

Work those Muscles

It's that time of year. The holidays are over. We start to think about how much we ate and how little we exercised during that time. We want to make good on those New Year's resolutions made only a few weeks ago. For people with physical impairments, exercise takes a new meaning. Much focus in conventional therapy is on exercising the limbs that have voluntary control or those that are fully functioning, but what about the areas that are paralyzed, impaired or just plain weak? This issue covers neurotechnology that addresses the exercise of muscles. Explore what is available and how it applies to exercise.

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Educate: Exercise Weak or Paralyzed Muscles

Before jumping into the exercising of weak or paralyzed muscles, let's establish the importance of exercise. According to the National Center on Physical Activity and Disability, "being active is an important part of getting and staying healthy." For persons with impairments, exercise can be a different ballgame. Accessibility issues, personal image and exercise guidelines come into play. To understand the importance of exercise, we turned to Exercise Physiologist, Dr. Patrick Jacobs, Ph.D. of Florida International University. Dr. Jacobs simply explains that exercise is "cheap" but health care is expensive. Exercise is really about the cardiovascular and circulatory systems of the body. These systems move nutrients, gases, and wastes to and from cells helping to fight diseases and stabilize the body. Dr. Jacobs starts with muscles that have voluntary movement. "If there is any voluntary movement, then exercise that muscle and slowly build it." Assistive devices can be used but should not become a "crutch" and shed them over time. For those with paralysis but with intact peripheral nerves, electrical stimulation is an option. These devices send pulses of electricity into the user's skin and contract the muscles. Even if they do not cause a twitch, they can help the blood flow. (Surface stimulation relies on the peripheral nerve system to activate the muscle.)

Dr. Jacobs advises, "Use it or lose it." Muscles are where we use the fuel for the body. Studies have confirmed that, during exercise, blood pressure control is dominated by peripheral neural feedback mechanisms; increasing the heart rate and moving blood throughout the circulatory system. Stimulating muscle activity through exercise can greatly benefit the circulatory system of the body, but also other systems such as the skeletal system. University of Iowa research team lead by Richard Shields reported that early intervention and long term treatments with electrical stimulation which causes muscle contractions exerting greater than body weight to bones is the best way to apply therapeutic stresses to keep the skeletal system healthy and significantly reduces the loss of bone mineral density. Dr. John McDonald of Johns Hopkins University published a paper in the 2002 Journal of Neurosurgery that demonstrated neurological restoration and functional recovery can occur even long after the nervous system is damaged. Studies have proven that active therapy improves patients' quality of life by promoting overall physical integrity such as improving cardiovascular health; preventing skin breakdown; and reducing the incidence of osteoporosis, scoliosis and other skeletal disorders.

For all those various health benefits, we have established that exercise is good for you. But that is nothing new. Now, let's turn to tools that can help. Two areas of neurotechnology relating directly to exercise are Electrical Muscle Stimulators and Movement Enhancement Systems. Each area is described below with resources available in the other sections of this newsletter.

Electrical Muscle Stimulators (EMS)

Electrical stimulation of the muscles may be employed to help maintain the muscles because the motor nerve is blocked but remains anatomically intact. EMS devices use pulses of electricity to contract or excite

Electrical stimulation of the muscles may be employed to help maintain the muscles because the motor nerve is blocked but remains anatomically intact. EMS devices use pulses of electricity to contract or excite the muscle. A “normal” muscle contracts during an exercise regime, whereas the weak or paralyzed muscle achieves a similar result with the assistance of electrical stimulation. Using EMS, it is possible to minimize the loss of muscle bulk, improve muscle size and performance, and enhance physical fitness. Investigators, who were interested in minimizing the muscle loss, have demonstrated the efficacy of electrical stimulation during the denervation, loss of nerve supply, period. Studies date back to the 1950s; the numbers of subjects or sample sizes are small but the results were applicable to clinical practice.

