

Neurotech

business report

from medical technology to commercial products

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Adaptive Control Methods Transform Neuroprosthetics

by James Cavuoto, editor

Currently, most of the systems on the market for neural prostheses and neurorehabilitation make use of electronic controllers that send regular signals to surface or implanted electrodes. Neural engineers at several research institutions and commercial firms are developing new systems that will be able to modify control signals automatically based on sensory feedback, discerned user intent, or adaptive algorithms that are modified on the fly.

One of the first categories of neuroprosthetics to employ adaptive control is foot-drop stimulators. The NESS L300 system from Bioness incorporates a gait sensor that adjusts control signals to accommodate uneven surfaces and changes in elevation. Victhom's implantable NeuroStep device incorporates a sensing cuff electrode that is used to detect afferent signals generated by mechanoreceptors in the foot.

The Center for Adaptive Neural Systems at Arizona State University is currently pursuing several research projects that may have commercial applications in neuroprosthetics and neurorehabilitation. One project involves adaptive electrical stimulation for locomotor retraining, which seeks to improve outcomes for locomotor therapy following spinal cord injury. The research team, led by Jimmy Abbas and Ranu Jung, wants to use more appropriately timed muscle contractions and generate more repeatable

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Researchers at the Center for Adaptive Neural Systems examine force and motion data in an effort to perfect control algorithms.

Complications in DBS Surgery Challenge Device Vendors

by Warren Grill, senior technical editor

Deep brain stimulation is an effective treatment for movement disorders including Parkinson's disease and essential tremor and is under investigation for treatment of depression and epilepsy. The advantages of DBS over ablative lesion procedures include that it is adjustable (i.e., the electrode geometry and stimulation parameters can be programmed), it is reversible, and it can be conducted bilaterally with a lower risk of neurological deficit than bilateral lesions.

Like lesions, however, DBS requires a stereotaxic neurosurgical procedure, and, in addition, the implantation of leads and a pulse generator. Thus, there may be both hardware- and surgery-related complications with DBS. The results of several recent studies suggest that while adverse events are not rare overall, the incidence of complications leading to permanent deficit is very small and most adverse events are mild to moderate.

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St. Jude Medical Receives Approvals of Extended Life Claim for Eon

St. Jude Medical, Inc., the St. Paul, MN manufacturer of neurostimulation systems, announced U.S. Food and Drug Administration and European CE Mark approvals of a 10-year battery longevity claim for the Eon neurostimulator, a rechargeable device used to treat chronic pain. The announcement was made at the 24th annual meeting of the American Academy of Pain Medicine in Orlando, FL. With neurostimulation therapy, devices with rechargeable batteries have quickly become the standard. At high stimulation parameters, a 10-year-old Eon device will maintain at least 24 hours of continuous therapy between recharges. For patients, this means the Eon device can provide sustainable therapy and maintain a reasonable recharge interval for 10 years, potentially resulting in fewer battery replacement surgeries. Rechargeable neurostimulators are designed with a battery reserve to protect the device from damage should a patient discontinue therapy. The Eon neurostimulator's battery reserve allows the device to be safely recharged for up to 18 months after stimulation has been discontinued. "We continually strive to develop best-in-class products that enhance patients' quality of life," said Chris Chavez, president of St. Jude Medical's ANS Division. "The addition of battery life-extending technology, which enables the 10-year battery capability, is a prime example of our commitment to making a good product even better."

EaglePicher Names Joseph Marotta VP Sales and Marketing

EaglePicher Medical Power, the Vancouver, BC manufacturer of batteries for implantable medical devices, announced that Joseph Marotta has joined the company as vice president of sales and marketing. In this position, Marotta will be responsible for the sales and marketing activities of EaglePicher Medical Power including customer development initiatives. Marotta joins EaglePicher with more than 20 years of sales and marketing experience. Most recently, he spent six years as vice president of worldwide sales and marketing at National Manufacturing Co, Inc., a global manufacturer of deep drawn component technology for medical, industrial, automotive, defense, and electronic applications. Prior to that, Marotta was vice president of sales and marketing at Wiedenbach Corp. Previously, he spent 10 years as national sales manager at Aeroquip Corp., a division of Eaton Corp.

EnteroMedics Announces Expansion of EMPOWER Pivotal Study for Obesity

EnteroMedics Inc., the St. Paul, MN manufacturer of neuromodulation devices for obesity and other gastrointestinal disorders, announced that the Food and Drug Administration has granted approval for the expansion of its pivotal clinical trial, known as the EMPOWER study, from 220 patients to 300 patients. Full enrollment is expected in the first half of 2008, consistent with previous projections, despite expansion of the study. The EMPOWER study, which is currently enrolling patients at 10 of its projected 15 clinical sites, is a randomized, double-blind, placebo-controlled study to evaluate the safety and effectiveness of investigational VBLOC vagal blocking therapy using the Maestro system in obese patients. VBLOC therapy is designed to empower weight loss by promoting earlier feelings of fullness and reduced hunger while minimizing the side effects and complications associated with existing surgical options and preserving the individual's normal anatomy. "In obesity trials, the problem is generally not finding patients for recruitment, but supporting our clinical centers in managing the number of patients with obesity seeking help. Because of this, we are able to expand the EMPOWER study, making its endpoint results more robust, while keeping to our original enrollment timeline," said Mark Knudson, president and CEO of EnteroMedics. "Our recruitment and screening systems, which include a registered nurse call center and informational meetings, are in place and have already handled the screening of thousands of potential candidates."

Adaptive Control

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movement patterns on a treadmill.

Abbas has spun off a commercial firm called customKYnetics Inc., which is developing a portable home-based stimulation system incorporating adaptive control. The ASU researchers make use of the entrainment of oscillations phenomenon to design algorithms and electronic circuits that mimic the functionality of neuromotor control systems.

A second commercial spinoff from the lab, Advensys LLC, received a \$1 million grant from the U.S. Army to develop powered limb splints that can be used in combat settings to provide bipedal mobility to injured soldiers. Founded in 2004 by Ranu Jung, the company seeks to commercialize a suite of products to provide new orthotic and prosthetic options for people with lower limb dysfunction or lower limb amputation. The products will integrate biologically-inspired adaptive neuromorphic control systems technology with biomorphic compliant actuators, sensor systems, and lightweight orthotic/prosthetic components. Advensys' first product, NOCS (neuromorphic orthotic control system), is a prototype control system based on neuromorphic principles that senses and controls an active powered orthosis for the lower extremity.

The Center for Adaptive Neural Systems recently received a \$3.3 million bioengineering research partnership award from the National Institute for Biomedical Imaging and Bioengineering for neural-enabled prostheses that make use of sensorimotor integration.

The project proposes to develop a prosthetic system with electrodes implanted within the fascicles of peripheral nerves to provide upper extremity amputees with sensory feedback and active volitional control. The ASU team and its partners at the Mayo Clinic Arizona and two commercial firms seek to elicit meaningful sensations of hand opening and grip force. The team will then focus on using the neural interface to provide both sensation and control. A key feature will be bidirectional communication at speeds that enable real-time sensorimotor control of the prosthesis.