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Permanent Peripheral Nerve Stimulator Lead Adhesions Leading to Loss of Therapy and Difficult Extraction: A Case Report

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Background: Over the past few decades, peripheral nerve stimulators (PNS) have become a useful option for treating refractory complex regional pain syndrome or neuralgia. Modern PNS are designed to prevent lead migration with tines or burs promoting tissue adhesion through fibrosis. However, few studies have examined the effect that this might have on nerve stimulation treatment. To our knowledge, this is the first documented case report describing how excessive scarring and fibrosis of leads may interfere with PNS therapy.

Case Report: This paper describes a 67-year-old male patient who presented with peripheral neuropathy and peripheral vascular disease which was complicated by multiple surgical interventions and ischemia to his right lower extremity. He underwent permanent PNS treatment, but experienced treatment failure in both PNS leads - early on from lead migration, and later from significant adhesions leading to a difficult extraction.

Conclusion: While tines and burs found on permanent PNS may prevent lead migration, the excessive scarring and fibrosis that they cause may interfere with PNS therapy by increasing impedance. More research is needed to better guide physicians in counseling and managing patients with refractory pain.

Key words: Case report, difficult extraction, lead migration, peripheral nerve stimulator

BACKGROUND

Peripheral nerve stimulators (PNS) have been used for over 50 years in patients with refractory complex regional pain syndrome (CRPS) or neuralgia (1). Although there are limited randomized controlled trials that encourage the routine use of PNS, they remain a safe intervention to turn to once conventional management has failed (2). Common complications for using PNS include lead migration, infection, or discomfort of implant (3). To combat lead migration, many modern permanent PNS have mechanisms in place to adhere the lead to the surrounding tissue. There is limited literature on complications or potential issues with extraction of these permanent implants, and the loss of efficacy due to decreased impedance from adhesions or scar tissue. We describe a case of a patient who underwent successful trial and implantation of a permanent PNS to the superficial peroneal nerve (SPN) and posterior tibial nerve (PTN). The patient suffered treatment failure due to suspected lead migration in the former lead to the SPN and significant adhesions to the latter lead to the PTN, resulting in a difficult extraction.

This manuscript adheres to the applicable EQUATOR guidelines.

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CASE REPORT

A 67-year-old man presented with peripheral neuropathy and chronic pain of his right lower extremity refractory to medical treatment. He had a past medical history of peripheral artery disease in the right leg, and underwent multiple procedures, including a right lower extremity popliteal to anterior tibial artery bypass, which was complicated by critical limb ischemia, necessitating 2-compartment fasciotomy and thrombectomy of popliteal, tibial, and superficial femoral arteries. He required a revision of his right lower extremity bypass to restore blood flow. Due to these complications, he ultimately required amputation of the fifth digit on his right foot, along with several split-thickness skin grafts. At the time of his initial clinic visit, his chief complaint was burning pain in the dorsal surface of his right foot and heel, which was constant in nature but most severe 3 to 4 nights per week, lasting for hours to days at a time in this severe state. The episodes of worsening pain were not provoked by movement; and during those episodes, the afflicted areas were allodynic. He was prescribed acetaminophen, pregabalin, and tramadol for his pain initially, but did not achieve the desired relief. He also attended several physical therapy sessions at the same time, without noticeable improvement. He was interested in neuromodulation as a treatment option.

Based on the distribution of his pain, it was suspected that the posterior tibial and superficial peroneal nerves were involved. Treatment options were discussed with the patient; and the patient voiced his preference for peripheral nerve stimulation, especially if the peripheral neuropathy could be isolated. He went on to have ultrasound-guided, single-shot blocks of the PTN and SPN with 9 mL of 0.25% and ropivacaine with 4 mg of dexamethasone. This resulted in almost 100% resolution of his pain for a total of 3 days, confirming the diagnosis and distribution of his peripheral neuropathy. During that time, the patient's medication use decreased, and his allodynia also resolved. Given that specific targets were found for his pain and relief of pain was so significant, it was deemed that the patient would be an excellent candidate for peripheral nerve stimulation. The patient also underwent psychiatric evaluation, as per our institution's protocol, and was cleared for implantation of the trial leads.

The patient underwent PNS trial using ultrasound-guided placement of leads targeting the SPN and PTN. During the first 2 days of the trial, stimulation was targeted at the SPN and provided 85% to 90% pain relief. For 2 days following the stimulation, the PTN lead was targeted, resulting in up to 50% pain relief. For the last 2 days of the trial, both leads were activated, and the patient was able to maintain pain relief at over 70% and did not report any allodynia. During this time, the patient reported that he only had to use his tramadol and acetaminophen sparingly. Of note, the stimulator leads for the trial were designed without tines to allow for ease of removal. The leads were removed without complication after 7 days, and the areas were allowed to heal prior to proceeding with implantation of permanent leads.

