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Electronic Orthoses: Technology, Prototypes, and Practices

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Introduction

Functional electrical stimulation (FES) promises a new era in rehabilitation and orthotics, and offers great hope for patients who are wheelchair bound or suffering ambulation difficulties as a result of a central nervous system dysfunction. Many centers around the world are engaged in the design of FES prototypes for ambulation and exercise in subjects who have lost some or all control of their lower extremity muscles.[1,2,3,4,5] Three FES systems of varying complexity and purpose are reviewed on an informative level. The first system looked at is for walking and standing, involves many muscles, and relies on minimal mechanical bracing. The second is for standing utilizing mechanical support to assist antigravity muscles. The third is an apparatus for conditioning of muscles consisting of commercial stimulators and a garment containing electrodes.

Orthotists and prosthetists should be aware of the advances in FES technology and participate in its development and clinical implementation. Despite the hope that FES offers, technology is limited in its ability to replicate normal muscle function; therefore, these systems must encompass a certain degree of bracing for support, safety, and reliability. The two functional systems discussed here involve fitting of orthoses and biomechanical analysis of standing and walking; these are two areas in which the orthotist and prosthetist are adept. Even the third type of system involves some aspects of fitting expertise and technical knowledge. It should be recognized that these orthoses of the future will greatly involve the prosthetic and orthotic profession and will most likely contribute to its advancement as the technology is disseminated.

General Perspective

Researchers have sought to link FES and modern external brace technologies to make their systems safe and practical. An electronic orthosis is a system composed of a microprocessor-based muscle stimulator for the generation of electrical stimuli, and electrodes for the transmission of the signal to the body. Purposeful movement of the extremities and trunk can be achieved through computer-augmented muscle stimulation. However, FES alone, in its present stage of development, has inherent limitations in restoring function to patients safely and efficaciously. For this reason the integration of braces with FES has been spurred. "Hybrid orthosis" is the term used to describe an electronic orthosis combined with a mechanical orthosis. Petrofsky relied extensively on the Reciprocating Gait Orthosis (RGO) to support the body against gravity.[2] The FES component of his system (six muscles) supplied hip extension moments for forward progression and assisted hip flexion through the RGO's cable mechanism. Marsolais's approach has been to maximize FES and the number of computer-stimulated muscles and to minimize bracing; his system entails 32 active muscles in the lower extremity and trunk, along with bilateral ankle-foot orthoses (AFOs).[3]

It is clear that FES walking is approaching normal walking, biomechanically. As advancements in computer software and sensors continue, the need for bracing will be limited to the prevention of injury to the joints, soft tissue, and bones as a result of unnatural muscle contraction and awkward walking surfaces, mounting surfaces for sensors, and for partial antigravity support.[7,8] At present, it appears that bracing will be an important aspect to future clinical FES systems.

In addition to functional restoration, electrical muscle stimulation (EMS) has therapeutic value. EMS has been shown to reverse muscular atrophy, temporarily relieve muscle spasticity, and reduce or prevent soft tissue contractures.[6,9,10,11,12,13,14] In contrast to its role in functional activities, muscle stimulation for exercise is no longer considered experimental. Surface electrodes are ideal for delivering stimuli to some muscles without invading the body, but patients have difficulty applying individual, conventional electrodes to multiple sites on their body. Routine EMS therapy, conducted by the lead author, with as many as 20 electrodes embodied in a body-tight garment, has been shown to be practical and cost effective in a home setting.

Wheelchair transportation and ambulation with Knee-Ankle-Foot Orthoses (KAFO) are considered safe, functional, and cosmetically acceptable to many patients and to society. Moreover, the ergonomics of wheelchair ambulation are very favorable when compared to normal walking in terms of kcal/kg/min. Brace ambulation requires up to nine times more energy in terms of kcal/kg/m than normal walking, and only highly motivated patients use braces for everyday walking.[15] On the other hand, the efficacy of most FES systems has not been proven outside the research laboratory, because existing systems are prototypes and unsafe to take out of the laboratory for determining the level of mobility attainable. Moreover, the energy expended in FES walking is reported to be higher than that of ambulation with KAFO's at speeds under 0.4 meters per second. With all this in mind, it must be asked what role will FES play in rehabilitation?

In complete paraplegia, it is believed that FES walking will not replace the wheelchair as a means for ambulation, but it will supply patients with the ability to walk around the home, office or work place, or in public places like shopping malls. In hemiplegia or stroke, paresis and sensation loss generally affects the limbs and trunk unilaterally. In this case, the application of FES for the return of function is not as involved and indeed the non-affected side can help accommodate for deficiencies in the gait. These patients may abandon the wheelchair or conventional orthosis for an electronic or hybrid orthosis attracted largely by the more physiologic use of their limbs. In any situation, FES must allow the user to negotiate curbs, stairs, ramps, and tight spaces safely at speeds up to 1.5 rn/s at low energy costs.

Wheelchair users often express the desire to stand in order to greet, converse, and socialize with people who are not wheelchair bound. Standing permits people to look at each other "eye to eye" and to reach for things commonly out of reach when in wheelchairs. Medically, standing relieves pressures associated with arteriole occlusion that has been linked in the etiology of pressure sores. In many cases, FES will not replace the wheelchair as a means of ambulation, though it could be used as a means to stand repetitively through the day without mechanical knee and hip locks.

