Case Series

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Amelioration of lower limb pain and foot drop with 10 kHz spinal cord stimulation: A case series

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Abstract

There are limited treatment options for patients with foot drop and associated lower back and/or leg pain. We present a case series of three patients who received permanent implantation of 10 kHz spinal cord stimulation (10 kHz SCS) devices. Following treatment, all patients reported sustained improvements in lower back and leg pain, foot mechanics and function which resulted in increased mobility and cessation of opioid use for pain management. Patients were followed up for approximately four years. Treatment with 10 kHz SCS may be a promising alternative to other interventional procedures commonly used for these patients.

Keywords

10 kHz SCS, high frequency, foot drop, lower limb pain, case series

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Introduction

Foot drop is a neurological condition defined by a weak anterior tibialis muscle impairing the ability to lift the toes completely off the ground during the swing phase of walking.[1,2] The disturbance in stance and gait makes standing and walking difficult and it can significantly impact the patient's quality of life.[1,3–5] Lumbar degenerative disease (LDD) which includes lumbar disc herniation and lumbar spinal stenosis, is known to be one of the causes of foot drop and in the majority of cases, patients have chronic back and leg pain.[6,7] While foot drop can be treated by surgery

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and other conservative treatments including orthotics, physical therapy and/or nerve stimulation, patients tend to depend on medications for pain management.[1,4,8–10]

Spinal cord stimulation (SCS) delivered at high frequency (10 kHz) has been shown to provide paraesthesia-free pain relief in patients with LDD and has been used successfully in the treatment of chronic, intractable pain in the trunk and lower limbs.[11–13] Indeed, several prospective and retrospective studies have reported pain relief and functional improvements in patients with back and leg pain following 10 kHz SCS.[14–18] However, to our knowledge, the effects of 10 kHz SCS in patients with back and/or leg pain and foot drop have not previously been reported. In this case series, we report three cases of adult patients with chronic pain and foot drop treated with 10 kHz SCS.

Methods

We identified patients who had low back pain and/or leg pain and foot drop and had been monitored, tested and/or permanently implanted with a Senza™ system delivering 10 kHz SCS (Nevro Corp., Redwood City, CA, USA) at our centre between January 2012 and December 2020. Signed consent was obtained from the patients for treatment with 10 kHz SCS and for publishing their anonymised data. Data were extracted from patient notes. The study was retrospective and so was exempt from ethical committee approval.

Test and permanent implantation procedures for SCS have been described previously.[11,13,19] According to recommendations,[11,20] the patients had standard lead placements at T8 and T9. Pain intensity was assessed using a verbal numeric rating scale (VNRS; 0 = no pain to 10 = worst possible pain) and pain relief was measured using a 0–100% scale where 0% = no pain relief and 100% = complete pain relief. Changes from baseline to last follow-up in foot sensory perception, foot motor symptoms and overall mobility were scored as (+) improvement, (0) no change or (−) worsening of parameter. Change from baseline to last follow-up in opioid use was recorded.

Case reports

Patient 1

A 72-year-old man presented to the clinic in December 2016 complaining that his left toes were curling under and he had chronic left foot drop. He had undergone left L5 hemilaminectomy and discectomy surgeries approximately 22 years previously (1994). He was unable to stand or walk more than five minutes due to intense back pain (6/10 on VNRS) and had intermittent neurogenic claudication. Imaging confirmed narrowing at L5/S1. His lumbar extension was slightly limited by pain and his left lower extremity showed limitations in hip abduction (4/5), left ankle dorsiflexion and toe intrinsics (3/5) and left ankle plantar flexors (4/5). The active range of motion (AROM) of his left foot and ankle dorsiflexion was 5 degrees, and his left toes were curled under with flexion contractures and the left second toe had a hammertoe deformity. His sensory examination showed decreased light touch sensation at the last L5 dermatome. Failure of orthoses and physical therapy and a disinterest in neuropathic pain medication, had resulted in him having a lumbosacral (left S1) transforaminal epidural steroid injection (TFESI) which also failed to provide lasting pain relief.

