The Bionic Glove: An Electrical Stimulator Garment That Provides Controlled Grasp and Hand Opening in Quadriplegia

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ABSTRACT. Prochazka A, Gauthier M, Wieler M, Kenwell Z. The bionic glove: an electrical stimulator garment that provides controlled grasp and hand opening in quadriplegia. Arch Phys Med Rehabil 1997;78:608-14.

Objective: This report describes the operation of the Bionic Glove, a new functional electrical stimulation (FES) device designed to improve the function of the paralyzed hand after spinal cord injury (SCI) or stroke.

Design: Signals from a sensor in the glove detecting voluntary wrist movement are used to control FES of muscles either to produce hand-grasp or to open the hand. When the glove is donned, conductive areas on its inside surface automatically make contact with self-adhesive electrodes on the skin.

Setting and Patients: This report concerns nine people with SCI who have used the device in their daily lives for up to a year or more. Measurements were made at clinics in Edmonton, Miami, and Chicago as part of a multicenter clinical trial.

Outcome Measures and Results: The mean peak force of tenodesis grasp in the nine subjects increased from 2.6N (passive) to 11.3N (glove active). Active force was significantly greater than passive grasp force even when muscles were fatigued after repetitive grasp-release cycles. Most manual tasks improved significantly with the use of the glove, as judged by the number of tasks completed in a minute or the subjects' qualitative ratings of task difficulty.

Conclusion: The Bionic Glove can provide significant improvement of hand function in people with C6-C7 SCI.

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THE PURPOSE OF THIS article is to provide technical and clinical information on a new electrical orthosis that improves hand function in people with spinal cord injury (SCI). Muscles paralyzed because of SCI or stroke may be stimulated electrically through their surviving motor nerve supply. This provides an opportunity to improve motor function by functional electrical stimulation (FES) or therapeutic electrical stimulation (TES). Many different FES applications have been explored since the pioneering work of Liberson et al¹ on footdrop.²³ Foot-drop stimulators became commercially available

around the world and were used by several thousand people with hemiplegia. After much optimism about FES in the 1960s and early 1970s, however, the field went into a decline. This was partly because of the reliability problems of early devices and a perception that there was insufficient motor gain in relation to their cost and the inconvenience of donning and doffing them. In the last few years, however, there have been some notable technical advances in both noninvasive FES devices and in implanted neuroprosthetic systems.^{2,4}

Some physiotherapy departments now routinely use portable muscle stimulators with surface electrodes to strengthen the ankle dorsiflexors or to provide orthotic assistance to muscles to correct foot-drop. Some people with hemiplegia and quadriplegia buy such stimulators for home use. Several thousand surface foot-drop stimulators have been used daily by people with hemiplegia. In the early 1970s, implantable, inductively coupled, single-channel stimulators for foot-drop were tested in more than 30 people with hemiplegia. 6 and in the early 1980s a few individuals were implanted with multichannel percutaneously controlled stimulators for hip and thigh muscle activation.

FES and TES have also been studied in the upper extremity. 4.8-12 There has been a slow but steadily increasing acceptance of surface TES for strengthening hand and forearm muscles. 13-15 After a series of experiments using percutaneous intramuscular wire electrodes to restore hand and leg function in people with SCI. 10.16-18 implanted multichannel FES stimulators were developed. 4 Since 1991, the CWRU-NeuroControl hand grasp/release neuroprosthesis has been implanted in 39 people with SCI, and initial clinical results show a high rate of compliance and satisfaction with these devices. 19 Implanted systems are fairly costly and not all subjects accept the idea of surgery for this purpose, at least at the outset. There is therefore a need for complementary noninvasive surface systems for upper extremity TES and FES.

