Supplemental material

Treatment of nonsurgical refractory back pain with high-frequency spinal cord stimulation at 10 kHz: 12-month results of a pragmatic, multicenter, randomized controlled trial
Kapural et al.
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DISCLAIMER The Journal of Neurosurgery acknowledges that the following section is published verbatim as submitted by the authors and did not go through either the Journal’s peer-review or editing process.
Supplemental Table 1A. Inclusion Criteria

1. Have been diagnosed with chronic, refractory\textsuperscript{1} axial low back pain and not a candidate for surgery based on a spine surgeons’ assessment.
2. Pain should have a predominant neuropathic component as per the investigator’s clinical assessment.
3. Have not had any surgery for back or leg pain, or any surgery resulting in back or leg pain.
4. Considering daily activity and rest, have average back pain intensity of $\geq 5$ out of 10 cm on the Visual Analog Scale (VAS) at enrollment.
5. Be on no or stable pain medications, as determined by the Investigator, for at least 28 days prior to enrolling in this study.
6. Be 18 years of age or older at the time of enrollment.
7. Be willing and capable of giving informed consent.
8. Be willing and able to comply with study-related requirements, procedures, and visits.
9. Be capable of subjective evaluation, able to read and understand written questionnaires in the local language and are able to read, understand and sign the written inform consent.

\textsuperscript{1}Pain is defined as refractory, regardless of etiology, when conventional medical management has failed to reach treatment goals that may include adequate pain reduction and/or improvement in daily functioning or have resulted in intolerable adverse effects.

Supplemental Table 1B. Exclusion Criteria

1. Have a diagnosed back condition with inflammatory causes of back pain (e.g., ankylosing spondylitis or diseases of the viscera).
2. Have a medical condition or pain in other area(s), not intended to be treated with SCS, that could interfere with study procedures, accurate pain reporting, and/or confound evaluation of study endpoints, as determined by the Investigator.
3. Have evidence of an active disruptive psychological or psychiatric disorder identified as the primary condition or other known condition significant enough to impact perception of pain, compliance of intervention and/or ability to evaluate treatment outcome, as determined by the investigator in consultation with a psychologist.
4. Have a current diagnosis of a progressive neurological disease, spinal cord tumor, or severe/critical spinal stenosis
5. Have a current diagnosis of a coagulation disorder, bleeding diathesis, progressive peripheral vascular disease or uncontrolled diabetes mellitus that would add unacceptable risk to the procedure
6. Be benefitting within 30 days prior to enrollment from an interventional procedure to treat back and/or leg pain
7. Have an opioid addiction or drug seeking behavior as determined by the Investigator
8. Have an existing drug pump and/or SCS system or another active implantable device such as a pacemaker
9. Have prior experience with neuromodulation devices (SCS, PNS, DRG, multifidus muscle stimulation)
10. Have a condition currently requiring or likely to require the use of diathermy or MRI that is inconsistent with Senza system guideline in the Physician’s Manual
11. Have metastatic malignant disease or active local malignant disease
12. Have a life expectancy of less than 1 year
13. Have an active systemic or local infection
14. Be pregnant (participants of child-bearing potential that are sexually active must use a reliable form of birth control).
15. Have within 6 months of enrollment a significant untreated addiction to dependency producing medications or have been a substance abuser (including alcohol and illicit drugs)
16. Be concomitantly participating in another clinical study
17. Be involved in an injury claim under current litigation
18. Have a pending or approved worker’s compensation claim

a Interventions should not be performed less than 30 days prior to enrollment, or a follow-up visit to ensure that pain level is stable and representative of their long-term response to CMM.
Supplemental Figure 1. Study Flow

10kHz SCS

Baseline

Randomization

CMM

Temporary Trial

No

Trial Success?

Yes

Permanent Implant

1 month

3 month

6 month Study Exit

3 month (1\textsuperscript{st} Endpoint)

6 month (2\textsuperscript{nd} Endpoint)

9 month

12 month

18 month

24 month

1 month

3 month (1\textsuperscript{st} Endpoint)

6 month (2\textsuperscript{nd} Endpoint)

9 month

12 month

18 month

24 month

Dashed lines show Crossover Option for both arms