In February 2019, (27 months after his initial visit) and following a successful trial procedure, he had a permanent implantable pulse generator (IPG) placed subcutaneously and leads placed midline at T8 and T9 for 10 kHz SCS. Thirteen days post-implant he reported 100% pain relief and 0/10 for VNRS. In addition, he was able to walk better and his toes were straighter than before the procedure; he was able to flare his toes up and fit a sock on his left foot for the first time in several years. Physical examination showed AROM of his bilateral ankles was now within normal limits and his left ankle dorsiflexion was 15 degrees. The flexion contractures of his left toes had also improved. Motor examination showed a minor improvement in left ankle plantar flexion (4/5), normalization of left ankle dorsiflexion (5/5) and improvement in left toe intrinsics (4/5). His sensory examination showed symmetrically intact light touch sensation in both legs.

In August 2020 (18 months post-implant), the patient reported that he had remained pain-free in his back and legs. He was able to stand for over 45 minutes and walk for two miles comfortably (Table 1). He used his 10 kHz SCS daily and was pleased with his mobility and reduction in pain. His motor and sensory responses were stable and showed no signs of regression. Furthermore, the patient did not have any safety concerns related to his implant.

Patient 2

A 48-year-old man presented to the clinic in 2012 with neck pain, burning dysesthesias in his hands and grip weakness. He also had back pain and bilateral leg weakness. The patient had experienced right foot drop since decompression/fusion surgery of L3/4/5 one year previously. He had tried, without success, ankle foot orthoses, multiple opioid analgesics, topical and muscle relaxant therapies as well as gabapentin. He was now unable to work. At the clinic visit, the patient was prescribed morphine sulphate (15 mg tablets bd) and hydrocodone/paracetamol (Vicodin, 5/300 mg qid) to manage his pain.

A magnetic resonance imaging (MRI) scan taken three years later (2015), showed moderate canal stenosis at L2-L3 that had worsened slightly compared with imaging taken in 2012. In March 2016, the patient reported that his pain was interfering with his ability to care for himself, disturbed his sleep and prevented him from walking more than 100 meters. Seven months later in October 2016 and following a successful trial procedure, he underwent a

Table 1. Summary of patient outcomes.

Patient no.	Follow-up	Pain and pain relief*	Foot sensory perception#	Foot motor symptoms#	Overall mobility#	Opioid medication
1	18 months	0/10/ and 100%	+	Ankle range of motion: + Ankle dorsiflexion, toe intrinsics and plantar flexors: +Toe curling: +	Walking + Standing +	NR
2	4 years	NR	NR	Motor strength: +	Gait + Walking range + Standing +	Stopped
3	Approx. 4 years	2/10 and NR	NR	Foot drop: +	Unaided walking +	Stopped

NR: not reported

*Pain assessed on scale ranging from 0 = no pain to 10 = worst possible pain; pain relief assessed on a 0–100% scale where 0% = no pain relief and 100% = complete pain relief.

#Changes from baseline to follow-up were scored as (+) improvement, (0) no change or (−) worsening of parameter.

permanent IPG implantation with leads positioned midline at T8-T9 level for 10 kHz SCS (Figure 1).

At a follow up visit, eight months post implant (May 2017) the patient reported substantial improvement in his leg pain and muscle strength that had enabled him to play catch with his children, walk without leg braces and perform work-out exercises. He was adjusting the stimulator to deal with burning sensations he experienced in his feet and toe pain. He showed improvement in his bilateral lower extremity weakness (4/5 strength in the anterior tibialis and 4/5 in the gastrocnemius) and his gait had markedly improved. However, his shin and calf remained numb and he had no improvement in his diminished sensation from L5 and S1.

At follow-up appointments in November 2018 and 2019 (i.e., two- and three-years post-implant) the patient showed substantial improvement in back pain and leg weakness. The patient continued to improve and at four years post-implant, his motor strength had improved at least one degree in the anterior tibialis and gastrocnemius; he no longer used ankle foot orthoses and had stopped all opioid analgesics (Table 1). No safety issues were reported during the entire four-year post-implant follow-up.

Figure 1. Representative image of lead placement. X-ray image showing leads positioned midline at T8-T9 for 10 kHz spinal cord stimulation (SCS).