Two hybrid orthotic systems under development at the Cleveland VAMC Motion Study Laboratory are discussed, with particular emphasis, given to the mechanical orthosis design. A garment embodied with electrodes designed by the author for EMS therapy is presented as well. An overview of electrical stimulation technology is given as the basis for understanding the present limitations of FES and the importance of mechanical orthotic components in the successful implementation of electronic orthoses.

Interaction of FES With the Body

The human body can be made to respond to different forms of stimuli, i.e., electrical, chemical, pressure. The neuromuscular system is especially responsive to electrical signals delivered in short pulses of given intensity, duration, and frequency from external sources such as a muscle stimulator (Figure 1) . Variations in these three parameters can grade muscle contraction forces.

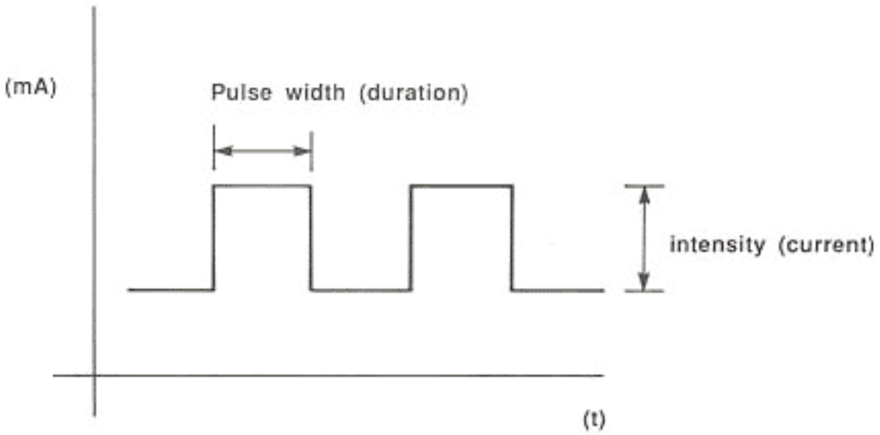

Figure 1.

A motorneuron is excitable by an external electrical source by inducing an exchange of ions (depolarization) between the interior and exterior aspects of the nerve cell membrane. The electrical threshold for depolarization must be met by the external source. However, nerves respond in an "all-or-none" fashion, and increases in the stimulus beyond the threshold will not result in an increase in motorneuron output. The increase in stimulus may result, though, in the recruitment of other motorneurons.

Muscle force is also modulated by the frequency of the stimulus. Muscle membrane or its electrical component has a refractory period to depolarization, but the actual contractile mechanism does not. By the time the membrane has resumed the capability of propagating another electrical wave through the muscle, the contractile mechanism is just beginning to shorten the muscle. A subsequent stimulus through the muscle fibers will shorten the muscle even further. As the frequency of the stimulus increases the distinction between muscle twitches decreases while the magnitude of the force increases.[16]

Electrodes

Three types of electrodes are used in EMS: (1) surface, (2) percutaneous, and (3) implanted. Each electrode has unique characteristics that make them advantageous for a particular use. In all cases, an active and an inactive electrode are necessary for current to flow through the tissues. Surface electrodes are placed on the skin of the patient, recruit large groups of muscles at once, and are removable after use. They are better at recruiting superficial muscles than deeper muscles, and do not select individual muscle groups as efficiently as the other two types of electrodes. Percutaneous electrodes are inserted with a needle through the skin deep into the muscle next to the motorneuron itself. With this electrode, individual muscles can easily be selected. Removal is possible, although they are generally kept in for long periods of time. However, they frequently break or move, and the potential for subdermal infections exists. Implanted electrodes are similar to percutaneous electrodes, except surgery is required for implantation and removal, and they generally are well secured. Therefore, the tendency to move away from the nerve is reduced.

Tissue Conductivity

The relative conductivity of tissue depends upon the water and ion content it contains. Muscle has 75%; fat 15%; skin and bone 5-15%. To pass current through tissues of higher impedance, a larger voltage is necessary. For instance, a higher voltage is necessary for surface electrodes to pass current through dry, low conductive skin and fat before reaching underlying motorneurons than for either percutaneous or implanted electrodes to elicit similar muscle contractions.[17]

Inadequacies of Artificially Evoked Muscle Contraction

Electrical stimulation of muscles is no match to normal neuromuscular physiology. The pathway from the motor cortex to a muscle consists of many interconnected excitatory and inhibitory synapses and a multitude of individual motor units that finely tune movements. The human body is a highly sophisticated neurological mechanism. In comparsion, electrical stimulation generates only one signal per muscle and all of the motor units elicited respond in unison. As a result, EMS lacks the ability to discreetly control a muscle.

Poor Selectivity of Afferent and Efferent Nerves

Two types of nerve fibers are prevalent in a peripheral nerve bundle; there are motor (efferent) and sensory (afferent) nerves arranged in an unpredictable manner. Normal volitional movement is the result of excitation from efferent fibers and inhibition from afferent fibers, both of which are controlled through the brain and reflex arcs in the spinal cord for fine motor control.

On the other hand, FES is primarily efferent stimulation, yielding gross muscular contractions as a result of excitation of afferent and efferent nerves that are, only coincidentally, in the proximity of the electric field and not according to any logical recruitment sequence.