However, the limitations of EMS systems for mimicking the effects of exercise are caused by the skin. Transcutaneous neural stimulators like surface stimulation garments and external FES (Functional Electrical Stimulation) devices are subject to a Catch-22. To achieve results, they have to push enough electricity through the skin to affect the nerve. Even with the limitations of the skin, the benefits of exercise can still be realized. FES bikes or rowing machines deliver electrical currents to activate the quadriceps, hamstring, and gluteus muscles enabling the legs to move through a regular patterned physical activity. EMS arm exercises deliver low level pulses of electrical current to paralyzed upper arm muscles and enable arm exercises. Therapeutic electrical stimulation used in conjunction with bilateral arm movement produce results for treatment of hemiparesis caused by stroke. More sophisticated devices work to improve the communication between the brain and the peripheral nervous system. This communication governs muscle activation. When a muscle contracts, there are areas in the brain activated to induce this activity. Disuse muscle atrophy results in the weakening of this area in the brain. Another form of rehabilitation for voluntary movement is to monitor the brain for activity to a muscle group. When strong muscle-movement signals are detected in the brain, a device induces movement by contracting the muscle through external electrical stimulation. These exercises are only possible provided the relevant nerves are not damaged.

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The market for these devices extends to a wide range of disabilities including stroke, brain injury, spinal cord injury and multiple sclerosis to name a few. In recent history, they have even extended to the mass exercise market. But buyers beware of manufacturer claims to over promise. The marketing of abdominal stimulators has drawn into question the claims of these devices to cause fat loss and to give users the “washboard abs”. Aside from these claims, EMS devices have been approved by the FDA and have long been used by physical therapists for rehabilitation of atrophied muscles, relaxation of muscle spasms, increase of range of motion and treating after effects of serious injury or surgery. The FDA does warn that EMS devices can be hazardous when used improperly especially when used on heart patients, persons with epilepsy or pregnant women. There are a variety of EMS devices available through a prescription or without one which may be found in the resources section of this newsletter. Before starting an EMS exercise regime, you should consult a physician or professional therapist.

Movement Enhancement Systems

What in the world are movement enhancement systems? After injury or even surgery, the muscle may still have voluntary movement but are weak and need to be reconditioned. The movement enhancement systems are systems used to “re-train” the muscle. Dr. Andrea Behrman, PhD, PT, in the Department of Physical Therapy at the University of Florida explains it this way.

“We used to believe the brain would issue the executive command or signal to walk to the muscles via the spinal cord. The spinal cord acted like a telephone cable and simply carried commands to the muscles. It turns out the spinal cord is not just a telephone cable but actually is, to some degree, "smart." If the sensory information that is provided to the spinal cord looks like walking, the spinal cord can recognize this information and responds by generating a stepping pattern of muscle activity.”

Aside from Dr. Behrman’s research, Reggie Edgerton at UCLA and colleagues have demonstrated promising results using locomotor training to restore function. There is a growing body of scientific evidence that points to the presence of central pattern generators in the spinal cord that can be activated despite loss of connection with higher centers of the nervous system. This applies to neurological disorders where voluntary muscle movement is available.

Treadmill systems, such as the Body Weight Support System, have been proven to improve locomotor skills with repetitive motion therapy. These systems can be used to provide stability during locomotion and to help progress weight bearing during stepping exercise. There are also seated systems used to assist in motion of the lower and upper limbs. The concept behind the therapy is to enhance the movement of a muscle that already exists voluntarily but needs a “boost” to make the contraction functional. Robotics technology has also been used to enhance muscle movement. One such therapy is used to improve upper extremity function for those with some voluntary muscle movement. It provides a fluid motion to extend the wrist and hand as much as possible voluntarily and then the device provides assistance to achieve full extension. This therapy is currently being used and tested for those who have suffered partial paralysis from stroke and other injuries. Movement enhancement devices do not replace therapy but improve it by providing tools. These tools go beyond traditional therapy to push the body toward more potential movement and improved exercise.