Patient 3

A 66-year-old woman with a history of diabetic neuropathy and eight fusion surgeries in her lower back and cervical spine for congenital spinal stenosis presented to the clinic in April 2015. She had abnormal electrodiagnostic evidence of sensorimotor axonal polyneuropathy dating back to her last surgery in February 2012 that indicated active denervation affecting the L5 root on the right side. Since her surgery she had experienced right foot drop and had used a cane and bilateral ankle braces for support. She managed the condition to a moderate degree with physical therapy, epidural steroid injections and opioids. On palpation of the lumbosacral spine, abnormalities were detected and physical examination showed a reduced range of motion. She had compromised sensation in her right foot and difficulties in rising from a chair. An MRI scan confirmed post-surgical changes with scar tissue formation in the lumbar region. Her average pain score was 9/10 for VNRS in her hands, back, legs and feet.

Eight months later, in January 2016, and following a successful trial procedure, she underwent permanent IPG implantation with leads positioned midline at T8-T9 level for 10 kHz SCS At six-months post-implant, the patient's pain score was 0/10 for VNRS in her legs and feet and her foot drop symptoms had resolved; she was able to walk unaided without orthotics or a walker.

After approximately four-years, the patient reported an average pain score of 2/10 for VNRS, she had stopped opioid treatment, was able to drive locally and had not used orthotics or a walker during the entire follow up period (Table 1). No safety issues were reported during the post-implant follow-up period.

Discussion

A growing body of evidence supports the application 10 kHz SCS for upper limb and neck, trunk, lower back and leg pain.[11,17,18,21,22] To our knowledge, there are no previous published reports on the effects of 10 kHz SCS in patients with back and/or leg pain associated with foot drop. Therefore, the three cases presented here add to the growing evidence of pain relief obtained with 10 kHz SCS. Not only did the patients experience pain relief and were able to stop opioids, but they also saw improvements in function. The pain relief, functional improvement and opioid reduction observed in these patients with foot drop was comparable with results from prospective and retrospective studies in patients with chronic back and/or leg pain.[11–20] Given foot drop is a chronic condition, a reduction in opioid use for pain management as well a decrease in the reliance on bulky walking aids and supportive devices are significant improvements for these patients. Although long-term opioid use for chronic pain conditions is not supported by evidence-based medicine, their use is well documented.[23] Our case series supports previous findings that 10 kHz SCS provides adequate pain relief in treatment-refractory patients that enables them to either reduce or cease opioid use altogether.[14]

Consistent with our findings, improvements in sensory and motor function have also been shown in a large randomized, controlled trial in patients with painful diabetic neuropathy.[24] In that study, 10 kHz SCS plus conventional medical management yielded an improvement in investigator-assessed sensation and a reduction in foot numbness. In addition, an analysis of patients with painful diabetic neuropathy enrolled in a prospective, multicentre study of peripheral polyneuropathy found that five out of seven patients showed improvements in sensory perception and reflexes.[25] Similarly, a case series involving patients with painful diabetic polyneuropathy reported either preservation or improvement in sensory perception in their lower limbs following treatment with 10 kHz SCS.[26] These results together with our findings suggest that 10 kHz SCS may have beneficial effects in addition to pain relief.

10 kHz SCS therapy is understood to possess a unique mechanism of action.[27] Unlike low-intensity SCS, high frequency stimulation has been shown to activate inhibitory interneurons in the spinal dorsal horn without activating dorsal column fibres and deliver paraesthesia-free pain relief.[28] In addition, in a rat model of neuropathic pain, 10 kHz SCS led to an improvement in mechanical hyperalgesia with a concurrent reduction in the activation of inflammatory kinases in the dorsal root ganglia and spinal dorsal horn relative to sham stimulation.[29] Compared with conventional SCS, 10 kHz SCS has also demonstrated changes in electroencephalogram peak frequencies, that correlated with improved measures of disability.[30] Other researchers using functional MRI of the brain in patients with chronic neuropathic pain have demonstrated structural volumetric changes associated with 10 kHz SCS linked with a reduction in pain intensity.[31] This case series presented here adds further data showing improvements in sensory and motor function produced by 10 kHz SCS therapy and warrants further investigation into its exact mechanism of action.

Given the small sample size and retrospective design of this case series, the results on functional improvements in foot drop should be interpreted with caution. Large, prospectively designed studies are required to determine the precise benefits of 10 kHz SCS for the management of foot drop. However, these three case reports suggest that 10 kHz SCS is effective in reducing pain and pain medication and improving foot function in patients with back and/or leg pain associated with foot drop. Our results suggest that 10 kHz SCS is a promising alternative to other interventional procedures and may improve motor and sensory function in foot drop associated with lower back and leg pain.

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Declaration of conflicting interests

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