In the 1960s an FES stimulator was combined with a mechanical hand orthosis and used successfully in tasks of daily life by a SCI man for more than a year.20 A hinged splint combined with FES was tested at Rancho Los Amigos Hospital.14 This device, which was intended for TES only, allowed users to control stimulation of finger extensors by push-button or wrist movements.21 In the last 5 years, two new surface FES systems have been developed for the upper extremity: the "Handmaster" 22-24 and the "Bionic Glove" 25.26 The Handmaster is similar in concept to the Rancho device.14 It consists of a hinged shell that partially envelops the forearm and a spiral segment that splints the wrist and extends over the thenar eminence. Electrodes on the inner surfaces of the shell and thenar plate are pressed onto the skin overlying forearm and thenar muscles when the splint is donned and the shell is closed. The electrical stimulator is in a box worn separately and linked to the splint by a cable. Stimulation is triggered via push-buttons on the box. The splinting of the wrist at a fixed angle is suitable for people without active wrist movement (C4-C5 quadriplegic and many

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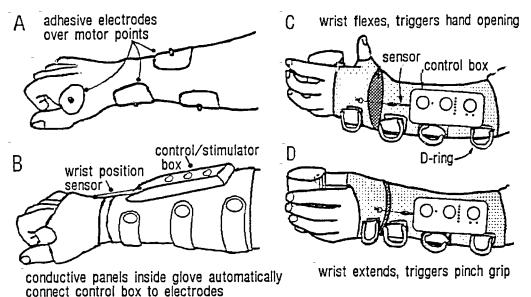


Fig 1. The Bionic Glove. (A) Selfadhesive electrodes are placed over motor points of the muscles to be stimulated. (B) The glove is donned and tightened onto the electrodes, making electrical contact with them (Fig 2). (C) Voluntary flexion of the wrist to a preset trigger angle initiates stimulation of the muscles that open the hand. (D) Extending the wrist to another trigger angle directs stimulation to the muscles that produce grasp.

hemiplegic subjects). However, it would impede movement in people with C6-C7 functional SCI and people with hemiplegia who have active wrist extension. An arm-cuff version has been suggested for such cases.²⁴ The Handmaster is currently in multicenter clinical trials, and it is available commercially in Europe, but few details are available about its performance at this stage. Recently it has been shown that, in principle, myographic control of FES of the upper extremity is feasible¹²; however, the problem of electromyogram electrode and stimulating electrode placement within a practical device has not yet been addressed.

In this article, we describe the design and operation of the Bionic Glove and present some preliminary clinical data on its use.

METHODS

The Device

The Bionic Glove was developed in 1989 and in that year the first prototype was used daily for several months by an 11year-old girl who had sustained a C6 SCI 2 years earlier. Since then, the device has had numerous design changes and improvements and at the time of writing, the sixth-generation prototype has been tested by 37 SCI people in seven centers in Canada. the United States, Europe, and Australia. The Bionic Glove is a fingerless glove that electronically senses voluntary wrist movements and provides FES of muscles controlling the fingers and thumb either to produce hand grasp or to open the hand (fig 1). The device may be donned independently or with minimal help. Conductive areas on the internal surface of the glove automatically make contact with self-adhesive electrodes previously placed on the skin over selected muscles. Trains of electrical pulses are delivered via these electrodes through the skin to the target muscles, causing them to contract. The electrode closest to the wrist is the anodic (indifferent) electrode. For hand opening, one motor point can usually be found on the posterior forearm that simultaneously stimulates the long finger flexors and thumb abductors. For grasp, the long finger and thumb flexors are stimulated through the proximal electrode on the anterior forearm shown in fig 1. In addition, flexor pollicis brevis is stimulated through a distal electrode over the thenar eminence.

The source of the electrical stimuli is a battery-powered electronic circuit located in a flat box in a pocket on the back of the glove. Wrist movements are sensed by a displacement transducer that spans the wrist joint from the box to a point on the back of the hand portion of the glove. The user selects the mode of operation by pressing one of the three buttons on the control box. Combinations of button presses and wrist movements allow the user to change stimulus strengths for each electrode, to change all four trigger angles described in figs 1 and 3, and to turn an audible stimulus-monitor on and off.

The glove is made of the elastic material Neoprene with 1-mm diameter perforations for ventilation. Lycra mesh links the hand and forearm portions of the glove over the wrist crease. Lycra and polyester nylon panels in the forearm portion of the glove further improve ventilation. Horse-hide patches on the palmar portion maximize traction on wheelchair rims. In some gloves a universal cuff was included as part of the palmar patch. The glove has four Velcro straps with D-rings that are used to close and tighten the garment onto the forearm and hand. The rings are large enough to enable the user to insert a finger to pull the strap tight.

The wrist-position sensor is an inductive linear variable displacement transducer. It comprises a glass tube located inside the control box with a multiturn coil of wire wound onto it. A multistranded metal stylus (bicycle brake cable) moves in and out of the tube as the wrist joint angle changes, changing the inductance of the wire coil. This change is converted into a control signal by the circuitry in the control box.