Finally, a few words regarding insurance coverage. Electrical stimulation and additional therapies can be covered by third party payers but it is not easy. Expect to provide research results, performance charts and letters of medical necessity. Reimbursement for FES systems can occur only after the patient has completed regular sessions of physical therapy with the device over a period of time. The Centers of Medicare and Medicaid have a standing non-coverage decision for electrical stimulation to treat disuse atrophy. Insurance reimbursement is possible, but that reward only comes with persistence.

Personal Experience: Susan & Matt

In this issue of *The Current*, we have stories from two users of electrical muscle stimulation devices. Each exercises daily but each started through different circumstances. Their experiences show that it is never too late or early to start exercising.

Susan Maus

For Susan Maus, combating secondary conditions is one of her concerns after acquiring a spinal cord injury. On June 30, 2000, outside Minneapolis, MN a driver drove through a stop sign and into Susan’s vehicle. She left the scene with a C4-5 incomplete spinal cord injury, and labeled a quadriplegic. Her most difficult challenge then was the lack of independence. With no wrist or hand function, she not only needed help transferring in and out of her wheelchair but also with adaptations for daily tasks like brushing her teeth. Four weeks of acute rehabilitation was “not good”. The only focus of those 4 weeks was getting her into the wheelchair and sending her home; sparking her concerns for acquiring secondary conditions, such as

wheelchair and sending her home; sparking her concerns for acquiring secondary conditions, such as increased risk of pressures sores, osteoporosis, diabetes and heart disease, which commonly accompany a spinal cord injury.

Motivated by this concern, Susan began to hunt the internet about spinal cord injury and rehabilitation. Her first introduction to Functional Electrical Stimulation (FES) was seeing the late Christopher Reeve use the FES bike and swim at Washington University. Armed with information, she encouraged her rehabilitation center to get an FES bike and she began riding during her outpatient physical therapy sessions. “Using the FES bike keeps you healthy,” explains Susan, “It helps to control my muscle spasms, fight off pressure sores, increases my range of motion, is great cardiovascular exercise and improves circulation.” This helps her fend off secondary conditions and allows her to continue rehabilitation. When her sessions stopped, she decided to get an FES bike for her home. “I’m lucky that I was able to purchase it outright and then work on reimbursement,” she reflects. With a prescription from her PM&R Doctor and a letter of medical necessity, she appealed for insurance coverage. The company, [Restorative Therapies](#), from whom she purchased the FES bike, handled much of the reimbursement process for her. Eight months later, it was approved and she received reimbursement from her medical insurance provider.

Excited about the progress made toward spinal cord injury over the past seven years, Susan continues to exercise with her FES bike 4-5 days per week for just over an hour per session. Although she has seen improvement in her condition from this therapy, she would like to also exercise her arms (which is an option recently added to the device) and stimulate her calves with the same device. Advice she provides to others with disabilities, “Reach out to others with the same injuries [conditions] and peers,” and “Get on an exercise routine and stay with it.”

Susan Maus lives in Minnesota with her husband and two daughters. She works in information technology for a health service company and is co-founder of [Unite 2 Fight Paralysis](#).

Matt Courson

Home-based exercise and therapy programs are what helped Matt. In April 2006, this college athlete fell down a 20 foot embankment with an ATV. He was recovered from the accident site five hours later and acquired paraplegia from a T-8 level spinal cord injury. After many hours of surgery and recovery he was transferred to the Baptist Rehabilitation Institute in Little Rock, Arkansas. One of his most difficult challenges facing a spinal cord injury was that he could not be active anymore. Being told the proverbial “you will not walk again,” shook up Matt but motivated him to do more.

