Pain Medicine Case Reports

ISSN 2768-5152

Volume 10, Number 4, pp. 353-359

Treatment of Chronic Postamputation Pain With High-Frequency Bioelectric Nerve Block Over 12 Years: A Case Report

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Background: Targeted application of high-frequency alternating current to induce reversible electrical nerve block (high-frequency nerve block [HFNB]) was recently approved for the treatment of chronic, intractable postamputation pain. Our case describes the use of HFNB for over 12 years.

Case Report: In 2012, a 55-year-old woman with above-the-knee lower-limb amputation reporting episodic residual limb pain for 19 years enrolled in a pilot study of HFNB for chronic postamputation pain. During the study, the external waveform generator was replaced with a permanent implantable pulse generator, and the patient continues to use the device today. Data collected regularly at follow-up visits demonstrate sustained improvements in pain and functional outcomes and provide a long-term profile of HFNB treatment.

Conclusion: Our case describes long-term benefit of HFNB for chronic postamputation pain and provides detail regarding this novel therapy that cannot be derived from large studies evaluating effectiveness on a population level.

Key words: High-frequency nerve block, chronic postamputation pain, residual limb pain, case report

BACKGROUND

Postamputation pain has profound impacts on mental health, function, and overall quality of life (QoL) of individuals who have undergone limb amputation (1). An estimated 60% to 80% of individuals with amputated limbs experience chronic postamputation pain (i.e., residual limb pain and/or phantom limb pain) (2-5). Conventional treatment for chronic postamputation pain ranges from nonpharmacological/noninvasive to surgical, with individual treatment pathways often spanning numerous therapeutic strategies and requiring a multidisciplinary specialist network to navigate the various modalities (6). However, despite its prevalence, postamputation pain remains difficult to treat (7).

Recently, the application of high-frequency alternating current (HFAC) via an implanted medical device (Altius Direct Electrical Nerve Stimulation System, Neuros Medical, Inc., Aliso Viejo, CA) was approved in the United States for the treatment of intractable chronic postamputation pain (8). The application of HFAC directly to damaged peripheral nerves induces reversible electrical nerve block (high-frequency nerve block [HFNB]) to inhibit ascending pain signaling originating from the site of amputation (9). The approval of HFNB was based on data from a prospective, multicenter, randomized, active-sham-controlled clinical trial (10,11), including 180 patients with lower-limb amputation ≥ 12 months prior and chronic (> 6 months) residual limb pain or phantom limb pain. The

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Disclaimer: Neuros Medical, Inc. sponsored the original pilot study described in this case and supports ongoing follow-up of the described case.
Conflict of interest: AS reports ownership of Soin Neuroscience and Soin BioScience; is an advisor for and investor in Neuros Medical, Inc. and holds stock options in the company; and provides research support for Avanos Medical, Inc. EB has nothing to disclose. NSS and NJH are employees of Neuros Medical, Inc. and hold stock options in the company. Writing support was provided under the direction of the authors by Elizabeth Justice, PhD, CMPP of Blue Heron Medical Communications, LLC, and funded by Neuros Medical, Inc. This case was previously presented at the 2025 annual meeting of the American Society of Pain and Neuroscience.
Patient consent for publication: Consent obtained directly from patient(s).
This case report adheres to CARE Guidelines and the CARE Checklist has been provided to the journal editor.
Accepted: 2026-02-04, Published: 2026-06-30

current case describes a patient who participated in an early pilot study (12) of HFNB over 13 years ago and is currently still using the device to help manage episodic residual limb pain, providing a long-term profile of this novel treatment modality.

