



PNT Reduced Pain and Improved Function for Two Patients with Acute-on-Chronic Low Back Pain

Summary

Two patients experienced acute exacerbations of chronic low back pain, and both had undergone treatment regimens that did not relieve their pain. Case No. 1 describes a female patient who was active until an acute flare-up prevented her from participating in many of her previous activities. The male patient in case No. 2 had a history of pain-related problems, including difficulty with walking and prolonged sitting. Additionally, his pain interfered with sleep and prevented him from participating in social activities.

In both of these cases, a course of percutaneous neuromodulation therapy (Vertis PNT™), administered as part of a clinical trial, resulted in reduced pain and improved function. Vertis PNT is a new, minimally invasive therapy for low back pain involving the delivery of electrical stimulation to the nerve pathways through temporarily placed, fine-gauge filament electrodes. In case No. 1 specifically (acute flare-up), the pain relief achieved using PNT enabled the patient to proceed with physical therapy, which was previously not possible. In both cases, PNT obviated other treatments under consideration, including epidural steroid injections.

Clinical History and Presentation

Case No. 1 This 53-year-old woman led an active lifestyle, participating in rowing, bicycling, and weight training before the onset of low back pain in June 2000. Her pain flared up in May 2001, and she saw her primary care physician for management of the acute exacerbation. Therapies, which included oral anti-inflammatory drugs, physical therapy, and acupuncture, did not result in measurable pain relief. The patient was referred to the Spaulding-Wellesley Outpatient Center in June 2001, seeking more effective pain relief and functional improvement than she was able to achieve with these initial therapies.

While her low back pain initially radiated to the left hip, by the time the patient was seen at Spaulding-Wellesley Outpatient Center, it had progressed down her leg

to the ankle. Overall, she was experiencing significant impairment in her normal level of physical activity, although she continued to work. She estimated that walking, sitting, standing, traveling, and sleeping were reduced 50%, and her ability to lift was decreased approximately 40%.

An MRI showed mild arthritis of the lumbar spine. Modest central and left lateral stenosis at L4-L5 was associated with a moderate-size disc protrusion. She also had facet arthritis at L4-L5 and L5-S1. X-rays of the back and pelvis also showed moderate arthritis.

Because the patient had a history of stomach upset with anti-inflammatory medications that had been taken periodically in the past, she initially was prescribed a COX-2 inhibitor, dosed twice

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a day, which was somewhat helpful. She also participated in four sessions of osteopathic spinal manipulation, which provided some pain relief. However, on a visual analog scale (VAS), the severity of her pain at that time was 6.5 out of 10, with 10 being the worst pain imaginable. An epidural steroid injection was being considered to reduce pain and allow progress to physical therapy. However, in July 2001, she opted to enroll in a clinical trial of PNT, during which she completed a course of six weekly, 30-minute treatment sessions.

Shortly after the first treatment, the patient reported significant improvement in her pain, and her dosage of the COX-2 inhibitor was reduced from twice to once daily. By the end of the six treatments, her pain had decreased in severity from a 6.5 to 3.0. More importantly, the patient reported she now was able to perform 70% of her normal daily activities. She was able to return to her usual exercise routine at the gym and begin physical therapy for back

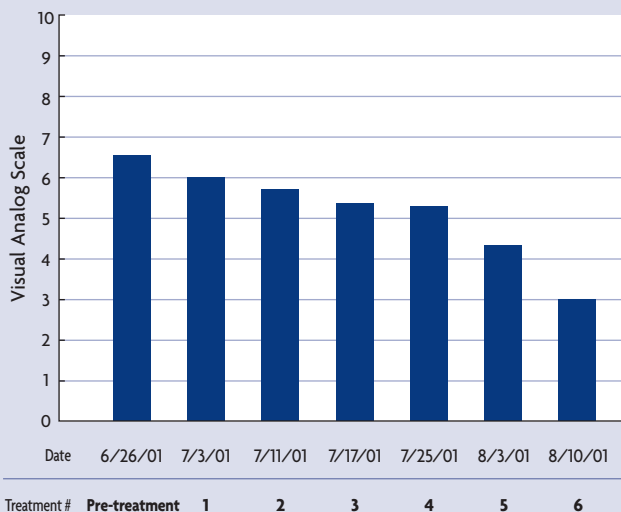
strengthening, which previously had been prohibitively painful. She also was able to participate in some mild hiking on a family vacation, which in her opinion, before the PNT trial would have been impossible. The patient now enjoys more activities than she has for the past several months, including gardening and housework.

