Falk Prosthetics & Orthotics
QUARTERLY

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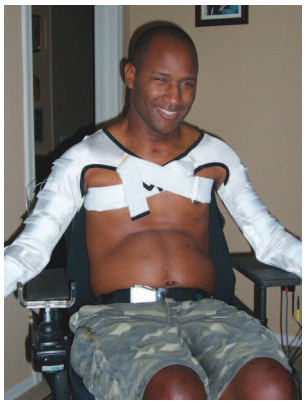
A 'Stimulating' Orthotics Advance

A new modality has taken up residence in the orthotics discipline, broadening rehabilitation horizons for many patients with neuromuscular dysfunction and/or chronic pain. This technology amplifies, and in some cases replaces, conventional orthotic management with neuromuscular electrical stimulation (NMES) to offer restored function, pain relief and other benefits to patients with paralysis or other deficit secondary to stroke, head or spinal cord injury, cerebral palsy, multiple sclerosis, or other conditions producing upper motor neuron pathway disruption.

In many central nervous system disorders, although the brain or spinal cord is damaged, the peripheral nerves connecting the cord to the muscles remain viable and thus responsive to electrical stimulation. NMES and its cousins FES (functional electrical stimulation) and TENS transcutaneous electrical nerve stimulation) are not new. However, recent improvements in miniaturizing and packaging componentry now allow stimulation devices to be worn effectively and comfortably on a patient's anatomy, much like a mechanical orthosis.

These components, variously termed neuroprosthetic or myo-orthotic devices, are being successfully applied to accomplish many traditional orthotic objectives, notably to...



Wearable therapy electrode garment

Courtesy Bioflex Electromedicine Inc.

- replicate normal muscle function
- enable standing and ambulation
- alleviate chronic pain
- reduce spasticity
- provide therapeutic exercise
- improve circulation and organ function
- increase joint range of motion
- re-educate voluntary muscles and
- reverse muscular atrophy.

NMES directs small electrical impulses to excite the nerves that supply paralyzed muscles. Electrodes may be applied on the skin surface, inserted deep into the muscle with a needle (percutaneous) or surgically implanted. Today's orthotic electrical stimulation strategies generally seek to maximize the effectiveness of surface applications, which are generally easier on the patient and thus advantageous in the long run.

Orthotics Today

Electrical stimulation for standing and ambulation may be used in a hybrid system in conjunction with traditional mechanical support, such as an AFO, walker, or elbow canes. However, in new devices developed for managing basic foot drop the stimulation unit may be used without auxiliary support.

Contraindications for using NMES include a history of cardiac or respiratory problems, seizure disorders, long bone stress fractures, osteoporosis or joint disease; irreversible contractures; Guillain-Barré Syndrome; pregnancy; skin disease or a fracture/dislocation near the stimulation site; morbid obesity; recent surgery; and use of certain types of pacemakers or implants.

WalkAide® FES system for addressing foot drop

Courtesy Innovative Neurotronics Inc.

Articles on pages 2 and 3 discuss three products producing excellent results in the management of foot drop and a unique approach to securely surface electrodes on almost any part of the body. We welcome you inquiries and referrals.

Welcome, Matthew Solazzo

Falk Prosthetics and Orthotics is pleased to introduce Matthew Solazzo, who recently joined our staff as an orthotic resident. Matthew is well-known to us, since we have been filling his prosthetic needs for the past nine years. He recently graduated from St. Petersburg College with a bachelor's degree in orthotics & prosthetics.

It is exciting to have worked with someone for many years as a patient and watch him transition into a peer. Matt will be a strong asset to our practice, and he should have an instant connection with our patients.

David Falk, CPO and staff hope you find **Falk's Quarterly** informative and welcome your questions, comments and suggestions.

Matthew Solazzo

Foot Drop Devices Enhance FES Popularity

Although functional electrical stimulation has been employed in the care of neurologically impaired patients for many years, the technology has proceeded in relative obscurity in the orthotics-prosthetics arena until the fairly recent introduction of portable FES systems for patients hampered by foot drop.

This condition is a frequent symptom of central nervous system dysfunction, can result from complete or partial paralysis or general weakness of the dorsiflexor muscles, and may be compounded by plantarflexor muscle group spasticity.