CASE PRESENTATION

Our case describes a 55-year-old woman who was recruited for participation in a pilot study (12) of HFNB treatment for chronic postamputation pain in June 2012. She consented to ongoing follow-up after the conclusion of the study and provided written informed consent for the current case description. The patient had a medical history of right leg infection requiring above-the-knee amputation 19 years prior (February 1993) with 2 revisions, the last occurring in June 2004. A neuroma excision was performed in 2008. She reported chronic episodic residual limb pain occurring approximately 2 times per week (spontaneous and triggered by physical activity) beginning 9 months after amputation. She was nonambulatory and preferred use of crutches over prosthesis for mobility. Other conditions at enrollment included migraines, fibromyalgia, and osteoporosis. Her pain was managed primarily by medications, including 50 mg milnacipran HCl twice daily, 2 mg lorazepam once daily, and naproxen sodium as needed. She also reported use of oxycodone-acetaminophen and hydrocodone-acetaminophen as needed for pain. At study eligibility assessment, her past 24-hour worst, least, and average Brief Pain Inventory (BPI) pain severity scores were 10, 2, and 4, respectively (scale, 0-10:0, no pain; 10, pain as bad as you can imagine) (13); she reported her current pain as 3. On the BPI interference with daily activities assessment, she reported a score of 10 (completely interferes) for all 7 items (general activity, mood, walking ability, normal work, interactions with others, sleep, and enjoyment of life). The patient described herself as active and social prior to her amputation. After her amputation, she indicated that not only did pain prevent her from maintaining her daily activities, but the constant worry of a potential pain flare-up prevented her from performing basic chores and activities. At enrollment, her therapeutic goals were to find a solution for her pain that did not involve titration of opioids, would allow her to maintain her daily activities, and would provide an option to reduce pain in cases of severe flare-ups.

A timeline of events is presented in Fig. 1. Device implantation, therapy optimization, and assessments within the first 15 months after implantation were performed according to the pilot study protocol (12). A cuff electrode was implanted on the distal sciatic nerve of the right leg in October 2012, and an external waveform generator was used to self-administer therapy on an as-needed basis. Treatment sessions consisted of a voltage ramp-up period of empirically determined duration (up to 15 minutes total) followed by sustained application of 10 kHz alternating current, resulting in total treatment session duration of 30 min per session; dosage (voltage) was adjusted at programming visits to address pain. During a follow-up interview one year after electrode implantation, the patient described her decision-making process regarding whether to initiate therapy. She noted that if her pain reached a level of 5-6 (out of 10), she would activate a treatment session, and her pain level was typically reduced to 0 when applying therapy at home. In September 2013, she experienced a mechanical fall unrelated to treatment resulting in a right intertrochanteric femur fracture. As a result, the patient underwent surgical reduction and stabilization.

A permanent implantable pulse generator (IPG) was implanted in the right upper anterior thigh in early 2014 as previously described (12). At follow-up after IPG implantation, a second dose level was programmed for at-home use. Over 12 years of follow-up, dosage was reprogrammed 5 times at patient request to address pain fluctuations. Peak voltage was recorded at each follow-up visit regardless of whether programming adjustments were made at that visit (Fig. 2). In May 2018, the patient requested relocation of the IPG because of discomfort resulting from soft tissue changes in the anterior thigh. At this time, a resection procedure was already planned for a recurrent neuroma, and the IPG was concurrently relocated and the cuff electrode replaced. At the first follow-up after the device was reactivated postrevision, she requested reprogramming to address increased pain. It was subsequently determined inclinic that the higher dose was suppressing her pain while the lower dose was insufficient to address the pain she was experiencing, resulting in the perception that pain was intensifying. The patient agreed to inactivate the device for a short period to allow her to monitor her pain intensity and duration without the impact of device stimulation. After the device was reactivated in February 2019, she requested a follow-up visit within one week to optimize the dosage. No additional adjustments to therapy parameters were necessary until dosage was decreased in January 2024.

