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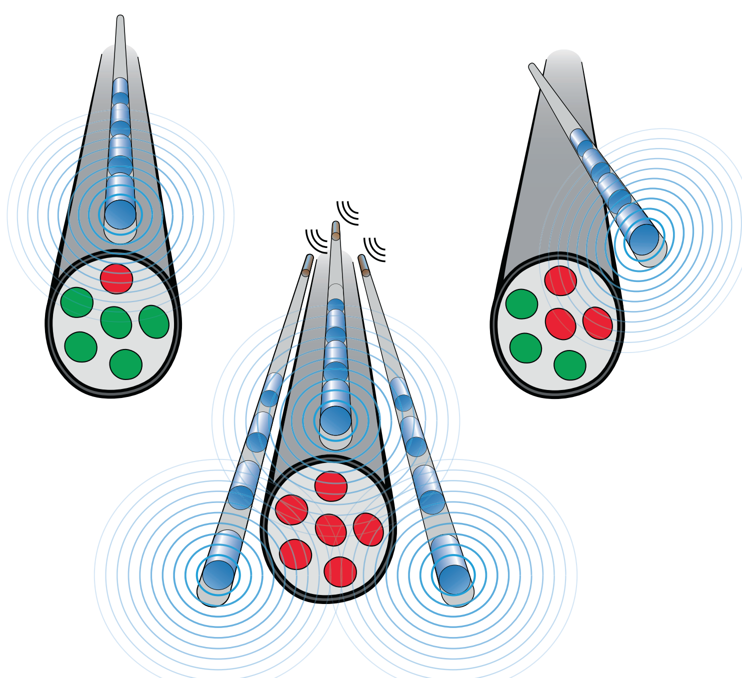
Stimulation of the Peripheral Nervous System

The Neuromodulation Frontier

Editor

K.V. Slavin



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L. Dade Lunsford Pittsburgh, Pa.

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Volume Editor

Konstantin V. Slavin Chicago, Ill.

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Series Editor's Note

As a series editor of *Progress in Neurological Surgery*, I would like to congratulate Dr. Slavin and the coauthors of this new update on the role of advanced stimulation technology in the management of patients with epilepsy, chronic pain, depression, treatment-resistant hypertension, obstructive sleep apnea, and other innovative indications.

The increasing adoption of peripheral nerve stimulation for a wide variety of patient conditions is a testament to the remarkable ingenuity and perseverance of this group of clinicians and investigators. Peripheral nerve stimulation techniques have continued to expand and have proven to be safe and effective for diverse conditions, often in clinical situations where virtually no other therapeutic option exists. The authors, who come from multidisciplinary backgrounds, work at centers with special expertise in the analysis and development of these technologies. The authors provide a striking example of how persistence and innovation pays off in terms of improving patient outcomes. This update on the current status of peripheral nerve stimulation should be a valuable resource to the field of neurosurgery and pain management specialists. I am sure it will become an important reference for specialists who care for these diverse patient problems that also include respiratory, gastrointestinal, genitourinary, and cardiac indications. The possibilities for neuromodulation have greatly expanded beyond its earlier role in the treatment of chronic pain and medically refractory epilepsy.

L. Dade Lunsford, MD, Pittsburgh, Pa.

Preface

In the most common impression, the term 'peripheral nerve' refers to the large nerves that travel through the trunk and extremities carrying motor, sensory, and autonomic information. These 'peripheral nerves' are then differentiated from 'cranial nerves' and used synonymously to the actual alternative of the cranial nerves, the spinal nerves. Even the most commonly used list of medical procedures, the Current Procedural Terminology (CPT) [1], differentiates interventions performed on 'peripheral' and 'cranial' nerves – thereby adding to the confusion in terminology.

Anatomy, however, is a precise science and anatomical terminology is very well defined. Even the most accepted compendium of anatomical terminology, the medical dictionary, provides clear division of the nervous system into central and peripheral parts, defining the peripheral nervous system as everything outside of the brain and spinal cord [2]. In vertebrates, mammals, primates, and humans, the central nervous system includes the brain and the spinal cord. According to the authoritative book *The Peripheral Nervous System* [3], the subject of the book's title is defined as the cranial nerves, spinal nerves, and peripheral ganglia which lie outside the brain and spinal cord. With this scheme, all nerves that originate from the cranial part of the central nervous system – the cranial nerves (with the exception of the olfactory and optic nerves which are considered parts of the central nervous system) – and all those that originate from the spinal cord – the spinal nerves – fall under the same category of the peripheral nerves, and this categorization is supported by their anatomy, histology, and physiology.

