



ENHANCING SPINAL CARE THROUGH INSIGHTS FROM DIGITAL HEALTH PLATFORMS

Abstract

As the cost of health care and its needs evolve, there is significant potential for digital health platforms to enhance existing treatment plans. In the case of spinal disorders, ongoing innovation in the medical devices industry is providing patients with better ways of dealing with their condition. When such device innovation is paired with digital advances, it opens new possibilities for effective health care. This point of view looks at spinal cord stimulators as a treatment for spinal disorders and examines how digital health platforms can support the function of these medical devices to be more effective and engaging.

Introduction

Spinal disorders are among the many conditions that can cause chronic pain and become more prevalent with age (1, 2). It ranks among the most expensive conditions to treat (3). With the population of individuals over the age of 65 expected to almost double by 2040 in the US, one can expect the economic toll of spinal disorders to also increase (1).

Lower back pain caused by spinal disorders is one of the most debilitating conditions (2). Its prevalence is correlated with age, making it imperative for providers to pay due attention to the management of spinal disorders among the elderly.

Spinal Cord Stimulators: Supporting Pain Management

Chronic pain management techniques can alleviate some of the discomfort associated with spinal disorders. However, there are some patients who do not respond to medication and back surgery. In these cases, an implantable spinal cord stimulator – along with exercise, medication, and relaxation strategies – may be needed to relieve lower back pain (4).

Spinal cord stimulators are implantable medical devices that deliver low-level electrical current to the spinal cord to provide pain relief. The electrical dosage is controlled by an external programmer with its settings pre-programmed by a doctor (4, 5). It is important to note that the use of spinal cord stimulators has highly variable patient outcomes. According to figures from 2017, sub-optimal outcomes were reported for a quarter of the 100,000 spinal cord stimulators implanted worldwide (6).

The electrodes delivering electricity to the spinal cord are fixed in the epidural space between the outermost membrane of the spinal cord and the vertebral wall (5). However, a key challenge is that the position of the spinal cord within the cerebrospinal fluid can be altered by even slight movements such as due to coughing or breathing (7). Though the magnitude of positional changes may be minor, even minuscule changes in the distance between the spinal cord and electrodes can lead to substantial changes in the electrical current delivered. This directly impacts the extent of nerve fiber stimulation and, thereby, pain relief (7).

When integrated with digital health platforms, spinal cord stimulators can help health care providers monitor device usage patterns and identify concerning trends in patient-generated data that need to be addressed, leading to better patient outcomes.

The Closed-loop Advantage

Many existing spinal cord stimulators operate as an open-loop system. The extent of nerve fiber stimulation in response to the administered electrical current is not measured (8). Additionally, no adjustments are made to the initial stimulation current. This leads to fluctuations in spinal cord activation due to movement or involuntary actions and can result in sub-optimal or unpredictable pain inhibition (7).

Newer closed-loop systems monitor the extent of nerve fiber activation and auto-adjust the stimulation current delivered to the spinal cord. By measuring fluctuations in spinal cord activation, the device can adjust the initial electrical dosage to maximize the amount of time nerve fiber stimulation remains within the therapeutic window (7,8). This feedback system is powered by algorithms integrated with the device (5).

A landmark study published in 2019 investigated whether pain inhibition differed between two groups of patients with chronic intractable back and leg pain when the same spinal cord stimulator was deployed either using its closed-loop or open-loop settings (7). Three months after device implantation, 82% of patients in the closed-loop group experienced at least a 50% reduction in overall pain, compared to 60% of individuals in the open-loop group. At 12 months, patients utilizing the closed-loop setting experienced more consistent nerve stimulation, with spinal activation remaining within the therapeutic target range 95.2% of the time. Compared to this, patients utilizing the open-loop setting experienced consistent nerve stimulation only 47.9% of the time (7).

Closed-loop stimulators for spinal pain can be integrated with digital health platforms to help monitor device usage and trends in patient-generated data. These platforms, powered by artificial intelligence (AI) and machine learning (ML), can produce activity reports that highlight key trends in user statistics. Real-time data facilitates better monitoring of the patient response, enabling clinicians to adjust the spinal cord stimulator's programmed settings to achieve maximal pain relief.

How Digital Health Platforms Support Spinal Cord Stimulators

Digital health platforms can enrich the patient experience by integrating and analyzing data generated by spinal cord stimulators. Some of the key capabilities of such digital health platforms for spinal care include:

- **Replacing the handheld programmer with a smart phone controller** – Compared to a traditional handheld programmer, the ability to control the delivery of electricity from a smart phone is vastly more convenient for patients. While these settings should be pre-programmed by a physician, patients can easily adjust parameters within the pre-defined range set by their doctor to maximize their comfort.
- **Personalized patient reports** – Using AI and ML, patient data generated by the

spinal cord stimulator can be analyzed and viewed on a smart device. Clinicians can quantify outcomes by tracking device usage, the amount of time spinal cord stimulation remains within the therapeutic window, and nerve fiber stimulation levels over a specific timeframe. Access to this information can help clinicians re-adjust device parameters to optimize pain relief and modify treatment plans.

- **Device alerts** – Good maintenance of a spinal cord stimulator is critical for device longevity. Alerts can notify patients to recharge their devices and enable individuals to seek immediate assistance from health care professionals to troubleshoot device issues. Digital tools can also provide patients with

access to videos that teach them how to care for their devices and the necessary precautions to take when living with a spinal cord stimulator.

A key element to bear in mind is that the chosen digital health platform should be compatible with FDA and EMA-regulated Class I, II and III medical devices in order to generate condition-specific and customized insights. It should also be able to aggregate data from wearables and mobile apps used for health purposes so that a holistic range of key health indicators can be viewed through a single dashboard. Moreover, insights drawn from such digital health platforms can help physicians better understand the patient experience of pain, improve treatment knowledge, and enhance the efficacy of modern health interventions.

Conclusion

As the aging population increases, spinal disorders and related chronic pain management will become a global challenge. Using patient-generated data to understand the efficacy of the current treatment and make prudent modifications to treatment plans is the way forward. In conjunction with digital health platforms, spinal cord stimulators provide a technology-driven approach to monitor and better manage treatment outcomes. Integrated digital health platforms can provide a continuously engaged and holistic solution to spinal pain management and overall patient care.



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