For this twenty-two year old from a small town in Arkansas, home-based programs are a must. He could not get to outpatient rehabilitation; it had to come to his house. Almost one year post injury and looking to do more therapy, Matt attended [Project Walk](#) in Carlsbad, California. There he was first introduced to the FES bike. “I was impressed with the active therapy. You can really feel the workout.” Then he knew he wanted to ride it more. Unable to afford to pay for the bike themselves, their southeast Arkansas community and family raised the money to purchase the bike for Matt. Insurance coverage was not easy to obtain. Matt’s father, John, was intimately involved with the process along with the FES bike company, [Restorative Therapies](#). Together they submitted graphs and progression charts, including medical records. After the initial denial, they came back armed with a strong letter of medical necessity. Six months later, the Courson family was reimbursed 80 percent of the cost for the FES bike.

Using this home-based exercise, Matt stays healthy by riding it for one hour every other day. The FES bike is accessible so he can hook himself up and gets feedback from the system. He has seen his muscle mass increase, improved circulation, better bladder/bowel management and no pressure sore problems. In December, Matt attended the [Kennedy Krieger Institute](#) in Maryland. Here he received an exercise regime consisting of the FES bike, surface stimulation for other muscles and leg braces. “If you can afford it [the FES bike], it is a must have device. And if you can’t, then raise the money.”

Matt lives in McGhee, Arkansas with his parents. He also maintains an internet blog at <http://www.mattcourson.org/>

Resources For Exercising Weak or Paralyzed Muscles

There are many resources available for those to exercise weak or paralyzed muscles. The following is a listing of support organizations and neurotechnology organizations offering solutions for this condition.

Support Organizations

FES Rowing <http://www.fesrowing.org/>

International Functional Electrical Stimulation Society <http://www.ifess.org/>

The National Center for Physical Activity and Disability <http://www.ncpad.org/>

Neurotechnology Organizations

Axelgaard <http://www.axelgaard.com/>

Compex Technologies <http://www.compextech.com/>

Columbia Scientific <http://www.columbiasci.com/>

Dynatronics <http://www.dynatronics.com/>

Empi <http://www.empi.com>

Neotonus <http://www.neotonus.com> NUberwalker <http://tp.northwestern.edu/abstracts/viewabs.php?id=281&cat=132>

Quadriciser <http://www.quadriciser.com/>

RECK MOTOMed <http://www.motomed.com/>

Restorative Therapies <http://www.restorative-therapies.com/>

Robomedica <http://www.robomedica.com/>

RS Medical <http://www.rsmedical.com/>

SpinoFLEX <http://www.spinoflex.com/>

Stroke Recovery Systems <http://www.neuromove.com/>

Therapeutic Alliances <http://www.musclepower.com/>

Wearable Therapy <http://wearabletherapy.com/>

Zynex Medical <http://www.zynexmed.com/>

Information regarding these devices and organizations is available in the Educate section of our website at