Case No. 2 This 72-year-old male pianist and music teacher has a history of multiple, pain-related medical problems. In addition to chronic low back pain, he also has a history of cervical myelopathy, with bilateral upper and lower extremity weakness. He wears a brace on his right foot for ankle weakness, and he has had a cervical decompression and fusion. He also has a history of carpal tunnel syndrome and lumbar spinal stenosis, as well as femoral mononeuropathy, which now is resolved.

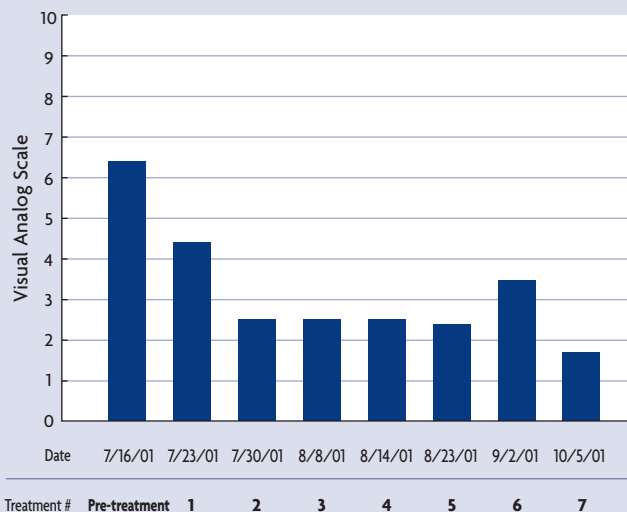
The patient had been seen at Spaulding-Wellesley Outpatient Center over the previous three years for these medical problems. In July 2001, he returned to the

Patient Visual Analog Scale (VAS) Scores

Case Study No. 1 (Female, Acute Flare-Up)



Case Study No. 2 (Male, Chronic Low Back Pain)



clinic with increasing low back pain radiating down the lateral aspect of his left leg to his foot. The severity of his pain was 6.4 out of 10 on the VAS scale. The pain occurred during the summer, when the patient was not teaching. Although at the time he was not spending long hours at the piano, he experienced difficulty walking and sitting for prolonged periods. The pain prevented him from participating in many of his usual social functions, and his sleep was being interrupted. The pain also caused the patient a great deal of anxiety, leading him to see a psychiatrist, who prescribed anxiolytic medication.

On physical examination, the patient showed decreased sensation to pinprick in his left leg, and his left ankle was slightly weaker than in previous examinations. His history, physical findings, and MRI were consistent with lumbar radiculopathy secondary to spondylosis.

The patient met enrollment criteria for a clinical trial of the Vertis PNT System and was interested in trying PNT before other more invasive treatment options. He completed a course of eight PNT sessions, which were delivered weekly (with the exception of the last session, which occurred four weeks following the 7th session). By the end of the trial, his back pain had decreased in severity from a VAS score of 6.4 to 1.75 (out of 10). The patient returned to work at the beginning of the school year without difficulty. He also reported that his anxiety decreased dramatically, enabling his psychiatrist to reduce his dosage of anxiolytic medication.

Discussion

Case No. 1 (Female, Acute Flare-Up)

In the first case, PNT quickly mitigated an exacerbation of chronic low back pain with associated pain radiating into the lower extremity. In management of this

patient's pain, PNT had the combined effects of enabling physical therapy and obviating another more invasive intervention. Prior to PNT, despite regular intake of the COX-2 inhibitor, pain prevented the patient from engaging in physical therapy. The pain reduction achieved with PNT allowed her to participate in physical therapy for back strengthening and exercise training. Before the patient's response to PNT, an epidural steroid injection was being considered to reduce pain and allow progress to physical therapy. PNT rendered the steroid injection unnecessary.

Case No. 2 (Male, Chronic Low Back Pain)

In the latter case, previous exacerbations of low back pain responded well to trigger-point injections into the muscles of the back. After undergoing PNT, however, the current flare-up resolved more quickly than previous exacerbations, and associated symptoms of lower extremity pain and weakness improved. With the extensive disease in his back, the patient likely will have other pain flare-ups in the future. It is encouraging, however, that the current episode of such exacerbation responded more quickly to PNT than past flare-ups had to other therapy regimens.

It also is noteworthy that this patient, who was being medically treated for anxiety, appeared more comfortable and relaxed throughout the PNT treatments than during previous interventions for similar acute-on-chronic pain flare-ups. With reduced pain and less anxiety, his psychiatrist was able to reduce the dosage of anxiolytic medication.

In both cases, the patients experienced no adverse effects as a result of the treatment and indicated that they were quite satisfied with the results of PNT. ■

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