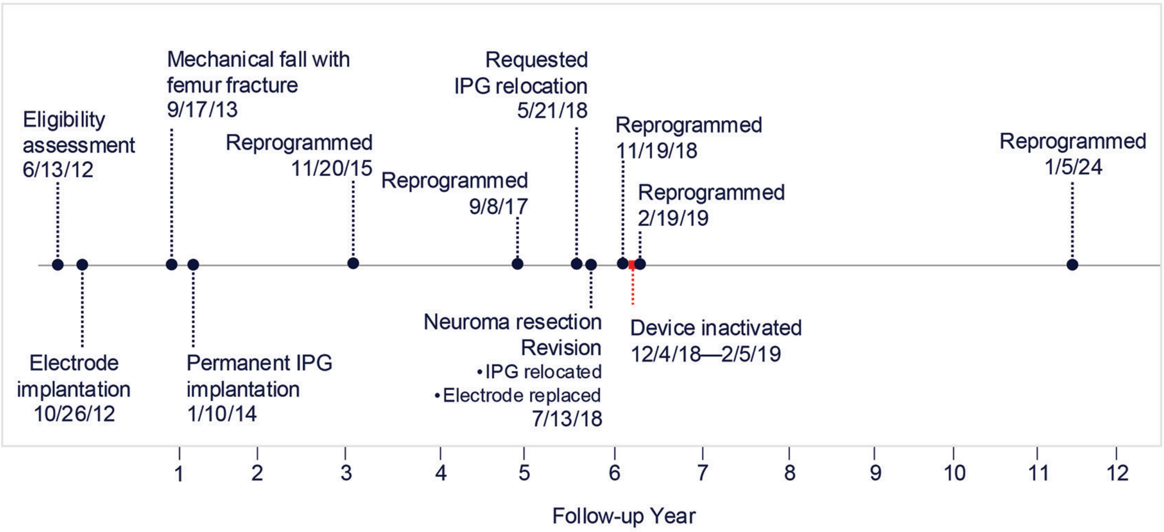

Fig. 1. Timeline of events.
IPG, implantable pulse generator.

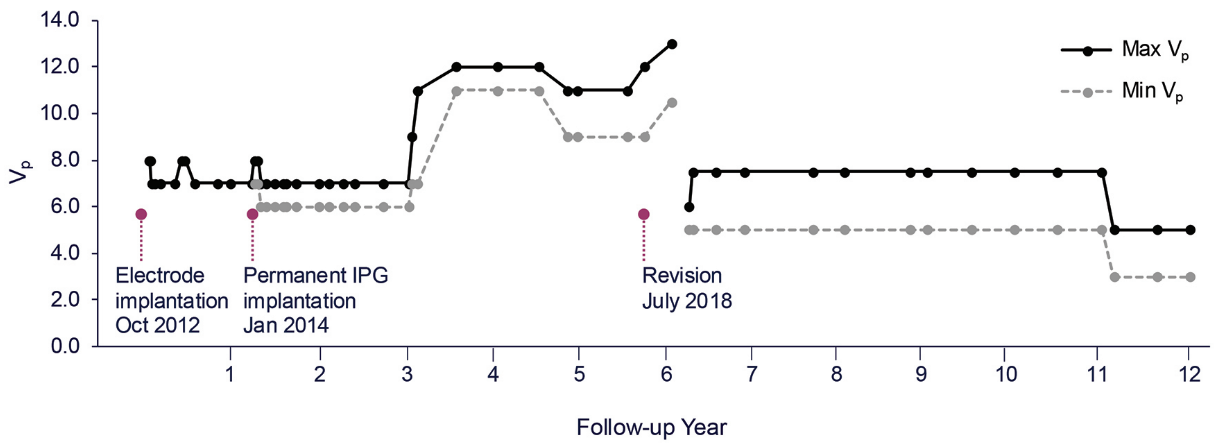

Fig. 2. Device peak voltage (Vp) by follow-up visit. The dosage (voltage) was recorded at each follow-up visit regardless of whether adjustments were made. The second dose level was not introduced until after permanent IPG implantation.
IPG, implantable pulse generator.