Figure 2 shows a self-adhesive FES electrode and a stainless-steel mesh contact panel sewn between the inner surface of the glove and a Neoprene inner lining. The lining has a window over each contact panel, with fingerlike extensions that prevent; the panel making contact with the skin. The electrode is pressed onto the skin over the muscle to be stimulated. It is provided with a metal stud similar to that in a snap connector but somewhat augmented in height. When the glove is donned, the metal stud on the back of the electrode presses through the window in the inner lining onto the contact panel. The contact panel is connected to the circuitry in the control box by an insulated stainless-steel wire. Donning the glove therefore automatically connects the output terminal in the control box to the skin through the wire, the contact panel, and the electrode. Electrical

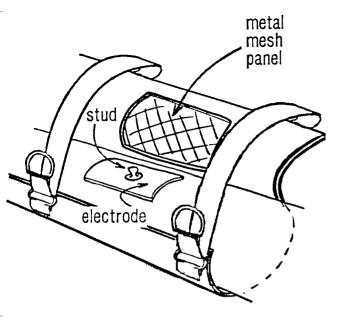


Fig 2. Electrode contact. When the glove is donned and tightened, a contact panel between the inner surface of the glove and an inner lining presses onto a metallic stud on the back of a self-adhesive gel electrode. The contact panel is connected to the circuitry in the control/stimulator box.

current is thereby transmitted through the conductive gel layer of the electrode into the user's skin.

Electrode Positioning

The motor points over the forearm and hand muscles to be stimulated were established empirically by the clinician during the initial fitting procedure. A conventional physiotherapy stimulator could have been used to identify the motor points. For convenience, however, the glove control box provided appropriate test pulse trains. Test leads were connected to the box by the clinician. The leads were then connected to pad electrodes suitable for exploratory stimulation of motor points on the subject's hand and forearm. The targeted motor points and corresponding muscles are as follows: thumb flexion motor point. flexor pollicis longus; finger flexion motor point, flexor digitorum superficialis; thumb flexion and adduction motor point. flexor pollicis brevis and adductor pollicis. An electrode just proximal to the wrist crease acted as the indifferent (anodic) electrode to return the current injected through each active electrode. The current was delivered in the form of biphasic pulse trains. When the glove was donned, pulses were routed to each cathodic electrode in turn in an interleaved sequence. The pulses had constant-current, biphasic, rectangular waveforms, the secondary pulse returning about 50% of the charge delivered by the primary pulse. Typical pulse parameters were 20 to 30pulses/sec, 100 to 200µsec primary pulse duration, 25 to 35mA, 25 to 35V amplitudes. All parameters were initially preset by connecting the Bionic Glove control box to a notebook computer via an isolated photoelectric communications port. Custom software allowed clinicians to set all parameters by point-and-click on graphical icons. Stimulation was essentially ON-OFF, though to reduce the abruptness of onset, pulse width was automatically ramped up from a minimum of 50 μ sec to the preset primary pulse duration within a time that could also be set by the clinician, typically 0.1sec. All parameter settings were done by interacting with the patients to establish the most comfortable and effective values.

Control Strategies

Stimulation of the muscles that produce hand grasp was triggered by extending the wrist. Stimulation of the muscles that produce hand opening was triggered by flexing the wrist. The precise trigger angles were set by the user to be optimal for particular motor tasks. This was achieved by pressing one of the buttons on the control box and flexing and extending the wrist back and forth between the desired new trigger points. The microprocessor controller allowed a settable time, typically 1.5sec, for this process and then assimilated the new settings. Some subjects used this feature, while others did not. Stimulus strength was preset for each muscle separately at the initial fitting session, but users could easily change these values by pressing one of the control buttons to select the appropriate muscle and then flexing or extending the wrist to increase or decrease the stimulus intensity. Again, some subjects used this feature while others made do with settings that provided a good compromise for a range of tasks.

