Technological Innovations in Implants Used for Pain Therapies

Andrew Shaw, MD, Mayur Sharma, MBBS,
Milind Deogaonkar, MD, Ali Rezai, MD*

KEYWORDS

• Peripheral field stimulation • Neuromodulation • Innovation • Technology • Spinal cord stimulation

KEY POINTS

- Spinal cord stimulation was first attempted in 1967 to relieve the pain of a patient dying with cancer. Since that time electrodes, implanted pulse generators, patient programmers, and techniques have drastically improved with the progress of technology.
- Implanters have a wide armamentarium of devices to implant electrodes in any part of the body. Traditional Tuohy needles have been adapted for not only spinal cord stimulation but also peripheral/field stimulation. The Epimed Coudé, Abbocath catheters, and ON-Q tunnelers have found new applications in neuromodulation and provide safe and effective alternatives to traditional approaches.
- There are a variety of electrodes available from percutaneous cylindrical electrodes to paddle leads. Through innovation there are now percutaneous paddle leads, paddle leads with five-column arrays, and 16-contact cylindrical electrodes that provide implanters and programmers greater ability to provide adequate pain coverage.
- Lead anchoring is essential to avoid lead migration with resultant loss of efficacy and need for revision surgery. There are compression and screw restraint devices that have significantly reduced rates of lead migration compared with suture anchoring alone.
- Implanted pulse generators have acquired new abilities with adaptive stimulation, MRI compatibility, rechargeability, and update capable devices. Adaptive stimulation changes stimulation automatically based on the patient's position. MRI compatibility allows for full-body MRIs, so patients requiring serial imaging can benefit from this therapy. Most recently, an IPG has been developed whose software can be updated remotely allowing for the most up-to-date algorithms to be applied to a battery that can last up to 10 years.
- Innovation is a result of dissatisfaction with the current paradigm and driven by curiosity to explore new avenues to relieve the suffering of patients.

INTRODUCTION

Pain management has experienced tremendous growth in implantable therapies secondary to the innovations of bioengineers, implanters, and industry. From the first trial of spinal cord stimulation (SCS) in 1967 using an externalized electrode and generator for intractable cancer pain to the introduction of positional stimulation using three-axis accelerometers, the treatment of chronic pain continues to evolve with the constant introduction

Conflict of Interest: We declare no conflict of interest.

Department of Neurological Surgery, Wexner Medical Center, Center for Neuromodulation, Ohio State University, 410 West 10th Avenue, Columbus, OH 43210, USA
* Corresponding author.
E-mail address: Ali.Rezai@osumc.edu

Neurosurg Clin N Am 25 (2014) 833–842
http://dx.doi.org/10.1016/j.nec.2014.07.008

of new innovations and technologies.[1,2] Every aspect of neuromodulation is amenable to innovation from implanting devices to anchors, electrodes, programming, and even patient programmers. Patients with previously refractory neuropathic pain syndromes have new and effective pain management strategies that are a direct result of innovations in implantable devices.

SCS and peripheral nerve field stimulation have been used for the treatment of numerous refractory chronic pain conditions including occipital neuralgia, trigeminal neuralgia, failed back surgery syndrome, chronic inguinal neuralgia, postherpetic neuralgia, and refractory angina.[3–14] Patients with severe refractory pain are often managed with a variety of treatment modalities that include narcotics, anticonvulsants, antidepressants, nerve blocks, and destructive procedures with limited or short-term benefit.[3–8,10–12] SCS and field stimulation have consistently been shown to reduce pain significantly in appropriately selected patients.[3–8,10–14] The mechanism of pain relief from neurostimulation has not been completely elucidated, but is based on the gate control theory of pain initially published by Melzack and Wall[15] with the blockade of distal nociceptive information and C fiber inhibition.[9,10] Later, the "neuromatrix theory of pain" was proposed by Melzack in 1989, which described the "neurosignature" patterns of nerve impulses by a widely distributed neural network in response to noxious stimuli.[16,17] Since the initial description of SCS in 1967, implanters, scientists, and innovators continue to change the face of neuromodulation with advances in implantable pain management technologies.

IMPLANTING DEVICES

Percutaneous implantation techniques for subcutaneous and SCS cylindrical electrodes involves the use of slightly curved 14- to 15-gauge Tuohy needles.[3–8,10–12,14,18]

From a historical perspective, field stimulators were placed in an open fashion with direct visualization of nerves and associated significant complications and poor efficacy.[19,20] Subcutaneous implantation started with tunneling using a curved hemostat.[10] The initial SCS experience also involved an open approach with a thoracic laminectomy and placement of electrodes under direct visualization.[1]

Tuohy needles are hollow hypodermic needles with a stylet and are of appropriate gauge to allow implantation of electrodes in a variety of locations (Fig. 1C). Several percutaneous techniques have been developed for the implantation of peripheral nerve/field stimulators including the use of curved Tuohy needles, intravenous catheters (Abbocath; Abbott Ireland), and the Epimed Coudé (Epimed, NY).[21,22] For percutaneous spinal cord stimulator implantation, Tuohy needles remain one of the primary instruments chosen for implantation of electrodes.

The Epimed Coudé has been chosen by some implanters because it is malleable and allows for improved steering and test stimulation before lead implantation.[22] It has a 14-gauge circular profile that facilitates the passage of multipolar electrodes without the risk of lead shearing. There is an associated 5-mm stimulating tip with an end connector at the proximal part of the needle that allows connection to standard regional-anesthesia nerve stimulators. This is especially useful in field or peripheral nerve stimulation when using test stimulation to determine the optimal site for electrode implantation.

Abbocath IV catheters (Abbott Ireland) have also been used for implantation of subcutaneous electrodes for peripheral nerve and field stimulation. Abbocaths come in two sizes and several different gauges. For neuromodulation a 14-gauge cannula is chosen because it is of sufficient size to accommodate an electrode. There are two different lengths (50- and 150-mm cannula) to choose from depending on the desired application. Here a sharp needle is used to make the preliminary trajectory through the subcutaneous tissues and a softer catheter is left behind for the implantation of the electrodes.

The ON-Q (Braun Melsungen AG, Pfieffewiesen, Germany) Pain Relief System and ON-Q Tunneling System have been used to deliver local anesthesia to surgical sites and have been shown to provide improved postoperative pain relief from orthopedic to cardiothoracic surgery.[23,24] Recently, ON-Q Tunneling System has been used for the implantation of peripheral nerve and field stimulators. This system involves the use of a blunt needle with a soft flexible silastic peel-away sheath that is left in place following tunneling. Multiple sheaths can be implanted with a single needle in the event multiple electrodes are planned. Furthermore, the stylet of the ON-Q is malleable and can be made to conform to specific body angles (see **Fig. 1** A and B). There are a variety of lengths of ON-Q systems available (3.25, 5, 8, and 12 inches), which can be tailored according to the region of interest. The 17-gauge cannula is preferred for peripheral field stimulators.

St. Jude Medical introduced the Epiducer (St. Jude Medical, Plano, TX) in 2009 as an innovative product to deliver an array of SCS leads including paddle leads, cylindrical leads, or combination of leads without the need for an open laminectomy or laminotomy (**Fig. 2**). This device has been shown to be safe in a multicenter trial involving 34 patients with no adverse events related to this