Courtesy Bioness Inc.

Patients with foot drop are seriously challenged when trying to walk. Unable to lift their forefoot normally during swing phase, they typically either drag their forefoot and toes—which can and often does precipitate a fall—or overcompensate with an exaggerated high-stepping pattern known as steppage gait. Often, the difficulties of ambulating with foot drop overcome the individual's motivation to walk at all.

Within the past few years, several lightweight, compact FES units providing stimulation of the peroneal nerve have been introduced to widespread market interest and acceptance and various medical product innovation awards. By enabling appropriate individuals to walk faster, longer and more confidently with reduced fatigue, these products are proving effective in helping people regain mobility and independence, thereby improving quality of life and productivity.

As a result, many patients afflicted with foot drop are able to replace their ankle foot orthosis or other type of mechanical brace with a small unobtrusive unit that can be worn out of sight under clothing.

This article will discuss the three leading foot drop FES orthotic systems in alphabetical order.

Bioness L300

Courtesy Bioness Inc.

Bioness L300

The Bioness L300 is the second product—the N200 Hand Rehabilitation System is the first—launched by Bioness Inc., a company formed in 2004 to help individuals with neurological impairment regain their independence. The Bioness system consists of three distinct elements "connected" by wireless communication:

1. A leg cuff containing the stimulator component attaches to the affected leg just below the knee. With the cuff properly in place, electrodes stimulate the peroneal nerve at the appropriate instant in the gait cycle to contract the dorsiflexors and thereby lift the forefoot.

2. A gait sensor attached to the wearer's shoe continuously tells the system where the leg is in the gait cycle and enables it to adjust for uneven terrain, ramps and stairs.

3. A hand-held remote control enables the wearer to adjust the level of stimulation and turn the unit on and off.

Bioness reports the L300 is finding particular applicability among M.S. patients.

FreeStep

Courtesy Bioflex Electromedicine

FreeStep™

The Bioflex Electromedicine FreeStep is described by its creator as a NeuroProsthesis™ (meaning a replacement for the impaired portion of the central nervous system). This system may be donned with a leg cuff to stimulate the peroneal nerve, or with the company's trademark spandex BioSleeve garment to function directly over the dorsiflexor muscle group.

The FreeStep also incorporates a heel switch, which triggers stimulation at heel-off at the initiation of swing phase and deactivates it at heel-strike and through stance phase. The stimulation dorsiflexes the foot in a physiological manner and does not restrict ankle motion.

Beyond re-energizing impaired dorsiflexors, the FreeStep has been cited as beneficial in chronic use for decreasing muscle atrophy and improving local blood circulation.

WalkAide®

Probably the best-known of the new FES orthoses for foot drop is the Innovative Neurotronics WalkAide® system. Unlike the aforementioned products, the WalkAide does not use a heel sensor after initial programming by a qualified practitioner, but relies on a self-contained tilt sensor in the stimulator unit to initiate and terminate stimulation during the gait cycle. The WalkAide is held in place just below the fibula head by a leg cuff.

After more than 10 years in development, the WalkAide has been shown to give patients a smoother, more natural and safer stepping motion. Successful users are able to walk faster and for longer distances with less fatigue.

WalkAide

Courtesy Innovative Neurotronics Inc.

The WalkAide is designed to be worn throughout the day, but is to be removed before retiring. Like the L300 and FreeStep, it should not be worn when showering, bathing, swimming, or otherwise immersed in water. Driving while wearing the WalkAide is strongly discouraged.

All of these systems are sophisticated medical products requiring a physician's prescription, thorough patient medical evaluation and programming by a qualified practitioner. Coverage for these still-new products varies by insurer.

Note to Our Readers

Mention of specific products in our newsletter neither constitutes endorsement nor implies that we will recommend selection of those particular products for use with any particular patient or application. We offer this information to enhance professional and individual understanding of the orthotic and prosthetic disciplines and the experience and capabilities of our practice.

Bioflex Electromedicine Inc. • Bioness Inc.
Innovative Neurotronics Inc.

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'Wearable Therapy' — Next Step In Electrical Stimulation Orthoses

Most of the buzz surrounding the incorporation of electrical stimulation technology into orthotic rehabilitation strategies has centered around the portable FES systems for foot drop described on page 2. However, the future of this modality extends far beyond that single application.

