

Oscillating Field Stimulator Technology

Each year, about 12,500 new individuals experience spinal cord injuries in the U.S. alone with the global occurrences being much higher. The estimated cost of care after spinal cord injury can range from \$2-\$5 million per person depending on life expectancy and injury severity. Currently, there are no FDA approved therapies that can significantly recover function in humans. As a result, permanent paralysis of some degree is common with spinal cord injury.

For over a hundred years, scientists have known that electric fields can impart strong cellular and biologic responses. Electric fields at the cell level help govern cell movement and orientation in the developing embryo. But in recent decades, the therapeutic role of electric fields has been of significant interest in regenerative medicine. In neurology, weak DC electric fields have been shown to induce nerve fibers to grow along the field lines, and in some cases, at rates faster than normal. Additionally, electric fields also reduce dieback often experienced by damaged nerve fibers. The scientific merit of DC electric fields in nerve regeneration has been demonstrated both in vitro and in vivo and the literature is replete with positive data in model organisms such as lamprey, rodents and dogs.

The Purdue Center for Paralysis Research has exploited the phenomenon of electric field based regeneration and has created an implantable device that provides DC current at the level of injury. This device, called the oscillating field stimulator (OFS) is a small implantable device that imparts the necessary DC fields via two pairs of three stimulating electrodes. The electrodes deliver a small current across the injury site to promote nerve regeneration. The polarity of the electric current oscillates several times an hour to reduce electrode byproducts and optimize the biological response (hence the device name). After the designated stimulation period (14-16 weeks), the implant is surgically removed.

Early OFS units (simple battery packs) have been tested in both dog¹ and human clinical trials² (FDA Phase 1) and have proven to be safe, with statistically significant improvements in light touch, pinprick sensation and motor function in patients with neurologically complete injuries². Further, the biological changes that occur after OFS application continue to improve even after a year or two post-treatment and one patient has regained toe movement and some walking ability. Using cutting edge microelectronics, our laboratory is pleased to announce the next generation of OFS units. The new OFS devices incorporate new stimulation circuitry (patent pending), wireless telemetry and real-time monitoring software. With the exception of the external casing which requires specialized machining/molding of biocompatible polymers, all components can be obtained off the shelf with no custom microfabrication required. The OFS units communicate with the user via an App based interface using wireless and encrypted protocols. This allows real-time device monitoring/reporting throughout the implantation period. With the new OFS, our group is addressing a significant clinical need. The OFS represent a promising and disruptive technology and may ultimately improve quality of life for those experiencing acute spinal cord injuries.

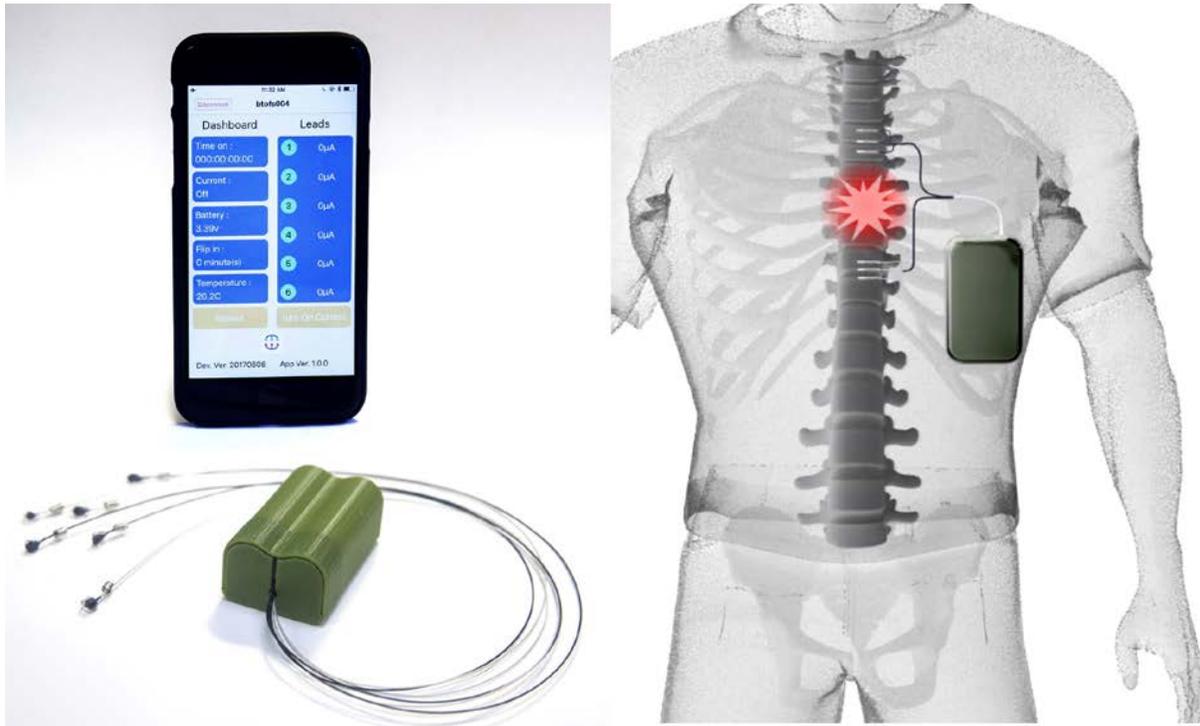


Figure 1

Left: Actual OFS device and App as featured on a smartphone running iOS. Right: Placement of stimulating leads in vivo. The stimulator ends are platinum coil electrodes connected to pacemaker leads. Electrodes are placed above and below the spinal injury. Note: Implant body can be placed anywhere in the trunk.