This discrepancy between a common misconception (i.e. peripheral nerves differ from cranial nerves) and the actual anatomophysiological similarity became obvious after the first volume of *Peripheral Nerve Stimulation* was published in 2011 [4]. Multiple clinical applications of cranial nerve stimulation remained omitted as most chapters concentrated on those nerves that travel through the trunk and extremities. Not surprisingly, those applications that dealt with indications other than pain (epilepsy, depression, sleep apnea, etc.) were not included in the book, as most of them specifically involve stimulation of the cranial nerves (vagus, hypoglossal). Along with these, the stimulation of the phrenic nerves used for respiratory insufficiency was left uncovered even though there is no controversy about phrenic nerve stimulation being a 'true' example of peripheral nerve stimulation (PNS). Moreover, several applications of neuromodulation that would not fall under strict definition of PNS, but instead represent so-called 'peripheral neurostimulation' – i.e. stimulation of the trigeminal ganglion, dorsal root ganglion, sacral nerves, and nerve roots – are covered in this second part of *Peripheral Nerve Stimulation* from the popular and well-established series *Progress in Neurological Surgery*.

In addition to all of these new topics, this volume includes other important chapters. One of them deals with theoretical and technical aspects of peripheral nerve interface with neurostimulation devices. Others describe principles of wireless energy transmission that are used in modern miniaturized neuromodulation devices and characteristics of high-frequency PNS that results in a block of nerve conduction. Several chapters are dedicated to in-depth updates on the most common PNS indications, such as migraines, low back pain, and pain in extremities. Not surprisingly, the field of PNS is rapidly progressing, and as our experience grows, so does our understanding of surgical indications, proper patient selection, technical nuances of operative procedures, and complication-avoidance techniques. Instead of case reports and small retrospective single-surgeon or single-institution studies, we now have multicenter prospective studies that may be used in critical analysis of clinical evidence that could justify our interventions.

The growing clinical experience is paralleled by industrial developments. Instead of routinely using devices designed for spinal cord stimulation in PNS applications, there are now more than a dozen device-manufacturing companies that dedicate themselves to the creation of a new generation of electrodes and generators specifically designed for PNS use. Miniaturization, rechargeability, wireless interfaces, and customized designs – terms that only recently were considered futuristic and not applicable to PNS – are becoming reality at a very rapid pace.

The final chapter of this volume deals with regulatory aspects of PNS and related applications since over the last few years the field of peripheral neuromodulation has enjoyed several important approvals, mainly in Europe, Canada, and Australia, making PNS, once again, a legitimate intervention in the spectrum of available interventions, alongside spinal cord stimulation and deep brain stimulation approaches.

Even though this is yet another volume in *Progress in Neurological Surgery*, not all interventions covered here are performed by the neurosurgeons. The uniqueness of the neuromodulation field is that it blossomed at the intersection of multiple medical specialties, including neurosurgery, neurology, anesthesiology, physiatry, orthopedics, cardiology, urology, gastroenterology, otolaryngology, pulmonology, psychiatry, oral surgery, colorectal surgery, and others – the field of PNS undoubtedly brings together physicians from different backgrounds. One has to keep in mind, however, that the implantable nature of neuromodulation still requires surgery, and the substrate of our interventions is still the nervous system. And who would be better qualified for surgery on the nervous system than neurosurgeons? Being a neurosurgeon myself, I can already hear the criticism from my nonneurosurgical colleagues who perform the overwhelming majority of neuromodulation procedures, including PNS and spinal cord stimulation, and who over the years have become much more comfortable with reaching the nerves all over the human body. And since I have taught hundreds of them how to make neuromodulation procedures safer, I feel confident that this volume will be of interest to the entire neuromodulation community, reflecting the interdisciplinary nature of our field and, among other things, reminding myself and other neurosurgeon readers what we may be missing!

Konstantin V. Slavin, MD, FAANS, Chicago, Ill.