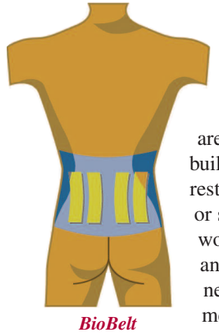
What's New

Electrical stimulation may be applied to any muscle group in the body to counter the effects of paralysis resulting from spinal cord injury, stroke or other neurological impairment. Stimulation has also proven valuable in the management of localized or widespread chronic pain.

BioVest

Essential to the effectiveness of this form of treatment is ensuring that the target muscle or muscle group is properly stimulated, which requires accurate positioning of electrodes over the affected area. While this outcome usually can be assured in a clinical setting, it is often advantageous for patients and their caregivers to be able to apply stimulation therapy at home, where correct electrode placement is both considerably less likely and generally more difficult. Moreover, the application of large numbers of electrodes sometimes required for aggressive stimulation management can be quite time-consuming...in any setting.

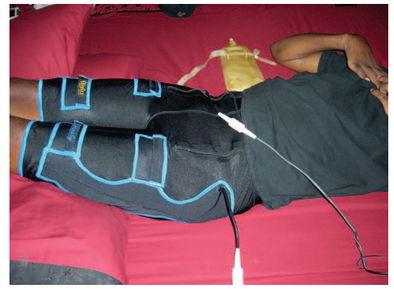
Wearable therapy, a concept developed by Bioflex Electromedicine Inc., tackles those problems with a line of custom "electrode garments" designed for easy donning and ensuring electrodes are positioned accurately with each application. The garments are made of spandex and feature built-in lead wires that do not restrict patients' movement, walking or sleeping. The wearable therapy system can work every major muscle group in the body and has been proven effective in functional, neuromuscular exercise, and pain management applications.



BioBelt

Functional enhancement: For patients whose neurological deficit will allow them to walk, wearable therapy can help provide the muscle strengthening, improved circulation and, where required, spasticity control and/or contracture reduction necessary for safe and sustained standing and ambulation. Similarly, the system can help paralyzed patients regain use of their upper extremities.

Neuromuscular exercise: Even patients whose deficit will not allow substantial functional improvement can benefit from wearable therapy. The late actor Christopher Reeve, who suffered a complete spinal cord injury with resulting quadriplegia in a fall during an equestrian competition, was an early user and active proponent of this system. Effectively bypassing the break in the actor's neurological system, the stimulation applied through Reeve's Bioflex garments kept his muscles functioning and his body healthy for several years through improved circulation, ongoing cardiopulmonary exercise, increased joint range of motion, diminished spasticity, and protection against undue skin pressure and attendant skin breakdown.

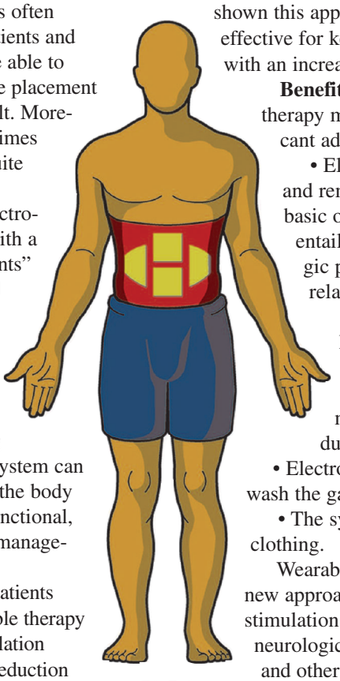


Wearable therapy electrode garment

Graphics courtesy Bioflex Electromedicine Inc.

Pain management: Neuromuscular stimulation with wearable therapy is also being effectively applied for reduction of chronic pain from different sources. Stimulation alleviates pain in various ways, including reducing tightness in muscles subject to spasm, improving circulation, and blocking pain signals from reaching the brain. Experience has shown this approach is in many cases effective for keeping pain at bay, even with an increase in physical activity.