Rapid Fatigue of Muscles

As a muscle continuously contracts, its force drops in reference to time as a percentage of its initial value. A 50% drop in 1 minute is typical in electrically stimulated muscle that has not been chronically stimulated, which is significantly faster than in normal muscle. Although the processes which cause rapid fatigue in FES muscle are not well understood, several theories are given:

Motor End Plate Failure Due to Excessive Stimulating Frequency

Motor end plates become incapable of depolarizing the muscle fibers when the firing frequency of action potentials exceed 15Hz according to Krnjevic and Miledi,[18] and 10 - 20Hz according to Kugelberg and Edstrom.[19] FES frequencies generally begin as low as 20Hz and can be as high as 70Hz. This is because only tetanic contractions are useful for purposeful movement. Lowering frequencies in FES results in degeneration of the smooth tetanic contraction into tremors and individual twitch responses. In normal contractions, the frequency of action potentials can be low because individual twitches in different muscles occur at different times. No matter how large the contraction, FES excites neurons simultaneously; thus, the same motor end plates are repeatedly activated.

Incorrect Recruitment Order of Muscle Fibers

The rapid fatigue rate in FES is also due to the reverse order of muscle fiber recruitment with increasing stimulus. Muscle is composed of two types of fibers, fast twitch (white) and slow twitch (red). Red fibers contract slowly, metabolize aerobically, and are fatigue resistant. Their axons have a high threshold to excitation. White fibers contract rapidly, metabolize anaerobically, and are less fatigue resistant than red fibers. Their axons have a lower electrical threshold than red fibers. During a sustained contraction, the natural recruitment order is first red fibers (fatigue resistant) then white fibers (non-fatigue resistant). FES recruits the fibers in reverse order due to the characteristically low electrical threshold of the white fibers: EMS invokes fast fatigue fibers before calling upon the more fatigue-resistant fibers.[20]

Blood Occlusion

For blood to flow adequately through muscle, the firing frequency must be lower than 20Hz for red muscle fibers and lower than 5Hz for white muscle fibers. As stated, FES firing frequencies are much higher than these values. Blood must flow through muscle to flush away metabolites that would otherwise accumulate and lead to fatigue.[21]

Excessive Stimulation of Muscle

Until closed-loop feedback control is developed with respect to timing of events in the gait cycle, overtaxation of muscles will be a major contributing factor to muscle fatigue. Openloop stimulation is a one-way delivery of electrical signals from a stimulator to a muscle. An open-loop stimulator is unable to turn on and turn off muscle contractions at precisely the right moment during the gait cycle; nor can it exactly balance the body against gravity or efficiently propel it forward because information about forces and moments are not sent to the computer. For example, in normal walking the quadriceps are active during the first 15% of stance, but they are inactive in the remaining 30%; thus, the duty cycle for the quadriceps in stance phase is 33%.[22] In FES open-loop walking, the duty cycle for the quadriceps may be as high as 75%-100% of stance phase.

In closed-loop stimulation, information about the condition of the body during standing or walking is taken from sensors mounted on the body and processed in the computer so that the muscles may be made to respond more appropriately to the environment and to perturbations. Closed-loop feedback control constantly analyzes the body much in the same way that the nervous system monitors the musculoskeletal system, i.e., proprioception, tendon-stretch reflex, and attempts to safely lower stimulation levels to the minimum necessary.

High Energy Standing and Walking

In two complete paraplegic subjects (T4 and T8), energy costs determined during FES walking using a rolling walker at a mean velocity of 0.24 m/sec was found to be 0.095 kcal/kg/min (SD 0.005), or roughly equivalent to that of a normal subject running a 13 to 15 minute mile.[23] In the same study, a comparison of standing with FES and with a KAFO showed that energy costs were 100% greater for FES, but when the minimum stimulus necessary to maintain a standing position was used, the energy costs decreased by 35% to 47%. It is theorized that the high energy in FES standing and walking is due to overstimulation and excessive torque production which should improve with advances in feedback control.

Although FES energy costs in reciprocal walking were found to be 39% higher than Knee-Ankle-Foot Orthoses (KAFO) ambulation (0.095 kcal/kg/min vs. 0.058 kcal/kg/ mm), there was a 75% or more increase in working muscle mass in the FES ambulator. This means that the intensity of work in FES walking is lower for individual muscle groups because the work load is dispersed among the upper and lower extremities and trunk muscles. In KAFO ambulation, the total body weight is elevated from the floor by the upper extremi ties, which only have 33% of the mass in the lower extremities. There are other means by which improvements in FES can lead to lower energy consumption. First, stimulation of the trunk and hip muscles can partially alleviate the demand on the upper extremities to balance and support the body weight during ambulation.

Second, faster walking cadences in terms of better muscle timing, longer stride length, and shorter stance and double stance times will mean increased energy efficiency per given distance covered. FES walking and KAFO ambulation are similar for speeds approaching 0.4 meters per second.

Electronic Orthoses

As an example of the variety of systems utilizing electronics to augment movement of the body, three electronic orthoses are outlined in regard to complexity, intended use, externally mounted device, and present results or impressions. Explicit detail is given of the mechanical brace components and electrode-body garment since these are the devices that orthotists and prosthetists should be most familiar with. The first two systems are still experimental and categorized as prototypes while the third system is classified under "practice" because it has been clinically implemented.