Six weeks later, implantation of permanent peripheral leads was done using ultrasound guidance targeting the PTN and SPN. To keep evidence of lead location, fluoroscopic images were obtained after permanent leads were sutured in (Fig. 1). Of note, the permanent leads for this device are designed with tines to reduce risk of migration of leads. The patient was discharged the same day without complications.

A few days later, at his next checkup the patient reported that he initially had 50% pain relief in both the dorsum of his foot and heel. His tramadol and acetaminophen use had decreased by half, and he did not report any allodynia. However, around the 2-week mark, he noticed that the lead stimulating the SPN had shifted, and he was no longer receiving any pain relief to the dorsum of his foot, and the allodynic episodes had returned. However, he continued to receive 50% pain relief to the heel of his foot, without allodynia. As one lead still worked, he opted not to undergo revision of his leads.

One year after his PNS lead implantation, the patient presented for follow-up and reported that the 50% relief in the distribution of the PTN had faded over time, and he no longer had any pain relief from the device, despite adjusting the PNS to the highest stimulator setting. The patient did not have any further reported episodes of allodynia to the distribution of the PTN, despite his chronic pain. One of the most commonly cited causes for PNS therapy failure is lead migration. However, since our patient's loss of relief happened gradually over time, rather than abruptly, we concluded that the cause was more likely to be increased impedance. This fits the fact that our patient did not receive any pain relief despite

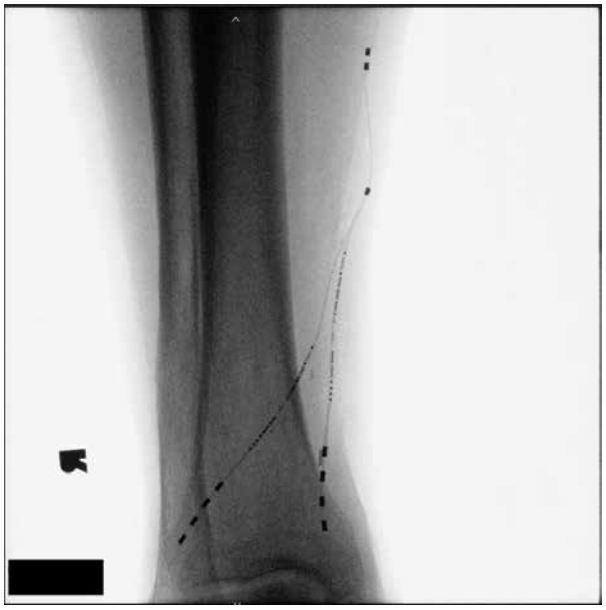

Fig. 1. Fluoroscopy during implantation of peripheral nerve stimulator.

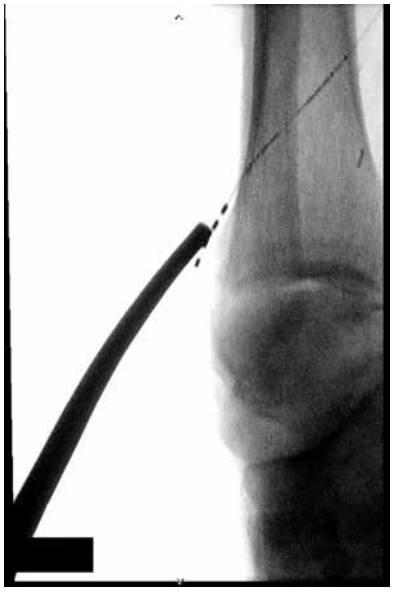

Fig. 2. Fluoroscopy during explant of peripheral nerve stimulator prior to removal.

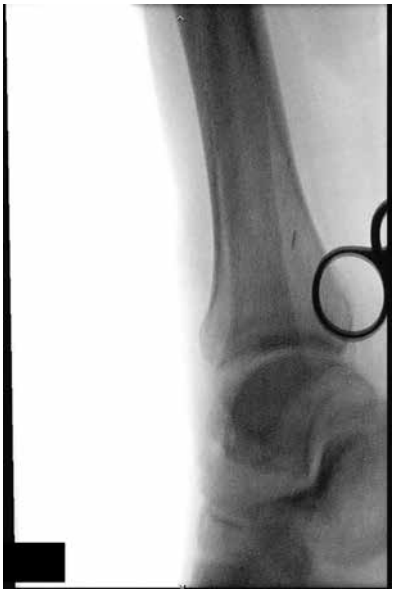

Fig. 3. Fluoroscopy during explant of peripheral nerve stimulator after removal

using the highest stimulator settings on his PNS. The decision was made to perform lead extraction. In the operating room setting, using fluoroscopic guidance, the leads and suture sites were identified. The lead targeting the SPN was removed without any incident. The PTN lead, however, was noted to be scarred down to the surrounding tissue, leading to a much more difficult extraction than anticipated. Another incision had to be made to completely free this lead from all the adhesions surrounding it. After careful dissection, the lead was taken out without any injury to surrounding blood vessels or nerves. Fluoroscopy confirmed that no lead fragments were retained. The patient went home the same day without complications (Figs. 2 and 3).

