Extremity Injury Management

Improving Functional Outcomes of Combat-injured Warfighters by Relieving Post-amputation Pain with Percutaneous Peripheral Nerve Stimulation

Peripheral nerve stimulation (PNS) is a promising non-opioid approach to pain management, but PNS systems have traditionally been limited by lead migration and the invasiveness of device implantation surgeries. A percutaneous PNS system was designed to reduce the risk of complications and enable delivery of stimulation without surgery. The therapy involves the percutaneous insertion of a fine-wire, coiled lead through an introducer needle to target one or more peripheral nerves with stimulation for up to 60 days, followed by removal of the leads (Figures 1 and 2).

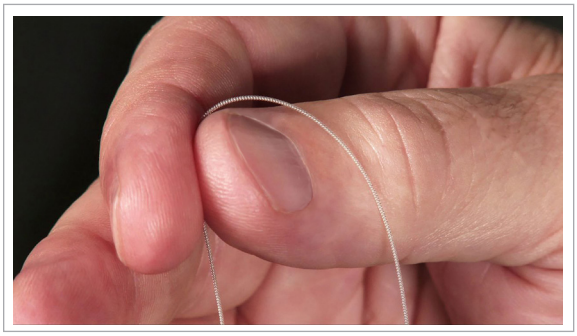

FIGURE 7-36: The novel percutaneous peripheral nerve stimulation system utilizes fine-wire coiled leads that are placed using an introducer needle, typically under ultrasound guidance. (Figure used with permission from the authors)

FIGURE 7-37: Fine-wire coiled peripheral nerve stimulation leads were placed percutaneously and connected to external, body-mounted stimulators. The stimulator is shown in place to treat post-amputation pain of the lower extremity. (Figure used with permission from the authors)

Researchers from SPR Therapeutics (Cleveland, OH; a portfolio company of NDI Medical, LLC) conducted a multicenter, randomized, placebo-controlled trial designed to collect data on the use of their percutaneous PNS therapy for improving functional outcomes by alleviating pain in individuals with major lower limb amputations. The study included 28 patients with chronic pain following traumatic lower limb amputation.

The PNS therapy successfully produced clinically significant (at least 50 percent) and statistically significant reductions in post-amputation pain in most patients. Follow-up is ongoing; among patients that have completed a one-year follow-up, 10 additional months after the 60-day therapy period, a majority of patients continued to report at least 50 percent pain relief. Participants also reported less opioid usage and major reductions in pain interference—a key measure of function and disability associated with pain. These findings provide support for the use of percutaneous PNS for the treatment of chronic post-amputation pain following blast injury.

This study demonstrates that percutaneous PNS can effectively treat pain in severely injured military Service members with amputations and may enable them to improve their quality of life, accelerate rehabilitation, and resume active duty activities.

This effort was supported by the PRORP with strategic alignment to CCCRP/JPC-6 and CRMRP/JPC-8.