System 1 (Prototype)

Eight paraplegic research subjects at the Cleveland VA Hospital have been using a hybrid orthosis consisting of a 32-channel muscle stimulator and bilateral AFOs.[4,7,8] They have received up to 24 percutaneous electrodes in the pelvis and lower extremities and six surface mounted electrodes for the trunk muscles below injury level. The gluteus maximus, gluteus medius, semitendinosus, semimembranosus, and biceps femoris as well as the posterior portion of adductor magnus provide hip extension and coronal plane stability. Vastus intermedius, lateralis, and medialis muscles are implanted for knee extension. Plantarflexion and dorsiflexion actions are performed by the gastrocnemius-soleus complex and tibialis anterior muscle, respectively. The sartorius and tensor fascia lata muscles flex the hip. And finally, the erector spinae and quadratus lumborum muscles stabilize the trunk in the sagittal and coronal planes.

With this system, subjects have achieved reciprocal walking from 200 to 1,000 feet per day with speeds up to 0.9m/s. Several subjects have been able to climb stairs step-over-step.

System 1 hybrid orthoses do not restrict motion of the trunk, hip, knees, nor ankle dorsiflexion/plantarflexion. Presently, no attempt has been made to control the ankle electronically in the coronal plane. The inherent instability of the subtalar joint laterally, the inverting effect of the plantarflexors, and unlevel walking surfaces predispose FES ambulators to severe injury and possibly degenerative joint disease if precautions are not taken.[24] An ankle-foot orthosis was designed to mechanically maintain the foot and ankle in a neutral position and to prevent inversion of the foot, but to allow unrestricted dorsiflexion and plantarflexion (Figure 2) .

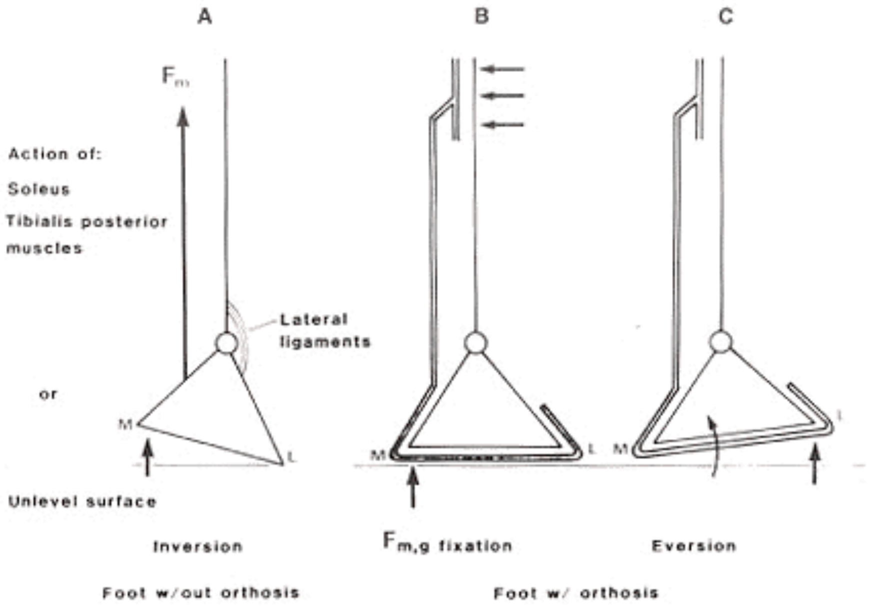

Figure 2. A. Inversion of foot due to muscle action and unlevel walking surface; B. foot and ankle fixed in coronal plane with orthosis to prevent inversion; and C. leg with orthosis, allowing eversion

The orthosis is constructed of lightweight graphite composite materials with a single, free-motion ankle joint on the medial side of the leg. The upper portion of the AFO extends along the medial aspect of the calf and wraps around the leg, proximally. The lower portion is a modified foot insert with standard UCBL trimlines, but cut away around the heel.

Some regions of the orthosis were purposely made resilient to accommodate the dynamic, physiological response of the lower extremity to FES (Figure 3) . Assuming the foot to be in plantarflexion, metatarsal-phalangeal (MP) extension is vital for the transference of body weight in "push-off" and in descending a step. The foot insert extends from the heel to the end of the toes, but the plantar surface from the MP joints distally is flexible to permit toe extension. The medial and lateral sides are also made flexible to conform to dimensional changes of the foot due to swelling, and to relieve the medial side of the foot of pressure caused by pronation in early stance.

Figure 3. Medial and lateral views of foot and foot orthosis: The flexible areas are shaded. The remaining aspects are rigid.

In response to a fracture at the base of the fifth metatarsal bone of one of the subjects while wearing an earlier version AFO (Figure 4B) , the foot insert was modified in a way that would allow a certain degree of eversion and, to a lesser degree, supination (Figure 2C) . The previous design rigidly fixed the foot in the neutral position so that weight was transmitted through the lateral border of the foot when the subject's hip adducted excessively , (Figure 4A) . In normal walking, exaggerated hip adduction does not occur because the center of gravity would fall too far lateral of the supporting foot and balance would be interrupted. But in walker or crutch ambulation, a wide base of support is maintained regardless of the position of the foot.

