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A novel method of neurostimulation of the peripheral nervous system: The StimRouter implantable device

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ABSTRACT

The nervous system is a dynamic and plastic structure that modulates the transduction and transmission of neuropathic and nociceptive pain. Traditionally, the focus of neuromodulation treatment has been on the central nervous system: spinal cord stimulation, motor cortex stimulation, and deep brain stimulation. Observational experience suggests that peripheral neuromodulatory techniques show promise as peripheral targets, both as stand-alone therapies and as an adjuvant in hybrid systems lead arrays. Currently, there are only a few neuromodulatory devices designed specifically for the periphery. We review one of these novel modalities: the StimRouter. We describe a novel strategy of stimulating named peripheral nerves with the StimRouter. Initial clinical data have shown successful implantation of this novel device and improvement in the acute setting. Currently, a multicenter study is under way to access the success of this novel method of stimulation in the long-term setting. The potential success of the StimRouter could affect peripheral neuromodulatory strategies.

Introduction

The nervous system is a complex structure that is intricately involved in many disease states, namely neuropathic pain transmission, transduction, and perception.[1-8] Since the advent of electrical neuromodulatory therapies by Norman Shealy following Melzak and Wall's gate control theory,[6] the field of neuromodulation has exploded. Although central strategies for neuromodulation, including spinal cord stimulation (SCS), motor cortex stimulation, and deep brain stimulation,[8] have a developing robust efficacy profile, challenges and limitations still remain. These limitations include creating discrete stimulation fields, potential complications of invading the neuroaxis (including paralysis and death), tunneling and implantation of an implanted pulse generator (IPG), and postural intensity changes of the perceived therapeutic stimulation. These challenges coupled with improvements in technology have advanced neuromodulation into the periphery.

Peripheral nerve stimulation (PNS) is the direct electrical stimulation of identifiable and named nerves outside the neuroaxis, directly inhibiting primary afferents. As the techniques of PNS evolved, the procedure went from one that required careful open dissection of the peripheral nerve target, as described by Stanton-Hicks and colleagues,[9,10] to techniques utilizing image guidance, potentiating a sleek, minimally invasive option.[11-13] Although there is a growing body of evidence supporting PNS, challenges still remain.[14]

Electrical neuromodulation of the periphery is oftentimes unpredictable regarding lead orientation to the named nerve. Architecturally, the inconsistent topographic arrangement of the fascicles within the nerve describes the anatomic foundation for the witnessed summative response to cathodal stimulation.[15] Furthermore, peripheral targets for mononeuropathies are commonly in the distal extremity, making site location of the IPG and tunneling across joints challenging. Lastly, many of the devices utilized for peripheral neuromodulation are adopted from equipment developed for the central neuroaxis, creating inherent shortcomings.[16,17]

The traditional SCS hardware, and its peripheral use, can be somewhat invasive, and involve placement of leads in the

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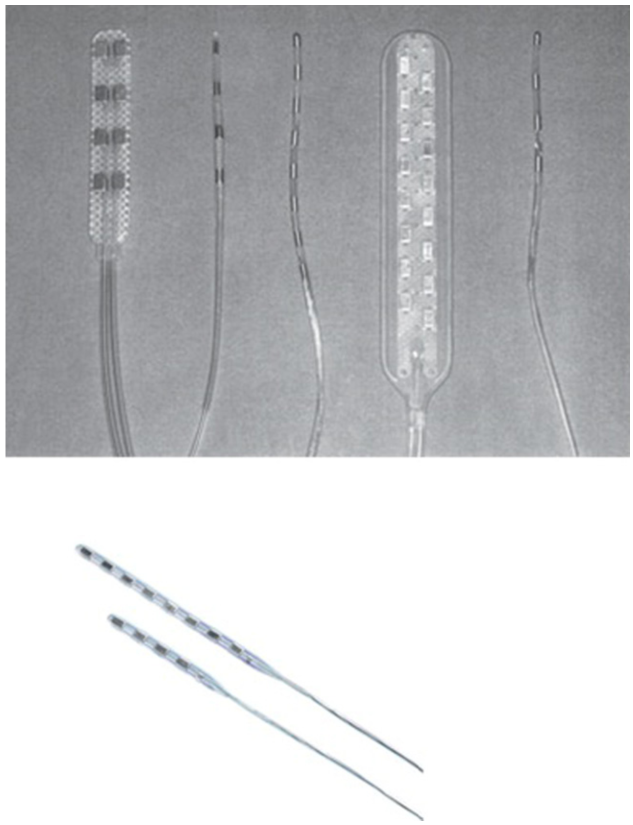

Fig. 1 – Percutaneous cylindrical and paddle leads used for PNS. (Pope JE, Deer TR. Reexamining a novel strategy for delivery of percutaneous paddle and cylindrical leads for spinal cord stimulation. *Minim Invasive Surg Pain*, in press.)[17]

vicinity of the nerve or directly on the nerve with a small graft of fascia. These leads vary in length from 30-90 cm, although the active requirement for stimulation is only a fraction of this length (Figure 1).