A feature that was important for some users was trigger hysteresis; when hand opening or grasp are triggered by moving the wrist to given positions, the wrist must be moved back beyond these points to turn stimulation OFF (fig 3). The amount of overshoot or hysteresis could be preset in the Bionic Glove to suit tasks performed by individual users. Hysteresis was expressed as a percentage of the angle subtended between the two (flexion and extension) ON trigger points. For example, if the ON trigger points were set to $\pm 20^{\circ}$ wrist angle, respectively. the subtended angle was then 40°. If hysteresis was set to 25%. the corresponding OFF trigger points became ±10° (ie. once triggered, stimulation was not turned OFF until the wrist was moved back to within 10° of neutral). For 40% hysteresis, the corresponding OFF trigger points became ±4°, and so on. High 🛝 levels of hysteresis (up to 90%) were found to be effective for using tools such as a hammer or screwdriver, because after triggering the grasp at a fairly extended wrist angle, the user could flex the wrist 90% of the way back to the hand-opening trigger point without inactivating the grasp.

Subjects

This report describes results obtained in 4 subjects in Alberta and 5 subjects in β test sites in the United States. The 9 included 8 men and 1 woman. All test procedures complied with protocols approved by our university hospital's Ethics Committee. with additional approval by the internal review boards at the test sites. The SCI subjects, whose age ranged from 22 to 41 years, had functional levels of injury in the range C6-C7. The

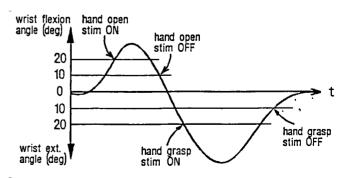


Fig 3. Hysteresis. Wrist angle is used to switch stimulation on and off. In this example, when the wrist flexes to 20°, stimulation causing hand opening is initiated. Hand-open stimulation is turned OFF by re-extending the wrist to 10° flexion. This mismatch in the ON and OFF trigger angles is termed hysteresis.

time after injury that subjects were first fitted with gloves ranged from 16 months to 22 years. All nine subjects were fitted with Bionic Gloves for use in activities of daily living. Their participation in the project ranged from 3 months to 7 years. Four subjects used their gloves for more than a year. The design of the device has evolved as a result of feedback and suggestions from the subjects.

Measurements

A battery of tests was performed on each of the subjects at different stages of their participation. Hand-grasp force was measured using a custom-built myometer, which consisted of an air-filled plastic pad 7 × 9cm in size, inflated to a central thickness of 1.5cm. This was preferable to a conventional physiotherapy pinch-grip gauge (Jamar hydraulic hand dynamometer) because it was less directionally selective in monitoring squeezing forces produced by finger flexion and different combinations of thumb flexion, opposition, and adduction. We did not differentiate between lateral prehension (key-grip) forces and palmar prehension forces: the sensor, which was placed between the interphalangeal joints of the thumb and forefinger, responded to a combination of the two. The force measurement protocol was designed to quantify peak dynamic force with and without stimulation as well as fatigue during prolonged stimulation. Statistical comparisons were performed using Jandel Sigmastat software. In addition to the force measurements, the subject's ability to perform standard manual tasks was timed by stopwatch with and without stimulation. All trials were videotaped for later analysis.

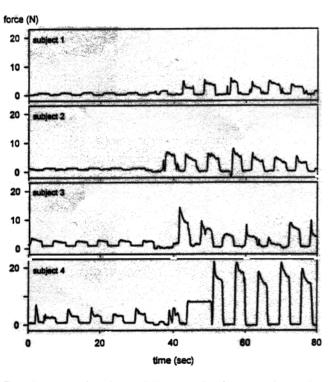


Fig 4. Hand-grasp force in four SCI users performing successive passive tenodesis grasps for about 35 seconds, followed by grasps with the active use of the glove. Across subjects, the mean peak force in passive tenodesis grasps was 2.3N, compared to 13.6N with the glove. The phasic nature of the active force profiles was consistent with muscle fatigue of fast-fatiguable muscle fibres, as expected of muscles that are rarely active.

Table 1: Peak Hand-Grasp Forces at Onset of Grasp and After 5 Seconds of Maintained Grasp

Passive Force (N)	Active Force (N)		
1st Grasp	1st Grasp 5th Gr		asp
Subject Onset Sec	Onset 5sec	Onset	5sec
			1000

The first passive grasp in each test sequence was measured. In active (FES-assisted) trials, the first and fifth grasp of a sequence was measured. The reductions in force values from the first to fifth grasps resulted from muscle fatigue.