Pain severity and pain-related QoL were quantitatively assessed at each follow-up visit using the BPI. Pain severity fluctuated over time (Fig. 3). Improvements in pain-related QoL were maintained over time, and notable fluctuations appeared to correspond to the timing of surgical interventions (Fig. 4). Improvements in the BPI interference walking item were not observed because the patient continued to prefer use of crutches for mobility. She also continued to use aspirin, lorazepam, and hydrocodone-acetaminophen (as needed) throughout follow-up.

After device implantation, the patient reported that she noted significant improvements physically as well as emotionally. She mentioned she was able to maintain and increase her daily activities without having to increase rescue medications. Additionally, she noted increased mobility and the ability to pursue social activities she was previously unable to participate in, such as dining out, shopping, and traveling. The most impactful change the patient mentioned was the lack of anxiety over having a significant pain flare. The fear of a debili-

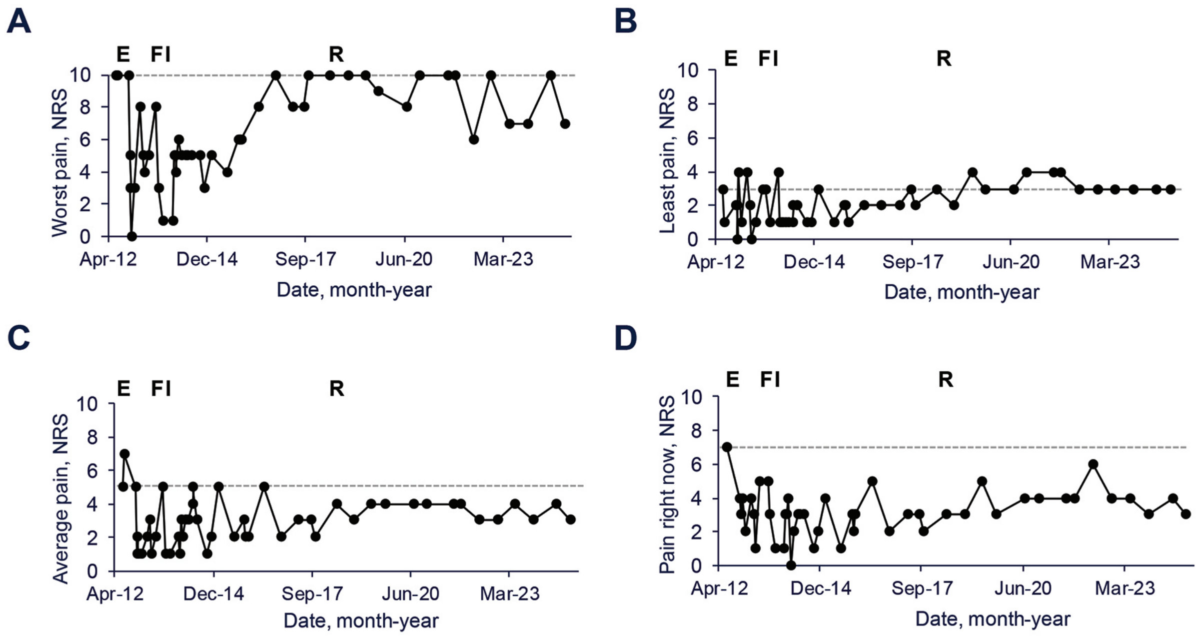

Fig. 3. BPI pain severity scores over time for previous 24-hour worst pain (A), previous 24-hour least pain (B), previous 24-hour average pain (C), and current pain (D).
Dotted lines represent baseline values. Capital letters above plots indicate approximate timing of notable events: E, initial electrode implantation; F, mechanical fall with femur fracture; I, permanent IPG implantation; R, revision and neuroma resection. BPI, Brief Pain Inventory; IPG, implantable pulse generator; NRS-11, Numeric Rating Scale.

tating pain episode has been generally eliminated, as she described that she knows she has an option to help her if she is struggling with pain. This added "peace of mind" has been one of the most important improvements she described to the treating physician.