On subsequent checkups, the patient reported that he had continued pain relief in his heel, which persisted for almost an entire year after the leads were removed. However, the dorsum of his foot continued to exhibit the same symptoms as those prior to neuromodulator implantation.

DISCUSSION

Modern PNS are designed to reduce lead migration - the most common mechanical complication of traditional PNS (3). These permanent lead implants often have tines, or burs, that help them scar and anchor down to where they are placed, preventing lead migration. Limited literature exists that compares the treatment efficacy of permanent PNS with tines to those without. In our patient, there is suspicion that the increased fibrosis was the main reason behind his gradual loss of pain relief, and the intended scarring resulted in a difficult extraction. To our knowledge, this is the first

documented case report describing how excessive scarring and fibrosis of leads may interfere with PNS therapy.

The current literature and case reports documenting the potential complications of adhesions from long-term PNS remain scarce (2). There is only one case study reporting 2 different lead extraction incidents. The report described difficult lead removal due to adhesions after initial lead migration, which necessitated an open dissection to achieve complete extraction (4). We encountered a similar situation when extracting the PTN lead from our patient; however, in our case, there was no lead migration.

The same study reported lead fragmentation and migration in both of their difficult lead removal cases. In their second case, fluoroscopy revealed that the fragmented lead was too close to a neurovascular bundle, and thus could not be safely removed (4). While we did not encounter this issue, depending on the surrounding anatomy, there is always the possibility that the implanted lead may adhere to nearby structures, compromising their integrity or function. Upper and lower limb percutaneous PNS approaches are at a higher risk, given how movement of tendons, nerves, and vascular structures have a higher chance of displacing the electrode (5). One study theorized that PTN stimulation was specifically prone to failure given its sensitivity to traction and weightbearing with everyday movement (6). Typically, tissue fibrosis requires months to form before it successfully isolates the foreign body from the surrounding tissue, although the exact time depends on the implant material, size, and location (9). Our patient reported that he lost pain relief to the dorsum of his foot abruptly, roughly 8 weeks after his initial implantation; this was likely the result of lead migration. Currently, no literature compares the rates of PNS lead migration between different implant sites; thus, further studies will be helpful in delineating when leads with tines would be preferred when placed in areas more prone to lead migration.

Though fibrosis and scarring of the implanted lead may reduce the risk of lead migration, it also likely decreases the efficacy of neuromodulation therapy by increasing the tissue's impedance (7). A study that looked at cochlear nerve implants showed correlation between fibrous tissue growth and tissue impedance over time, especially at around the 3-month mark (8). It is unclear how much fibrosis must occur to completely disrupt neuromodulation therapy, but some case studies reported that most of their PNS initially had good pain relief followed by rapid decline within 6 months (6). This agrees with a hypothesis that success of a long-term implanted device is disrupted by foreign body reactions (9). It is possible that peripheral nerve stimulation, much like cochlear nerve implantation, may benefit from the addition of coating the leads with anti-inflammatory medications (such as dexamethasone), to reduce the increased impedance inevitably associated with scar formation and adhesions (8). This could improve treatment outcomes for patients in the future, as this may be a reason behind unexplained treatment failure in those with longstanding PNS.

Ultimately, scarring and adhesions from permanent PNS may be a temporary concern. Recent literature looking into the long-term effects of neuromodulation has shown that certain patients may continue to benefit from pain relief for up to 12 months after PNS removal (10). This is similar to what we observed in our patient after extraction of his PTN lead. More research is needed to elucidate the optimal duration PNS needs to be implanted to achieve this continued pain relief after device removal.

CONCLUSION

This case report documents a 67-year-old man who experienced treatment failure in 2 permanent PNS leads. To our knowledge, this is the first case report to discuss the possibility that excessive scarring and fibrosis promoted by tines and burs on permanent PNSs may interfere with PNS therapy by increasing impedance. More research is needed to better guide physicians in counseling and management of patients with refractory pain, and to explore further possible adjuvants to reduce loss of treatment efficacy from increased impedance.

Contributions

Dr. Hall Wu: This author helped compile and draft the manuscript.

Dr. Talin Evazyan: This author helped compile and edit the manuscript.

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