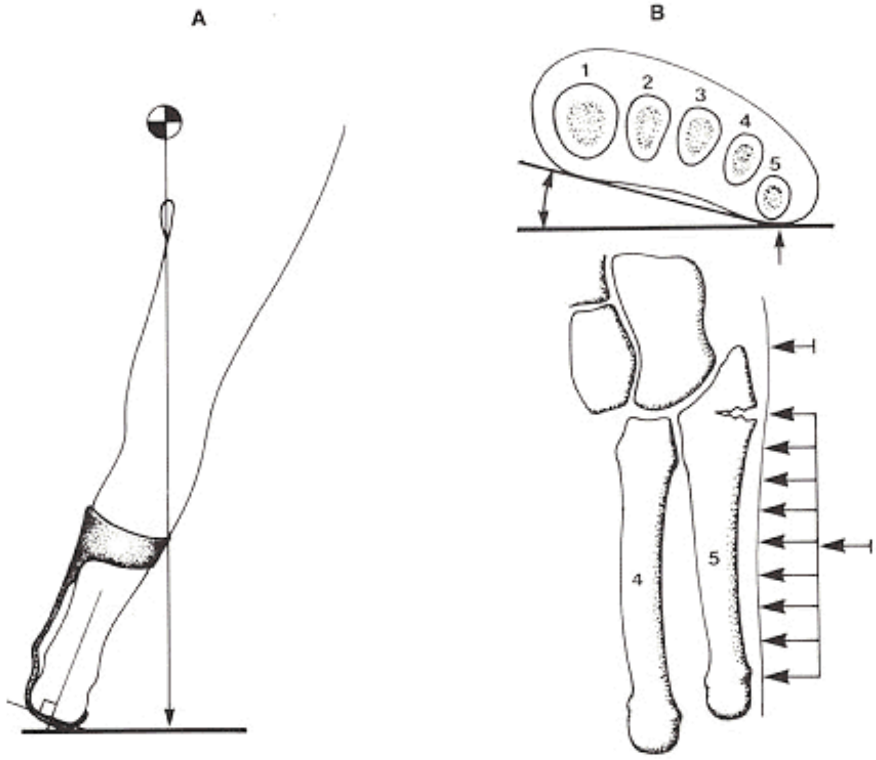

Figure 4. A. Posterior view of the foot in a rigid orthosis. The weight of the body is distributed to the lateral border of the foot. B. The arrows show the forces which may cause metatarsal fracture. Above: front view through metatarsal shafts; below: partial dorsal view.

For rigidity, unidirectional carbon fiber tape was used in the construction of the orthosis (Figure 5) . To satisfy the above criteria of flexibility, carbon fiber was not included in the relevant area; or as in the last example, the fibers were simply cut along the junction of the medial and plantar surface to create a "hinge" in the lamination (Figure 6) . The remaining aspects of the orthosis are rigid to provide the necessary support and protection of the foot and ankle. Sorbothane, 1/8" thick, was used as insole material the full length of the foot.[8]

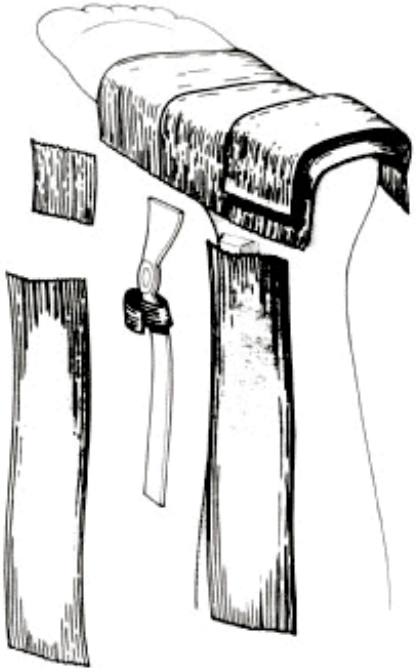

Figure 5. Exploded view of carbon tape and joint lay-up on a modified cast prior to trim.

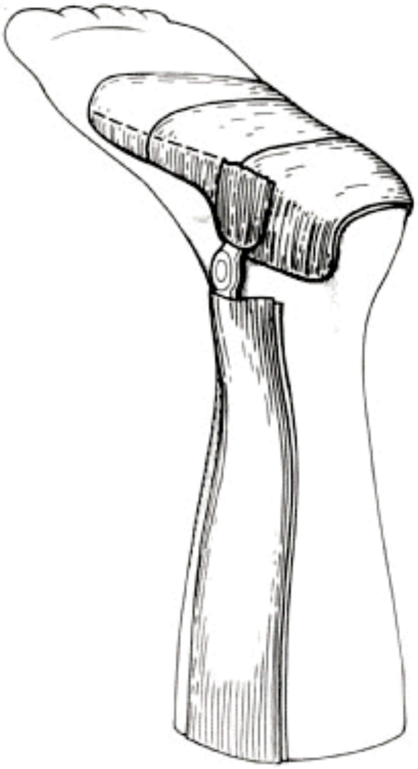

Figure 6. A view of carbon tape and joint lay-up after trimming. The dotted line represents a cut through the fibers of the carbon tape prior to lamination. When cured, the orthosis is flexible along this line.