RESULTS

The Bionic Glove was designed to be donned and doffed unaided by people with C6-C7 SCI. Only one of the 9 subjects relied on an assistant for help. Typically, subjects required 5 to 10 minutes to don the glove. Most of the time was taken in detaching the adhesive electrodes from their backing and placing them accurately on the skin. To make this task easier, we attached a loop of ribbon to each electrode and this decreased the donning time by about a minute. We have recently developed wettable electrodes within the glove that do not need to be separately attached to the skin. Early results indicate that these reduce the donning time to less than 1 minute.

Force Measurements

Figure 4 shows the hand-grasp force measured in four subjects during passive and FES-activated tenodesis grasp. The subjects generated the grasps by extending their wrist to about 30° to 40° from neutral. They were asked to grasp for about 5 seconds and relax for about 5 seconds and repeat this for 2 minutes. Five to 6 passive grasp cycles were followed by a similar number of cycles in which the Bionic Glove was active.

Subjects 3, 4, and 8 (the latter not illustrated in fig 4) showed marked phasic components in their passive tenodesis grasps, with peak forces of 3.0, 4.8, and 11.9N, respectively (table 1). The high forces and the phasic profiles suggest reflex activation of the muscles in the passive grasps of these subjects. The peak passive grasp forces of the other six subjects were all below 1.3N, phasic components of force were absent, and so the muscles were presumably inactive throughout.

The active grasps of all nine subjects were nearly all characterized by phasic force profiles and a tendency for a decline in peak and mean forces in consecutive cycles. This is consistent with muscle fatigue of fast-fatiguable (type FF) muscle fibres.²⁷ The three subjects with strong, phasic passive grasps discontinued regular use of the Bionic Glove after 3 to 4 months, partly because the motor improvement did not outweigh inconvenience.

Table 1 shows results from all nine subjects. We measured the forces at the onset and termination of the first passive grasp in a sequence and the first and fifth active grasps. The latter provided a measure of fatigue. The peak passive force at grasp onset (F_p) across the nine subjects was $2.6N \pm 3.8N$ (mean \pm SD). The peak force in the first active grasp $(11.3N \pm 7.4N)$ was significantly greater than F_p (p = .0064, t test). Even the

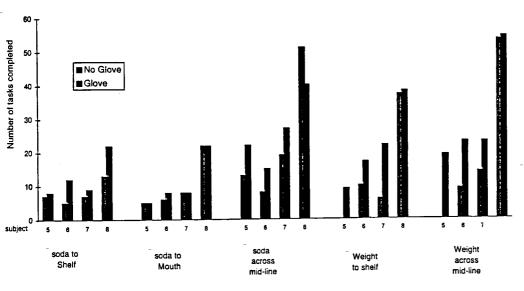


Fig 5. Manual tasks performed with and without active use of the glove, timed by a stopwatch over a 1-minute period. Most of the tasks were done more frequently with the glove active. Notable exceptions were the soda-can-to-mouth task in three subjects and the soda can across

the midline in subject 8.

active force at the end of the fifth grasp $(6.8 \pm 4.2N)$ was significantly greater than F_p (p = .0064, Mann-Whitney rank sum test).

Figure 5 shows the results of standardized tests in four subjects involving the transfer of test objects from one place to another with and without FES. The test objects were a full soda can with a mass of .355kg and a test weight with a mass of .26kg (a metal disc 5cm in diameter and 1.5cm thick embedded vertically in a wooden base.²⁸ Subjects were asked to perform each test using only one hand. In the first and fourth tests the soda can or weight was lifted from a table at which the subject was seated to a shelf of height .41m. In the second test the soda can was lifted to the subject's mouth, in a drinking motion. The third and fifth tests consisted of lifting the can or weight from the table, moving it across the subject's midline, and placing it on the table. Qualitatively, no task was judged by the subjects as more difficult to accomplish with the use of the glove than without. Transferring the objects from one place to another was easier in nearly all cases.

In each of the tests the subjects were asked to perform as many repetitions of the standardized task as they could within one minute. Figure 5 shows that in most cases more tasks were performed per minute with the glove than without. Manipulations of the test weight were improved more than those of the soda can. This is because sometimes the finger and thumb did not curl around the can enough to retain it in a secure grasp. Better grasping might be achieved by activating the deeper muscles in the forearm that flex the terminal phalanges of the fingers, or the intrinsic muscles of the hand, but these muscles are difficult to recruit with surface electrodes. For objects of this type, implanted electrodes⁴ or implanted microstimulators²⁹ might improve dexterity.

