Critique author	**Ed Whitney**

Bibliographic Data	
Authors	Kapural L, Yu C, et al
Title	Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain
PMID	26218762
Citation	Anesthesiology 2015; 123:00-00
Other information if relevant	

Methods	
Aim of study	To compare the safety and effectiveness of a novel high frequency spinal cord stimulator (SCS) with a traditional low frequency stimulator in patients with chronic back and leg pain
Design	Randomized controlled trial The study was designed as a noninferiority study for the experimental SCS system, and testing for superiority was done if the noninferiority margins were met for the outcomes under consideration

Participants	
Population from which participants are drawn	Patients already under the care of the study investigators, predominantly with failed back pain following previous back surgery
Setting (location and type of facility)	Multiple centers throughout the United States
Age	55
Sex	106 women, 73 men

Total number of participants for whom outcome data were reported	179
Inclusion criteria	- Chronic intractable pain of the trunk and/or limbs, refractory to at least 3 months of conservative therapy (including analgesics and other medications, physical therapy, spine injections, and behavioral treatment) - An average score of 5 or more on a 10 point scale for back pain and/or leg pain - Being an appropriate candidate for treatment in the judgment of the treating physicians
Exclusion criteria	- Psychological or psychiatric conditions known to impact perception of pain - Mechanical spine instability based on flexion/extension films - Prior experience with SCS
Other information if relevant	- The study protocol at clinicaltrials.gov also indicates that exclusion criteria applied to patients who were likely to need an MRI, patients with a pending litigation claim, and having a pending or approved workers' compensation claim - Although Table 1 gives baseline data on 179 participants (92 in the experimental and 87 in the control groups), outcome data are reported on only 171 patients (90 experimental and 81 control) - The randomization initially allocated 101 patients to the experimental group and 97 to the control group - All eligible patients were first referred for a trial to determine short term response; a 40% pain reduction was considered a response sufficient to proceed to a surgical implant - Of the 101 patients allocated to experimental treatment, 97 had a 14 day trial with an external stimulator, and 90 responded to the trial and received an experimental implant - Of the 97 allocated to control treatment, 92 had a 14 day trial and 81 responded and received a control implant - About two thirds of the patients had radiculopathy and about half had predominant back pain, and three quarters had "failed back surgery syndrome"

Intervention Groups

Group 1	
Group name	High frequency (HF) SCS
Number in group	90

Description of intervention	- HF pulses at 10 KHz in 30 microsecond pulses were done intraoperatively, and paresthesias were not elicited because these are not a goal of HF SCS treatment
Duration of treatment period	Followup for assessment of outcomes was done at 3 months (primary endpoint) and at 12 months
Co-interventions if reported	Oral analgesics under the guidance of a study investigator as medically necessary
Additional information if relevant	

Group 2	
Group name	Traditional SCS
Number in group	81
Description of intervention	- Stimulation parameters were adjusted intraoperatively based on patient feedback regarding the induction of paresthesias in the affected region in order to obtain overlap with painful areas - The average frequency after adjustments had been made was 39.2 Hz; average amplitude was 3.6 mA, and average pulse width was 347 microseconds - Additional adjustments were made on followup visits
Duration of treatment period	Followup for assessment of outcomes was done at 3 months (primary endpoint) and at 12 months
Co-interventions if reported	Oral analgesics under the guidance of a study investigator as medically necessary
Additional information if relevant	

Primary outcome	
Outcome name and criteria for definition	- Responder analysis (at least 50% pain reduction) at 3 months was the primary outcome - There was also a category of “remitter” patients, defined as having a pain VAS of 2.5 points or less at followup
Time points measured and/or reported	3,6,9, and 12 months

Differences between groups	- At 3 months, the HF SCS group had 84.5% responders for back pain, compared to 43.8% responders for traditional SCS - At 3 months, the HF SCS group had 83.1% responders for leg pain, compared to 55.5% responders for traditional SCS - Throughout the 12 months of followup, the subsequent responder rates remained similar to the 3 month rates: approximately 80% for HF SCS and 50% for traditional SCS - The HF group had 67% remitters for back and leg pain throughout the 12 months of followup, compared with remitter rates in the control group of 35% for back pain and 40% for leg pain
Additional information if relevant	