Results

All eight subjects have stood and walked reciprocally using the hybrid orthosis system with varying degrees of success (Figure 7) . Two subjects have been using the electronic orthosis with the AFO's for three years. Blisters and a fifth metatarsal bone fracture have occurred while using the AFO. The orthosis prevents inversion of the foot (Only one subject had to be strapped to the orthosis just above the ankle to counteract the strong muscular forces causing his foot to invert.).

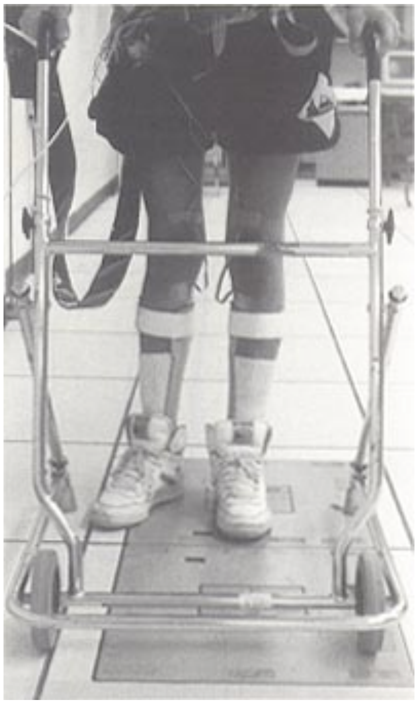

Figure 7. An anterior view of a subject standing using system 1 hybrid orthosis.

Since the newly modified orthosis has been implemented, no other foot fractures have occurred. This brace yields under loading to safely redistribute pressure from the lateral border to the entire sole of the foot if the lower limb is adducted. Moreover, the "hinge" is pliable enough to permit a small degree of supin that has been shown to be important when making the arch of the foot rigid in the late stance phase.

System 2 (Prototype)

The Cleveland VA Hospital Motion Study Laboratory, in conjunction with the Bioengineering Unit at the University of Strathclyde in Scotland, is developing a hybrid orthosis for standing which is comprised of a Supracondylar Knee-Ankle-Foot Orthosis (SKAFO), percutaneous electrodes, and a multichannel muscle stimulator. The hybrid prototype is designed to maximize standing time by minimizing quadriceps fatigue, primarily by reducing its duty cycle. This system is based upon a physiological principle seen in normal standing where knee moments are generated according to the position of the ground reaction vector (GRV) relative to the axis of the knee. In normal standing with the body erect, very little muscular activity is required to prevent collapse of the knee, particularly of the quadriceps which are the primary knee extensors. Forward sway tends to increase knee extension moments if the ankle is held rigid, while posterior sway beyond the vertical will induce a knee flexion moment that is counteracted by activation of the quadriceps. System 2 hybrid orthoses are designed to mimic this natural reflex.

The University of Strathclyde used a Floor Reaction Orthosis (FRO) with a tension sensor placed in-line with the subpatella pad along with surface mounted electrodes over the quadriceps muscle.[5] Supplementary sensory feed back was used during the laboratory standing tests to assist the patient in maintaining a set posture.

Floor reaction orthoses that provide knee stability to patients with partial voluntary knee control have been reported.[24] Clinical use of the FRO is based on the assumption that the patient's quadriceps, albeit weak, can compensate for destabilizing events when the orthosis is ineffective (Figure 8) . In complete upper motor neuron paralysis of the quadriceps, an FRO is not indicated, but a KAFO with knee locks is. The hybrid SKAFO attempts to eliminate mechanical locking of the knee by detecting knee moments and sending this information to the computer, which decides to turn on or off the signal to the quadriceps. The ngidity of the SKAFO ankle and foot plate allows considerable postural sway before the GRV passes behind the knee, indicating that the quadriceps should be activated.

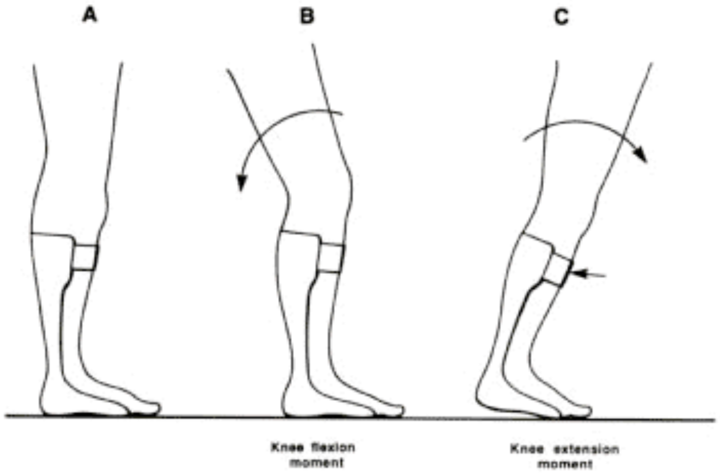

Figure 8. A Floor Reaction Orthosis (FRO) in quiet standing; B. A FRO has no effect in maintaining knee stability when the ground force vector passes behind the knee; and C. A FRO imposes knee extension when the ground force vector passes anterior to the knee.