Other researchers have reported improvements in muscle strength and fatigue resistance with regular FES over a period of weeks or months. 11.13.14.21.30 The force data were collected over several months with four users are consistent with these effects, but because the amount and type of usage of the Bionic Glove varied from one person to another, our observations in this regard remain anecdotal. Some of our subjects reported carry-over effects, that is to say, improvements in unaided hand movements after some weeks of using the device. 11.30

Control

We tried proportional control of grasp force and hand-opening aperture, the command signal being wrist position. We soon

had to be maintained at a constant angle to maintain a constant grasp force. This made it difficult to manipulate or transfer the object. We then adopted a simpler ON-OFF stimulation strategy, whereby stimulation was triggered at a wrist position preset by the user. The OFF-ON transition was graded by ramping pulse widths from 50μ sec to the ON pulse width, usually 300µsec, typically in 0.1sec. Ramp-up time, pulse amplitude. and ON pulse width for each muscle were all preset by the clinician using a notebook computer communicating with the Bionic Glove through an optically isolated connection. Presetting of wrist trigger positions was performed at will by the user, by selecting the so-called "calibration" mode by a single push-button press on the control box and flexing and extending the wrist between the desired new grasp and opening trigger points for about 1.5 seconds. We predicted that this feature would be used many times a day to match trigger points to particular tasks. We found, however, that most subjects preferred to use one trigger setting all day. This meant that ON-OFF positions were not optimized for different tasks, but rather they were maintained at some level that gave acceptable function. In the version of the Bionic Glove now being developed. we will incorporate self-calibration and selectable motor programs to allow subjects to choose whole sets of parameters preset by the clinician to suit different motor tasks. These will include stimulus amplitudes, ON-OFF trigger points, and ramp-

found, however, that this theoretically attractive approach was

impractical, because once an object had been grasped, the wrist

The data on standardized motor tasks capture only a small part of the motor improvement reported to us by the subjects. Many simple tasks of daily living were improved. Among these were picking objects up from the floor, manipulating and transferring objects such as books and kitchen utensils, wood carving, model assembly, oil painting, personal grooming, and eating.

DISCUSSION

This report introduces a new FES device, the Bionic Glove, designed to activate muscles controlling the fingers and thumb to improve manual motor function in people in whom these muscles are paralyzed or paretic because of an upper motor neuron lesion. The device is intended for individuals with quadriplegia or hemiplegia who are able to extend the wrist against gravity but have reduced hand-grasp and hand-opening ability.

The device is not suitable for people with brachial plexus lesions, polyneuropathy, polio, and amyotrophic lateral sclerosis, because the threshold for activating peripherally denervated muscle is about ten times that of innervated muscle. Voluntary wrist flexion is advantageous but not essential to operate the device, because gravity-assisted passive flexion usually provides enough variation in the control signal to allow the subject to control stimulation. In certain postures, for example when the forearm is supinated, gravity may not assist passive flexion. Subjects may then use the contralateral hand to push the glove-bearing hand into sufficient flexion to inactivate hand-grasp or to trigger hand-opening stimulation.

In the nine subjects in whom force measurements were made, the Bionic Glove increased the peak force of the tenodesis grasp from a mean of 2.6N without stimulation to 11.3N in electrically assisted trials. Hand-opening aperture measured between the tips of the forefinger and thumb was increased by up to 15cm. In three subjects the strength and time course of passive tenodesis grasp indicated that stretch reflexes were contributing. These subjects stopped using the Bionic Glove regularly after some months, even though it improved their grasp force substantially. This indicates that for these subjects, in whom the passive grasp was also more functional in the standardized tasks and tasks of daily life, the costs/benefits ratio of the prototype device was too high. We believe that when the physical bulk of the control box and garment are reduced and the electrodes do not have to be attached separately, the motor benefits delivered by the glove will outweigh the costs in this subgroup of users. In more general terms, it is clear that measuring the time course of passive tenodesis grasp with an electronic myometer provides useful information on function and on the potential benefits of devices such as the Bionic Glove and/or surgical procedures such as tendon transfers.