Secondary outcomes	
Outcome name and criteria for definition	- Reduction of pain medication was reported in both groups, with no statistical difference between groups with respect to decreasing or eliminating opioid analgesics: 35.5% of HF SCS and 26.4% of traditional SCS - Disability as measured by Oswestry improved about equally for both groups (by an average of 16.5 points for HF SCS and 13.0 for traditional SCS), and at 12 months, more HF patients (62.9%) had minimal or moderate disability than traditional SCS patients (45.7%) - More HF patients (55.4%) were very satisfied than traditional patients (32.3%) - HF patients did not experience paresthesias, but 46.5% of traditional patients reported some discomfort from paresthesias
Time points measured	3,6,9, and 12 months
Differences between groups	As above
Additional information if relevant	- Lead migration was rare in both groups: 3.0% of HF and 5.2% of traditional SCS patients - Patients with HF implants need to recharge their devices daily, with recharges typically lasting 30 to 45 minutes, while traditional implants are recharged about 5 times per month with each recharge taking about 2.3 hours

Conclusions	
Key conclusions of study authors	- Traditional SCS was successful, as measured by responder rates of 50% pain relief, in about half of patients, consistent with what has been reported in past studies of SCS - HF SCS was more successful than traditional with respect to responder rates for both back and leg pain - Blinding was not possible because the SCS devices have different effects, with the traditional device producing paresthesias and the HF device producing no paresthesias

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	
Allocation concealment *(selection bias)*	Low	Centrally administered block randomization is likely to conceal allocation when patients are being enrolled into the study
Blinding of participants and personnel *(performance bias)*	High	
Blinding of outcome assessment *(detection bias)*	High	
Incomplete outcome data *(attrition bias)*	Low	
Selective outcome reporting? *(reporting bias)*	Low	Study protocol on clinicaltrials.gov has the same primary outcome reported in the study

Other bias		Sponsorship of the study by the device maker has the potential to favor the device over the control intervention

Sponsorship if reported		
Study funding sources if reported	Nevro Corporation, which manufactures the HF device	
Possible conflicts of interest for study authors	Some of the authors have received fees from Nevro Corporation and from Boston Scientific, as well as from Medtronic, but the authors declare no competing interests	
Notes: The definition of competing interests is not clear, but receiving personal fees from the study sponsor has the potential to create them		

Comments by DOWC staff

- Randomization appears to have been done before the 14 day trial of spinal cord stimulation rather than randomizing patients who remained candidates for SCS following a trial
- This may not create bias, but differences in the numbers of patients allocated to HF and traditional SCS may have arisen from this method of allocation
- The majority of patients are likely to resemble those who would be considered for SCS in Colorado Workers' Compensation, having chronic pain with failed conservative and surgical treatment, and having been cleared from a psychiatric and psychological point of view
- Kapural 2016 followed the study cohort for another year to obtain 24 month followup data, which was available for 85 HF and 71 traditional SCS patients
- The advantage of HF over traditional SCS was maintained at the 24 month followup; using the same definition of responders which was used in the original study, the HF group had 76.5% responders for back pain and 72.9% for leg pain, compared to 49.3% responders for both back pain and leg pain in the traditional HF group

Assessment by DOWC staff	

Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	The study supports some evidence that a high-frequency, 10 KHz spinal cord stimulator is more effective than a traditional low frequency 50 Hz stimulator in reducing both back pain and leg pain in patients who have had a successful trial of an external stimulator. The high frequency device appears to lead to greater patient satisfaction than the low frequency device, which is likely to be related to the fact that the high frequency device does not produce paresthesias in order to produce a pain response. In contrast to the low frequency stimulator, which requires recharging about five times per month, the high frequency stimulator is recommended for daily recharging for 30 to 45 minutes.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant
- Kapural L, Yu C, et al. Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial. Neurosurgery 2016;79:667-677