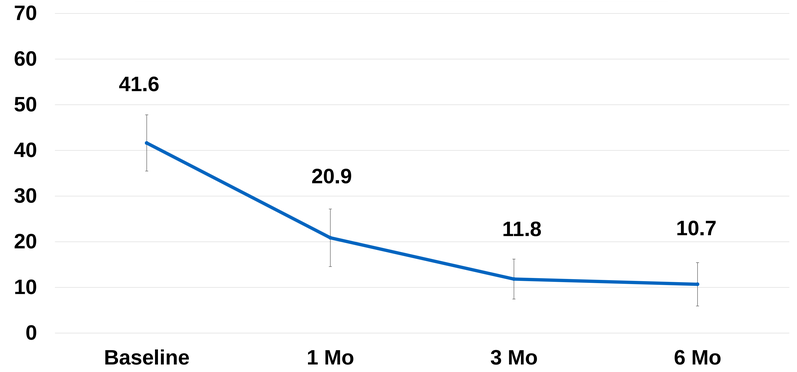
- Trialed: 28
- Trial success: 23/28 (82%)
- Location of pain
  - Upper extremity: 3
  - Trunk: 8
  - Lower extremity: 17

Results: Pain Scores



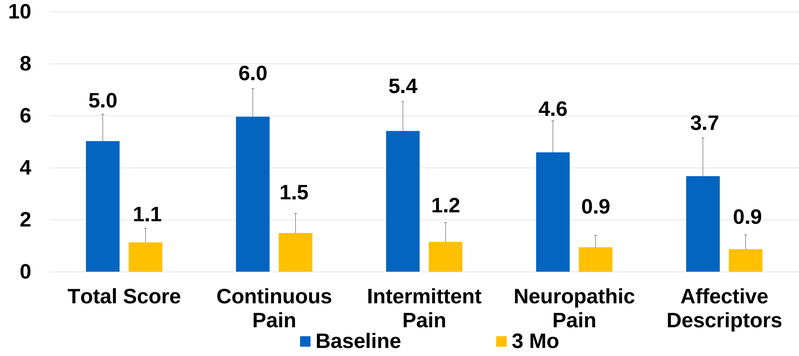


Results: Pain Disability Index (PDI)



- Disability assessed by PDI (Range: 0-70)
- Lower index score = Less disability
- Minimal clinically important difference (MCID): 8.5-9.5[2]
- At 3 months: 20.7 point reduction in PDI or over 2X MCID

Results: Pain Interference



- Measured by McGill Pain Questionnaire (SF-MPQ-2)
- Significant reduction in all dimensions of pain including affective descriptors

References
[1]Macrae WA (2008). Chronic post-surgical pain. Br J Anaesth. 101(1): 77-86.
[2]Soer et al. (2012) Spine.