DISCUSSION

The use of HFNB for the management of chronic postamputation pain has been commercially available for about a year; however, our case provides an example of the use of HFNB in a single individual for more than a decade. The pilot study infrastructure provided the unique advantage of scheduled quantitative assessments and facilitated detailed recording of the patient experience with this novel therapy. Notably, therapy parameters were adjusted to address fluctuations in the patient's pain, but adjustments were rarely needed after optimization, with a 5-year period of no change to dosage observed. Our case provides valuable insight into the long-term use of HFNB that is not easily extracted from a large population study.

Effective treatment of chronic postamputation pain is challenging, and individuals often require multiple approaches for pain management. The patient in the current case presented with a medical history of pain medication use and neuroma resection, but she continued to experience pain that she reported completely interfered with daily activities. The pathophysiology of chronic residual limb pain and phantom limb pain is not completely understood, but involves both peripheral and central mechanisms (9). After nerve transection, voltage-gated sodium channels (VGSCs) are overexpressed by regenerating axons and drive ectopic firing of the sensory afferents of the dorsal root ganglion in the absence of stimulation (14-16). This continuous spontaneous activity drives central sensitization to pain, inducing long-term potentiation at the level of the spinal column and enhancing pain signaling to the cortex (17). Increased ascending pain signaling is accompanied by decreased activity in descending inhibitory pain pathways, further exacerbating pain sensation (17,18). Medications, including opioids, are generally effective for addressing the central mechanisms driving pain, but their long-term use is not recommended because