Several prototypes of the SKAFO have been made of lightweight, graphite composite materials with rigid foot plates, lateral ankle joint, and medial and lateral knee joints. The foot plate is very rigid and extends beyond the toes to maximize forward position of the GRV relative to the knee axis. The knee joints permit full knee flexion, but they do have an extension stop. The knee joint uprights are instrumented with resistive strain gauges that detect changes in strain of the metal uprights when the joints have reached the extension stop (Figure 9) . The strain gauge signal is processed and interpolated into a knee extension moment value, which is a function of both the magnitude and line of action of the GRV relative to the ankle joint. A zero value is assigned to the flexed position because there is no strain in the metal. When a zero value is read by the computer, its response is to stimulate the quadriceps in anticipation of a pending flexion moment. A single, lateral double-action ankle joint with a dorsiflexion stop and free plantarflexion range was incorporated into the foot plate and leg sections. Variation of ankle stop position made it possible to isolate a comfortable standing posture prior to each standing session.

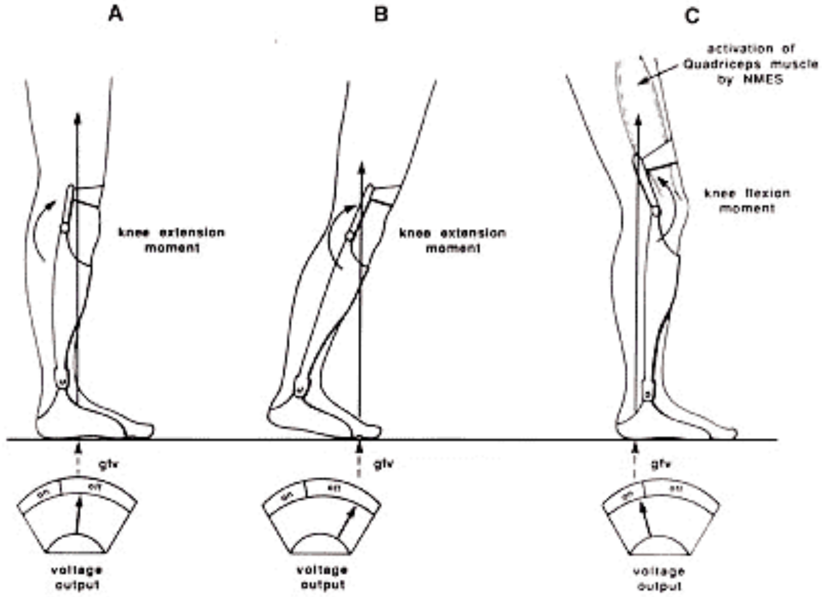

Figure 9. A system 2 hybrid orthosis with free-flexion knee joint and dorsiflexionstop ankle joint. A. A small knee extension moment is detected; the quadriceps are inactive; B. A large knee extension

moment is detected; the quadriceps are inactive, and C. The computer detects an impending knee flexion moment as voltage output nears set value; the quadriceps are activated.

Results

The University of Strathclyde reported standing in excess of 30 minutes for test subject #1 and more than one hour for test subject #2, with no quadriceps activity apart from that during the initial maneuver of standing-up. Subject #1 was male, aged 21 years, lesion T6-7 complete, and one year post-injury. Subject #2 was male, aged 23 years, incompletely lesioned at the level C6, and six years post-injury.

The Cleveland VA SKAFO is still under investigation. Preliminary standing and walking tests show that the unilateral upright design appears to be mechanically feasible. Conventional lamination techniques using unidirec .tional carbon fiber were used in the preparation of the SKAFO. Delamination occurred in the toe section, indicating a need for modification in lay-up technique to enhance strength in this and other areas.

System 3 (Practices)

A third type of electronic orthosis has been developed for practical administration of EMS therapeutically. It consists of a garment incorporating surface electrodes and portable multichannel stimulators. Whereas systems 1 and 2 are experimental in terms of the focus on future function and reliability, the benefits that the musculoskeletal system can derive from EMS presently are the basis for clinical implementation of System 3. Researchers had to demonstrate first that paralyzed muscle could hypertrophy from EMS so that forces would be sufficient for mobility activities. In addition, EMS has been shown to address some of the other sequelae of spinal injury and stroke. The garment system merely eliminates the need for patients to locate and tape to the skin a multiplicity of electrodes each time therapy is performed.

A form-fitting garment (NEUROpulse APPAREL$^{\text{Patent Pending}}$) containing transcutaneous electrodes was developed by the first author to overcome some of the problems with conventional electrodes. Conventional electrodes are individually applied and taped to the skin. On many occasions they peel away from the skin as the body moves. It is impractical for patients to apply these electrodes on a routine basis, and sometimes it is impossible to place them in areas unreachable by the hand. The garment is made of stretchable material with an array of electrodes in specific formation so that they line up over the motor points of the muscles every time the garment is donned. The garment material stretches with the skin and does not restrict movement.

Standard lower extremity garment sizes, i.e., small, medium, large, with fixed electrode patterns, are routinely used for spinal cord injury and other patients that have normal morphological structure. Sometimes it's necessary to custom-fit a garment to exactly locate an electrode over a motorpoint to achieve a good contraction or to adapt the garment for a better fit. When sensation is intact, it is especially important that electrodes be positioned properly to avoid pain from excessive sensory stimulation.