Once the lead is in place, it is then connected to an implantable programable generator, serving as a power source

Table 1 – Common sites of polyneuropathy or mononeuropahy or neuropathic pain conditions.

Common sites of polyneuropathy or mononeuropahy or neuropathic pain conditions
• Supraorbital nerve
• Infraorbital nerve
• Greater occipital nerve
• Ulnar nerve
• Median nerve (carpal tunnel)
• Suprascapular nerve
• Intercostal nerves
• Illioinguinal nerve
• Llioypogastric nerve
• Genitofemoral nerve
• Lateral femoral cutaneous nerve
• Saphenous nerve
• Sciatic nerve
• Posterior tibial nerve
• Trigeminal neuralgia
• Postherpetic neuralgia

Table 2 – Contraindications for use.

- Local infection near the surgical site
- Untreated or irreversible coagulopathy
- Allergy to device materials
- Comorbidities and uncontrolled coexisting disease states
- Inability to obtain consent
- Cognitive impairment that prohibits use

and programing platform. The successes with these systems are fairly robust, but it does require a fairly invasive surgery and an expensive product ($25,000-$30,000) to achieve an outcome that potentially could be equaled by a small ultra-minimally invasive device at a much lower cost. The device is specifically made for the periphery. The lead is deployed near the target nerve and the external pulse generator (EPG) on the skin surface, eliminating the need to connect an implantable device.

The StimRouter was born out of interest to address and remedy these limitations. The device is specifically made for the periphery, and once the lead is deployed near the target nerve, the external pulse generator (EPG) on the skin surface, eliminating the need to connect to an implantable device. After an enjoyed feasibility trial success, a multicenter US pivotal trial is ongoing.[18]

The StimRouter system is composed of a sizably smaller lead, measuring 17 cm and 1.2 mm in diameter. It is composed of platinum, titanium and iridium with a 3-electrode lead array distal end and a receiver on the proximal end. The EPG is placed overlying the receiver end of the lead, allowing for programability and power delivery.[18]

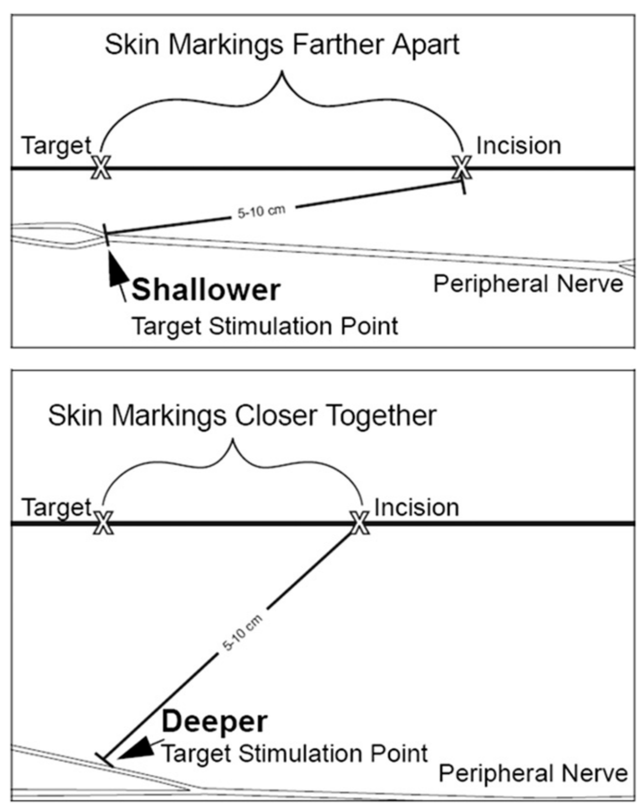

Fig. 2 – Appropriate intended device trajectory toward target nerve [courtesy of Bioness].