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Technology for Peripheral Nerve Stimulation

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Abstract

Peripheral nerve stimulation (PNS) has been in use for over 50 years to treat patients suffering from chronic pain who have failed conservative treatments. Despite this long history, the devices being used have changed very little. In fact, current PNS technology was developed specifically for spinal cord stimulation. The use of technology developed for other applications in PNS has led to an unnecessary number of device complications and the limited adoption of this promising therapy. The following chapter provides an overview of PNS technology throughout the years, outlining both the benefits and limitations. We will briefly explore the electrophysiology of PNS stimulation, with an emphasis on technology and indication-specific devices. Finally, design and technical requirements of an ideal PNS device will be discussed.

Peripheral Nerve Stimulation Technology Throughout the Years

Compared to other types of medical devices, technological advances in peripheral nerve stimulation (PNS) have been rather few and far between. Only a few minor improvements have been made over the years and many of these improvements have been the result of the application of new technology developed in other neuromodulation therapies such as spinal cord stimulation (SCS). The following sections summarize PNS technology (fig. 1), with an emphasis on device complications and limitations.

Early Devices

The earliest recorded use of PNS was in 1962 by Shelden [1] who implanted 3 patients for the indication of pain due to trigeminal neuralgia. This was several years before the publication of the gate control theory [2] and was based on the rationale of

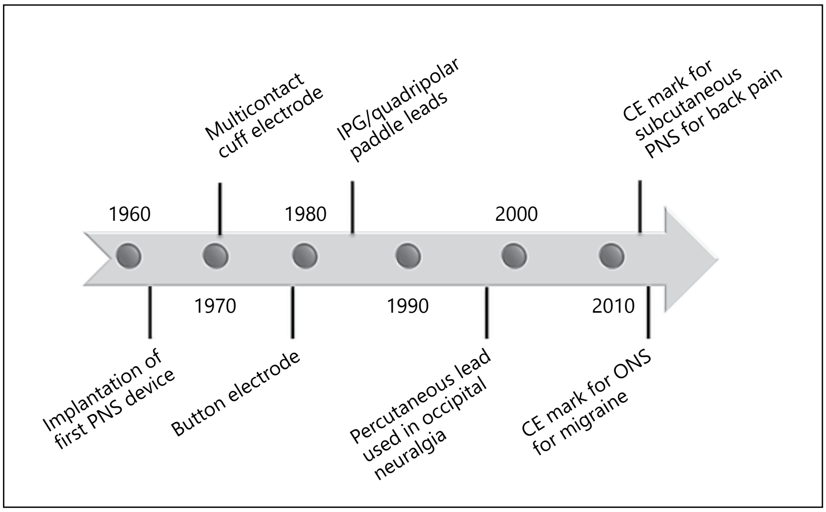

Fig. 1. Timeline of the significant technological changes since the inception of PNS. ONS = Occipital nerve stimulation.

depressing excitatory transmission by depolarization of the nerves [3]. The device was fully implantable and powered by an external radiofrequency (RF) generator. The RF device was capable of delivering 10 V at a frequency of 14.5 kHz. Shelden implanted platinum electrodes over the mandibular division of the trigeminal nerve in all 3 patients. One patient reported favorable outcomes up to 31 months after surgery. Single case reports by other researchers appearing around the same time [4] found stimulation of a variety of peripheral nerves was able to suppress chronic pain caused by complex regional pain syndrome and neural trauma.

PNS with RF generators and nerve cuff electrodes became much more common in the 1970s [5–8]. A device described by Long [5] in 1973 had the bipolar or monopolar electrodes wired directly to the RF-receiving coil. This required that the location of the receiving coil be determined by the position of the stimulating electrode. Long reported complete pain relief in 6 out of 10 patients. He found the device to be more efficacious in the upper extremities than the lower, likely due to increased difficulty in implanting electrodes in the hip area. Long did not report any complications due to the device. Patient selection was performed by a short period of percutaneous trial stimulation (in the order of minutes) with cordotomy electrodes connected to either a StimTech (StimTech Corporation, Minneapolis, Minn., USA) or Medtronic (Medtronic, Minneapolis, Minn., USA) external stimulator (1-ms pulse width, 10–25 pulses/s, 1–4 V).

Campbell and Long [6] continued to implant and reported a further 33 patients also using a bipolar nerve cuff and RF receiver. Electrodes were wrapped around the nerve corresponding to the area of the patient's pain (sciatic, brachial plexus, median, and ulnar nerves). They reported an overall success rate of 45%. Of the 17 failures, 12 were in patients with either low back pain with sciatica or pain from metastatic disease.

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