Wireless spinal cord stimulation

New wireless spinal cord stimulation (SCS) technology, introduced in recent years, promises minimal invasive SCS as well as additional advantages such as a wide range of stimulation paradigms and 3 Tesla magnetic resonance imaging (MRI) conditionality.

Ahmadi et al. prospectively evaluated 12 patients suffering from therapy-resistant neuropathic pain, who were implanted with a wireless SCS system from 2017 to 2019. Potential issues pertaining to handling and usability of the SCS device were evaluated from a patients' as well as from a surgeon's perspective.

The mean follow-up was 228.0 days (95% CI, 20.0-518.0 days). We did not record any handling issues nor did we record any relevant local discomfort associated with the implanted SCS device. N = 3/12 patients reported discomfort from wearing the SCS antenna and one patient complained about the short battery life of the controller device. There were no reported incidents during 3-T MRI studies. After an average test period of 51.7 days (95% CI, 11.0-104.0 days), N = 9/12 patients (75%) had reached pain relief of 50% or more with an average pain relief (responders and partial responders) of 67.4% (95% CI, 50.0%-85.0%). On average, patients tested 2.2 different stimulation paradigms, with frequencies ranging from 60 Hz to 10 kHz, but there was no preferred stimulation paradigm.

Minimal invasive implantation of wireless SCS systems was feasible and safe. The device offered a broader range of stimulation paradigms compared to conventional SCS devices, an allowed for a prolonged testing phase and continuous adjustment of SCS programs [1)].

Wireless optogenetics based on the photon upconversion technique has recently provided an effective and interference-free alternative for remote brain stimulation and inhibition in behaving animals, which is of great promise for neuroscience research. However, more versatile upconversion devices are yet to be implemented for neural tissues other than the brain. In a study, a flexible and fully implantable upconversion device was developed for epidural spinal cord stimulation. The upconversion device was fabricated via a straightforward, two-step, heat-pulling process using biocompatible thermoplastic polypropylene as a backbone, which is mixed with upconversion nanoparticles (UCNPs) to form a flexible optrode device that converts near-infrared (NIR) irradiation to visible light for the optogenetic manipulation of spinal cord tissues. In this system, the flexible upconversion device is fully implantable within the rigid spine structure and shows excellent long-term biocompatibility even after a four-month experiment. In anesthetized mice, the UCNP device implanted at the L4 vertebra can be used to reliably evoke hindlimb muscular activity upon NIR triggering. In behaving mice, neural modulation by the same UCNP devices effectively inhibits the animals' movement as a result of remote spinal cord stimulation. We believe that the flexible upconversion device provides new possibilities for wireless neural modulation in spinal cord tissues, and will become a valuable supplement to the current toolsets of upconversion based wireless optogenetics [2)].

A study aimed to evaluate the wireless Freedom Spinal Cord Stimulator (WSCS) System for the treatment of chronic back and/or leg pain associated with failed back surgery syndrome (FBSS) refractory to standard medical treatment utilizing 10-kHz stimulation (high-frequency [HF]) in comparison with 10-1,500-Hz stimulation (low-frequency [LF]) waveforms.

Ninety-nine subjects were randomized in a 1:1 ratio to receive either HF or LF stimulation waveforms utilizing the same Freedom WSCS System. All subjects were implanted with two 8-electrode arrays in the exact same anatomical positions within the dorsal epidural spinal column, with the top electrode positioned at the T8 and T9 vertebrae levels, respectively, and the wireless receiver placed under the skin in a subcutaneous pocket.

Seventy-two (HF: N = 38; LF: N = 34) subjects had completed the six-month follow-up after an initial 30-day trial period at the time of this report. For both the HF and LF arms, mean visual analog scale (VAS) scores for back and leg pain decreased significantly: 77% and 76%, respectively, for the HF arm and 64% and 64%, respectively, for the LF arm. In addition, most subjects experienced significant improvements in VAS, Oswestry Disability Index, European Quality of Life 5 Dimension questionnaire, Patient Global Impression of Change, and sleep duration.

These preliminary results demonstrate that WSCS devices can reduce FBSS chronic pain substantially with both LF and HF stimulation waveforms over a seven-month period (30-day trial period and six-month post-trial evaluation) [3].

Cost-effectiveness

North et al. evaluated the cost-effectiveness of wireless spinal cord stimulation (Wireless SCS) with single stage “direct to permanent” implantation vs. screening with temporary electrodes and an external pulse generator followed by implantation of a system for long-term use (IPG SCS).

They created a cost model that takes a 2019 United States (U.S.) payer perspective and is based on IPG SCS cost models for subjects with chronic back and/or leg pain. Our six-month decision tree includes the screening trial period (success ≥50% relief) and leads to various levels of pain relief with or without complications for IPG SCS and Wireless SCS and without complications for conventional medical management (CMM). Every three months in the follow-on 15-year Markov model (with costs and quality-adjusted life years discounted 3.5% annually), subjects remain stable or transition to deteriorated health or death. Subjects who fail SCS receive CMM. After 60 Markov cycles, a 100,000-sample simulation reveals the impact of maximum willingness-to-pay (WTP) from $10,000 to $100,000 per quality-adjusted life year on net monetary benefit (NMB). Sensitivity analyses considered the impact of the Wireless SCS screening success rate, Wireless SCS device cost, and IPG SCS device longevity.

Compared with IPG SCS, Wireless SCS offers higher clinical effectiveness at a lower cost and a higher NMB for our WTP thresholds and is, thus, dominant. Wireless SCS is also cost-effective compared with CMM. Results remain robust with 1) Wireless SCS screening success rates as low as 85% (dominant), 2) the cost of the Wireless SCS devices as high as $55,000 (cost-effective), and 3) IPG SCS devices lasting 12 years (dominant).

In this model, compared with IPG SCS or with CMM, Wireless SCS is a superior strategy [4].

References

[1]
Ahmadi R, Hajiabadi MM, Unterberg A, Geist C, Campos B. Wireless Spinal Cord Stimulation Technology for the Treatment of Neuropathic Pain: A Single-Center Experience. Neuromodulation.

2020 Mar 31. doi: 10.1111/ner.13149. [Epub ahead of print] PubMed PMID: 32232943.

2) Wang Y, Xie K, Yue H, Chen X, Luo X, Liao Q, Liu M, Wang F, Shi P. Flexible and fully implantable upconversion device for wireless optogenetic stimulation of the spinal cord in behaving animals. Nanoscale. 2020 Jan 28;12(4):2406-2414. doi: 10.1039/c9nr07583f. Epub 2019 Nov 29. PubMed PMID: 31782467.

3) Bolash R, Creamer M, Rauck R, Vahedifar P, Calodney A, Fox I, Özaktay C, Panchal S, Vanquathem N, Yasin M. Wireless High-Frequency Spinal Cord Stimulation (10 kHz) Compared with Multiwaveform Low-Frequency Spinal Cord Stimulation in the Management of Chronic Pain in Failed Back Surgery Syndrome Subjects: Preliminary Results of a Multicenter, Prospective Randomized Controlled Study. Pain Med. 2019 Oct 1;20(10):1971-1979. doi: 10.1093/pm/pnz019. PubMed PMID: 30908577.

4) North RB, Parihar HS, Spencer SD, Spalding AF, Shipley J. Cost-Effectiveness Model Shows Superiority of Wireless Spinal Cord Stimulation Implantation Without a Separate Trial. Neuromodulation. 2020 Feb 17. doi: 10.1111/ner.13102. [Epub ahead of print] PubMed PMID: 32065696.