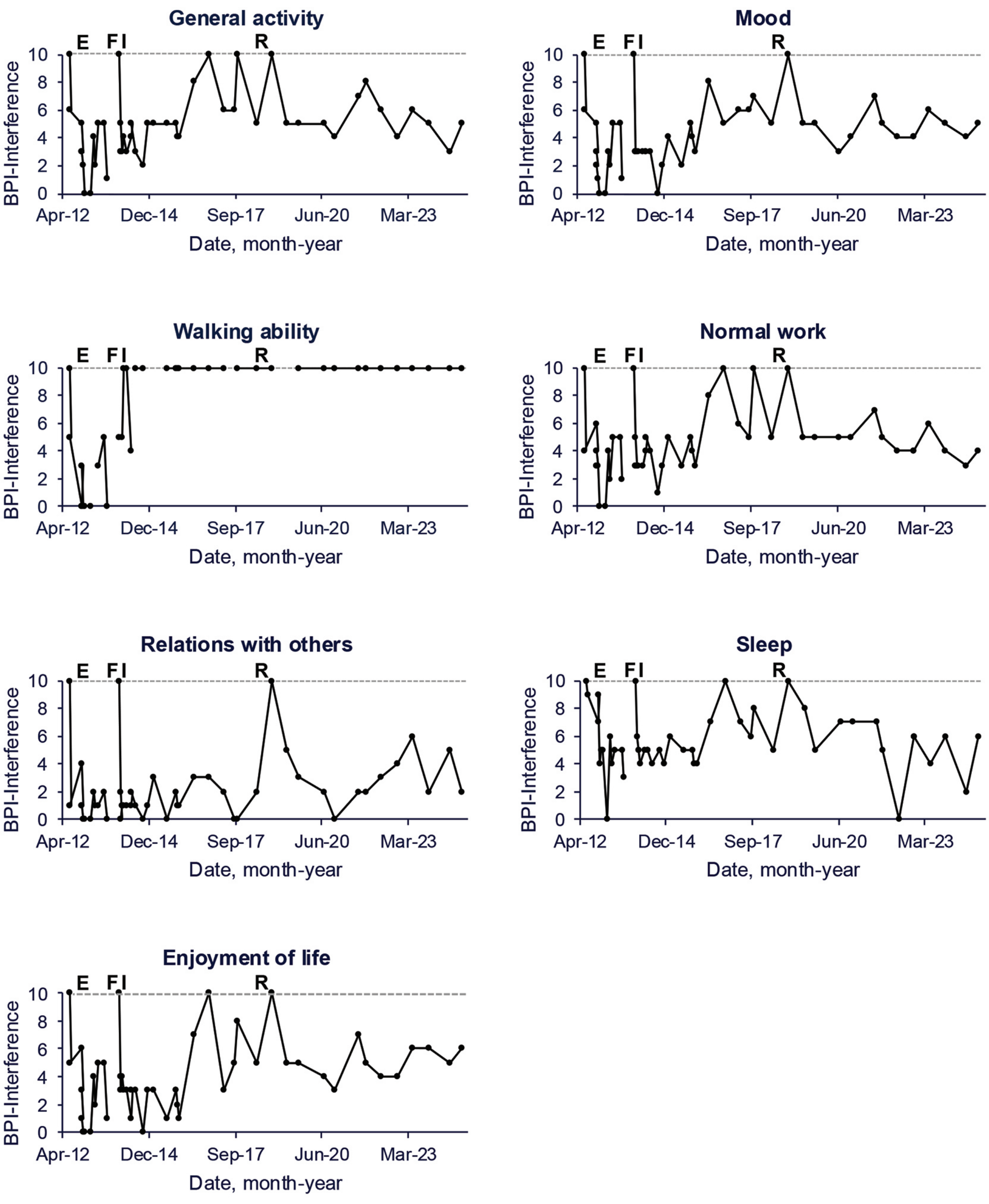

Fig. 4. BPI interference with daily activities scores over time.
Capital letters above plots indicate approximate timing of notable events: E, initial electrode implantation; F, mechanical fall with femur fracture; I, permanent IPG implantation; R, revision and neuroma resection. BPI, Brief Pain Inventory; IPG, implantable pulse generator.

of adverse side effects (19,20). When present, painful neuromas can be surgically removed to address the source of peripheral pain inputs, but recurrence rate is high after neurectomy (21,22), as evidenced by the patient in this case.

Neuromodulation therapies offer approaches to address the peripheral source of chronic postamputation pain. Spinal cord stimulation (SCS) and peripheral nerve stimulation (PNS) are based on the gate control theory (23). Both approaches seek to indirectly inhibit ascending pain signaling from peripheral nociceptive inputs by activating nonnociceptive afferents and have shown some effectiveness for postamputation pain (24-27). Large supportive clinical trials for SCS and PNS in postamputation pain are lacking, although promising results have been reported for PNS in a small placebo-controlled trial (n=6) (28). In contrast, HFNB administers HFAC directly to the damaged nerve to inactivate local VGSCs, thereby producing reversible bioelectric conduction blockade and preventing the propagation of pain signals to the spinal cord (29). In the randomized, active-sham-controlled QUEST study (10,11) of 180 patients with lower limb amputations and chronic postamputation pain, on-demand HFNB treatment significantly reduced acute pain relative to controls and improved BPI-interference scores, with effectiveness maintained out to one year of follow-up. Mean past 24-hour worst, least, and average pain scores also decreased over time, consistent with previous observations indicating central sensitization is maintained by ongoing peripheral inputs and suggesting repeated blockade of ascending pain signaling can impact chronic postamputation pain (11,30).

CONCLUSIONS

In our case, the treatment of chronic residual limb pain using HFNB over 12 years of follow-up was associated with lasting improvements in pain-related QoL as assessed using the BPI. The modest changes observed in BPI pain severity over the follow-up period contrast with the striking improvements observed in BPI interference with daily activities scores over time. Despite the relatively moderate improvements in pain scores, the patient has chosen to retain the device, and she consistently expresses satisfaction with therapy. This discrepancy may reflect the subjectivity of pain reporting and highlights the importance of functional outcomes and qualitative assessments when evaluating the effectiveness of a chosen therapy for pain management (31).

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