The garment electrode is a pocket for containment of electrolytic gel. The garment itself forms the underside of the electrode and is in contact with the skin. The topside is an insulating patch. In between the top and bottom of the electrode, but secured to the top, is a conductive silicone rubber electrode that disperses the incoming electrical charge to the full area of the electrode.

Gel is introduced into the electrode pocket via a large syringe through the underside of the fabric. Once inside the pocket, the gel wicks through and saturates the fabric. This procedure is performed with the garment turned insideout, and when all the electrodes are filled, it is turned right side out. Once the garment is donned, the wet fabric contacts the skin to complete the circuit between the electrode and the skin.

The garment system makes it possible to apply electrodes to the posterior aspect of the body. When using conventional electrodes, many patients have trouble dealing with posterior electrode placement because they cannot reach the intended area with their hand to adhere the electrode, or they have difficulty finding the exact location where the electrode should go because they cannot see the area directly. For example, in spinal cord injury, selfapplication of conventional electrodes to the gluteal muscles is nearly impossible.

A brief-style garment containing electrodes for the gluteals has made it possible for paraplegic patients to stimulate these muscles on a routine basis (Figure 10) . The garment is easy to slip on and once in place, the patient can plug the stimulator lead wire into anterior receptacles. Each posterior electrode is electrically connected to the anterior receptacle by means of an elastic wire that wraps around from front to back. Other garments have been made for the back of the neck, shoulder, arm, trunk, and lower extremity muscles.

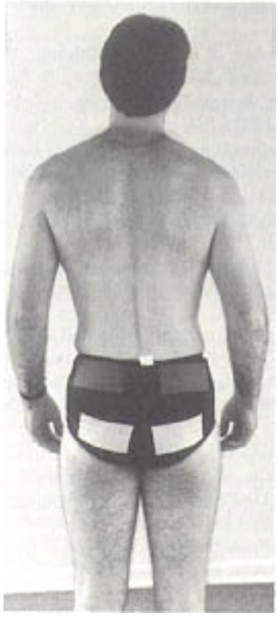

Figure 10. System 3: A pair of briefs incorporates electrodes for bilateral stimulation of the gluteus maximus.

Clinical Impressions

Although scientific evaluations of this particular garment design are not presently available, a lot can be said about the clinical experience, both physically and psychologically. In general, the garment has shown that home EMS therapy is significantly more practical for patients in various disability groups than with conventional stick-on electrodes in terms of set up time and accurate and consistent relocation of electrodes. Patients have demonstrated the ability to don and doff the garments in less than five minutes and have no difficulty ensuring that the electrodes have been aligned properly; only minor adjustments have been necessary.

Patients using the garment system have reported improvements in the physical condition of their body. A spinal injury patient that had partial pelvic sensation stated that he felt relief from pressure on the sacrum after several weeks of gluteal muscle stimulation as a result of increases in muscle bulk in that area. Another spinal injury patient noticed that getting into her KAFOs was easier due to a decrease in hypertonicity of the ankle muscles. EMS has been shown to reduce spasticity in multiple sclerosis patients, thereby allowing voluntary movements to manifest themselves without spasticity.

A positive psychological effect has been noted in patients using the garment system. Patients look upon electrotherapy favorably because it usually improves the function, condition, or appearance of the body. In fact, it has been the authors' experience that patients enjoy learning about different muscle groups, seeing their muscles contract and their body responding to EMS over time. Application of the garment is easy; therefore, patients are usually willing to comply with the protocol set up by the therapist.

In 20 spinal cord injury patients fitted with stock briefs for the gluteals, and pants for the hamstrings, quadriceps, plantarflexors, and dorsiflexors, no alteration in the garment size nor electrode position was necessary. A head injury, cerebral palsy, and club foot patient also received stock garments. Alteration of a stock model or. complete customization occurred in seven spinal, one multiple sclerosis, and one sports medicine patients. Basically, the factors indicating custom garments are: (1) sensitivity to electrode position; (2) inability of stock garment to conform to the body; and (3) intended muscle group stimulation pattern not available in stock garment electrode array.

Discussion

Worldwide participation in the development of ambulatory and therapeutic electronic orthoses has led researchers to believe that these systems are feasible in terms of restoration of function and reconditioning of atrophied muscles. For electronic orthoses to be implemented clinically, researchers must prove that these systems can be practical for everyday use. In other words, the gadget tolerance must not be exceeded; the electronics, electrodes, and wires must not fail more than once or twice per year; the systems must be easy to don and doff in less than five minutes; and they must be reliable and safe. The function derived from electronic orthoses must meet or exceed the expectations of the users so that patients will be motivated to use the system and not reject it during times of frustration when the system fails.

Only therapeutic electronic orthoses have been shown practical at this stage for clinical use. The garment system described allows patients to don more than 18 surface electrodes in less than five minutes and exercise five major muscle groups in one and a half hours.

Current attempts to substitute the nervous system with electronics and electrodes has given tremendous hope that walking can one day be restored to patients who have suffered spinal injury or stroke. To make this dream turn to reality, it must be shown that advances in sensory feedback control and innovative mechanical orthosis design can solve many of the shortcomings of artifical muscle contraction. The orthotic and prosthetic profession has been intimately involved thus far in research and development and it stands to reason that the hybrid orthosis will require the talents of orthotists in the delivery of future clinical systems.

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