On the Horizon: Updates in the World of Neurotech

- ◆ [Defense Advanced Research Projects Agency \(DARPA\)](#). DARPA's push to jump-start the production of an advanced, neurally controlled prosthesis with a Revolutionizing Prosthetics 2009 program, which will have a neurally-controlled arm and hand prosthesis ready for FDA approval and clinical trials in four years.
- ◆ [Cyberkinetics Neurotechnology Systems, Inc.](#), the Foxborough, MA, announced that it has received a letter from the U.S. FDA requesting additional analyses and data regarding its Humanitarian Device Exemption marketing application for the Andara Oscillating Field Stimulator system, a nerve growth stimulator designed as a treatment for acute spinal cord injuries. Based on the FDA's request, the company now expects that approval for treatment of acute spinal cord injury may be delayed until at least the first half of 2008.
- ◆ [Victhom Human Bionics Inc.](#), the Quebec, Canada manufacturer of neural prostheses, announced the first implantation of its Neurostep device, a fully implantable lower extremity FES system, in a patient suffering from foot drop secondary to a stroke. This implantation is the first in a clinical study which will evaluate the safety and performance of Victhom's Neurostep product at centers in Europe, Canada, and India.
- ◆ [Cleveland Medical Devices, Inc.](#) announced that it was awarded two U.S. patents for a shear force sensor that will be used in the prevention of pressure sores. Pressure sores develop when constant pressure reduces blood supply to the area. People confined to a bed or frequent wheelchair users are at greatest risk for developing pressure sores.
- ◆ At the Neurotech Leaders Forum in Newport Beach, CA, Neurotech Network hosted a Consumer Panel with disability leaders and individuals with neurological diseases and disorders. This panel discussion focused on issues of access, reimbursement and awareness. Among the participants were representatives from the Huntington's Disease Society, the Christopher and Dana Reeve Foundation and the National Multiple Sclerosis Society. A summary of the session and a link to the YouTube video can be found in the [Advocate](#) section of our website.
- ◆ [Med-El](#), the Innsbruck, Austria manufacturer of cochlear implants, announced it has received European market approval for the first EAS Hearing System. EAS is an implantable hearing system that is specifically designed for individuals with partial deafness—a mild to moderate low-frequency hearing loss combined with a profound hearing loss in the higher frequencies.
- ◆ [Northstar Neuroscience, Inc.](#), Seattle, WA announced that preliminary data from its PROSPECT feasibility study, which indicates that 10 or the 12 subjects using the Northstar cortical stimulation therapy contributed to an overall decrease in severity of depression and an overall increase in psychological functioning. The study was designed to assess the basic safety and effectiveness of cortical stimulation for patients diagnosed with major depressive disorder.
- ◆ A major study published in the journal *Pain* and supported by [Medtronic, Inc.](#) found that people with chronic neuropathic leg and back pain benefited significantly more from neurostimulation therapy plus conventional medical management than from conventional medical management alone. This therapy provided patients with significantly greater pain relief, quality of life, functional capacity, and

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therapy provided patients with significantly greater pain relief, quality of life, functional capacity, and treatment satisfaction.

Updates are available on our website. Stay updated by signing up for email notifications too. Visit our website at www.NeurotechNetwork.org.

Neurotech Awareness Coalition Unveiled

Neurotech Network announced the launching of a campaign titled the Neurotech Awareness Coalition. Jennifer French, Executive Director of Neurotech Network, announced details of the campaign on October 26 at the Neurotech Leaders Forum in Newport Beach, CA.

The goal of the new campaign is to target three major challenges facing the industry, the disability community and the medical professionals: reimbursement, market access and awareness. A major part of the initiative is public relations targeted toward medical and consumer media. French is also planning a direct outreach efforts, which will include coordination with patient advocacy organization.

Neurotech Network projects a budget of \$500,000 for the campaign and will be seeking financial support from manufacturers of neurotechnology, research centers and foundation grants. Several organizations announced their support for the initiative on October 26, including [Neurotech Reports](#), the [Neurotechnology Industry Organization](#), the [International Neuromodulation Society](#) and [CoActive Public Relations](#) of San Francisco, CA.

For more information, please visit the [Neurotech Awareness Coalition](#) website or contact us at info@neurotechnetwork.org or call 727-321-0150.

Neurotech Network awarded Conference Grant

Neurotech Network has been approved for a grant from the NIH/NINDS. This grant provides vital funding to proceed with a needed project to bridge the communication between neurotechnology scientists and clinicians. In conjunction with a compiled panel of industry experts, Neurotech Network will initiate this project to develop a session to be presented at the 2008 American Physical Therapy Association meeting in San Antonio, Texas.

This session will provide a forum for the presentation and demonstration of the most recent scientific and clinical findings in the field of neurotechnology for treating people with paralysis. It will also foster discussions and collaborations with investigators engaged in the development of these technologies to further translational and clinical applications, along with identifying key barriers to acceptance in practice. At conclusion, Neurotech Network will provide novel insights between front line clinicians, leaders in neurotechnology and end users. Results from this project will be posted to the Neurotech Network website.