BioSleeve

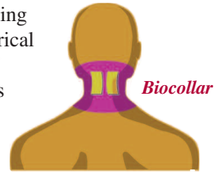


BioBelt

Benefits: Though still relatively new, the wearable therapy method of electrical stimulation offers significant advantages to patients and caregivers:

- Electrodes align correctly as the suit is donned and remain in place with activity. From a relatively basic one-site system to a multiple-site arrangement entailing as many as 46 electrodes for a quadriplegic patient, Bioflex garments can be donned with relative ease.
- Wearable therapy systems can be worn 6-8 hours a day to strengthen and refunctionalize muscles, combat spasticity and counter contractures. For pain applications, the system may be used up to 24 hours a day, including during sleep.
- Electrodes and wiring do not need to be removed to wash the garment.
- The system may be worn and concealed under clothing.

Wearable therapy is a promising new approach to delivering electrical stimulation therapy to a range of neurologically impaired patients and other individuals battling chronic pain. Insurance coverage varies with the provider and specifics of the patient's condition.



Biocollar

Additional information on wearable therapy can be found at **wearabletherapy.com**.

Navigating the O&P Insurance Maze

The Financial Side

Patients receiving a prosthetic or orthotic device for the first time may experience confusion and frustration at the often lengthy and mysterious process of obtaining insurance approval for the prescription their doctor has written for them.

In what some remember as the "good old days" of private indemnity insurance, delivery of orthoses and prosthetic limbs was seldom delayed by third-party intervention. The insurance company paid for the device the doctor prescribed minus any deductibles specified in the policy. That was then. Today, we operate under a whole new "alphabet soup" of insurance plans with different and detailed rules and requirements.

The net result is that doctors and prosthetist-orthotists no longer fully determine what prosthetic or orthotic device a patient will receive under insurance coverage...the ultimate decision-maker in many cases has become the insurance carrier. Particularly in situations involving newer high-tech componentry, the prescription is more of a recommendation to be submitted up the line for approval (unless the payment is coming from private funds). Obtaining that approval is not always easy or expeditious.

When we receive a referral for orthotic or prosthetic services, we initially verify the patient's coverage, normally a quick and simple process. Then, after an initial patient evaluation based on the doctor's prescription, we compile an authorization request to the insurer for services we intend to provide, using a series of "L-codes" established by the Centers for Medicare & Medicaid Services (CMS) and used by all U.S. payers and providers. Generally each insurer will follow CMS coverage parameters, amplified by its own policy limitations and exclusions.

While we can usually fabricate and fit, repair or enhance a brace or replacement limb in a timely fashion, we normally cannot begin the process until we can be certain the services will be reimbursed by the insurer. The review process varies by insurance company and sometimes results in a denial (which we may appeal) or a request for additional information...and time passes.

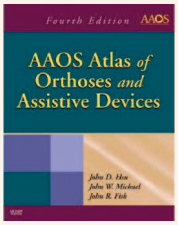
Prosthetic and orthotic coverage definitions in many policies may be vague and thus open to interpretation as to whether requested items or services are "medically necessary." Coverage is also generally limited to the item or service deemed the "least costly most functional alternative," also often undefined. As a result, we are many times required to justify each of the components and services we intend to provide with numerous back-and-forth communications between our staff and the case manager...and the clock keeps ticking.

Eventually, we are usually able to provide a satisfactory prosthetic or orthotic solution for the patient's needs. It's an imperfect system, but we strive to help all concerned navigate the O&P insurance maze.

If you have a specific question about Medicare or private insurance coverage, contact our office.

New AAOS Orthotics Atlas Arrives

The fourth edition of the *AAOS Atlas of Orthoses and Assistive Devices* is now available. Working in conjunction with the American Association of Orthopaedic Surgeons (AAOS), authors John Hsu, M.D.; John Michael, CPO; and John Fisk, M.D. have significantly revised the Atlas content and added a helpful two-color format.



The 672-page edition contains new chapters on cranial orthoses and orthoses for persons with post-polio syndromes. Each chapter includes sidebars with personal perspectives and tips from well-known physiatrists.

Existing, revised chapters cover orthotic prescription, strength and materials, normal and pathologic gait, and biomechanics of the spine, upper limb, hand, and lower limb. The chapters on spinal and upper- and lower-limb orthoses include new evidence-based recommendations for prescription.

The revised Atlas was recently priced at $159.20 at Amazon.com.

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