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Remembering the Consumer

One of the most useful sessions at the 2007 Neurotech Leaders Forum in Newport Beach, California was a consumer/end-user panel discussion led by Jennifer French of Neurotech Network. In the session, French quizzed representatives of the Southern California neurological disabilities community about their attitudes and awareness of neurotechnology devices and therapies. Their answers shed considerable light on some of the challenges facing our industry in the years ahead.

In response to a question about sources of information about their condition, the users all said they relied on the Internet to stay informed. Several Internet resource services were named, but every panel member agreed that they use multiple resources, including news sites, disease/disorder-specific sites and Internet discussion forums to remain updated and learn about medical and technological advances. Other sources mentioned were peer support groups, association magazines or newsletters, local and national condition-based societies, and participation in clinical trials.

One panelist mentioned hearing about neurotechnology advances, such as brain computer interfaces and cochlear implants, in the media. Other panelists agreed that a media story could impact awareness, but that they then take that information and investigate it on the Internet, with a physician or a support group.

Regarding reimbursement for neurotech therapies, the panel offered some useful information to help make a case with insurers. For example, how the device or technology would reduce long-term care as well as cost-benefit analyses, are critical pieces of information. One user of an FES system mentioned that the ability to do home therapy is valuable. Another panelist spoke of the need for data to show increased independence, increased function, and increased ability to return to work. The ability to track costs was mentioned by an audience member. A neurotechnology device might not allow a person living with a disability to return to work but it may provide enough independence to allow a caregiver in the household to return to work. True daily costs of a person with a disability are not necessarily known or understood by third-party payers.

The information gleaned from these end-users highlights the useful role they can play in the design, development, and marketing of a new neurotechnology device. Vendors who take the time to cultivate this strategic resource will most likely find an essential partner to help them over the life cycle of a new product or therapy.

Commentary provided by Jim Cavuoto, Neurotech Reports

Impacting Government

Dealing with the government has always been one of the greatest challenges facing the neurotechnology industry. Whether waiting to get a new device approved by the FDA or jumping through hoops to get reimbursement by the Centers for Medicare and Medicaid Services, neurotech device firms frequently find themselves at the mercy of some government entity at every stage of the commercialization process.

Fortunately, there are signs that the situation is improving. Mark McClellan, former head of both the FDA and CMS, was generally upbeat on some of the trends affecting these two agencies. He praised Congress and the administration for passing the FDA Amendment Act of 2007, which reauthorizes FDA funding and user fees for the FDA. He pointed to FDA's commitment to more review milestones, support for critical path initiatives to streamline product approval cycles, and the government's endorsement of Bayesian statistical models.

We're also encouraged by the activity of nonprofit organizations active in our industry. Neurotech Network's new Neurotech Awareness Coalition specifically targets the challenges of neurotech device reimbursement and market access. Executive director Jennifer French believes that the key to addressing these two issues is increasing public awareness and understanding of neurotechnology device therapies. As more users and potential users of neurotech therapies become aware that there are viable alternatives to pharmaceuticals, they will exert more pressure on clinicians, regulators, and insurers to ease some of the pain associated with getting access to these devices.

We believe that Neurotech Network's activity will mesh nicely with the Neurotechnology Industry Organization's public policy campaign, which brings neurotech executives to Washington to interact with Congress and federal agencies. We also recognize the valuable lobbying efforts of the Medical Device Manufacturers Association and the more clinically oriented National Task Force on Consumer Access to Emerging Neurotechnologies.

Still, despite these positive efforts, it is in the interest of all neurotechnology vendors to maintain a proactive

Still, despite these positive efforts, it is in the interest of all neurotechnology vendors to maintain a proactive stance with government entities. McClellan recommends that device company executives meet early on in a product's life cycle with representatives from both CMS and FDA. He believes, as we do, that we're still only scratching the surface of the potential health impact of technologies. The combination of a more responsive federal government and a more alert private sector can only bring good things to our industry.

Commentary provided by Jim Cavuoto, Neurotech Reports

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