In this preliminary study, standardized motor tasks were improved in most cases, as shown by timed repetitions as well as the subjects' own subjective ratings. The relative lack of improvement in lifting the can to the subjects' mouths was surprising and was attributed to an inadequate flexion of the distal interphalangeal joints of forefinger and thumb. Several subjects said that if the can was first pushed into the thumb webspace, the electrically assisted grasp was more secure than a passive tenodesis grasp and this allowed them to confidently hold glasses or cans in one hand in a social setting. The standardized trials did not capture improvements such as these. although these improvements did influence the usage patterns of the device in daily life. Ultimately the most objective measure of the costs/benefits ratio of the Bionic Glove will be determined in long-term compliance figures. Preliminary data on the present prototypes suggest that about 60% of the subjects fitted with the device would still be using them after 6 months. Compliance can be expected to increase with improved versions.

Practical Problems Encountered

Several practical problems were reported by users. Some were solved as the study proceeded and others are being addressed in the version of the device currently under development. Problems included a lack of reliability in the early prototypes, manipulating and accurately placing electrodes, intermittency of contact between glove and electrodes, drying out of electrodes, and displacement of the thumb electrode during wheeling. Some subjects found it difficult or inconvenient to set stimulus parameters. Users who were more at ease with consumer electronic devices had less trouble in this regard. However, to cater to all potential users, most parameter settings will be automated in the next version of the Bionic Glove. Other

problems being addressed include the fit of the garment on the arm and hand, the orientation of the control box on the subject's forearm, and the weight and bulk of both the box and the garment in the prototypes, which limited the types of clothing that could be worn over the device. Finally, in SCI subjects who do not have voluntary wrist extension, tendon transfers might be used to provide sufficient control of the wrist joint to use the glove.

Other Motor Disorders

The device has not yet been tested in people with hemiplegia, although we believe that it will be of therapeutic value in about 5% to 10% of cases. ^{21,31} The hemiplegic hand generally adopts a chronically flexed posture. When electrotherapy has been used in the past, the aim has been to stimulate the finger and thumb extensors to open the hand. ^{13,21,31} The Bionic Glove is suited to perform this function in people with hemiplegia who have some voluntary wrist movement. A related device, the Handmaster, ²⁴ splints the wrist into a fixed posture and stimulates finger and thumb extensors when a button is pressed by the contralateral hand. This device is available commercially in Europe, but to our knowledge there have been no published reports on its efficacy. Because it splints the wrist, it may be more suitable than the Bionic Glove in hemiplegic people who lack wrist movement.

Pathological tremor about the wrist or elbow can be substantially attenuated with FES, without affecting voluntary movements, provided the movements are not too rapid. 32.33 Our group is implementing this idea in a practical tremor attenuation device based on the design features of the Bionic Glove. The prototype device is in the form of an armlet that receives feedback from an accelerometer attached to the subject's hand. Clinical trials are underway.

Conclusion

The Bionic Glove is a new FES device designed to boost hand function in people with C6-C7 quadriplegia and hemiplegia. It is noninvasive and relatively inexpensive. We are optimistic that with some improvements the device will enhance motor function and quality of life in a substantial number of people. It offers a complementary solution to the sophisticated implanted systems currently in clinical trials, allowing potential recipients of these systems to experience the benefits of FES in a relatively simple manner and, consequently, helping them in making their decision regarding implantation. In many people it may provide sufficient motor improvement and therapeutic effects to be used in the long term.

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References

- Liberson WT, Holmquest HJ. Scott D, Dow M. Functional electrotherapy: stimulation of the peroneal nerve synchronized with the swing phase of the gait of hemiplegic patients. Arch Phys Med Rehabil 1961;42:101-5.
- Kralj A. Bajd T. Functional electrical stimulation: standing and walking after spinal cord injury. Boca Raton (FL): CRC Press. 1989
- Loeb GE. Neural prosthetic interfaces with the nervous system. Trends Neurosci 1989;12:195-201.
- Peckham PH, Keith MW. Motor prostheses for restoration of upper extremity function. In: Stein RB. Peckham PH, Popovic DB, editors.

- 20. Long C, Masciarelli VD. An electrophysiological splint for the Neural prostheses: replacing motor function after disease or disabil-
- ity. New York: Oxford University Press, 1992:162-87. 5. McNeal D. Peripheral nerve stimulation—superficial and implanted. In: Fields WS, Leavitt LA, editors. Neural organization and its relevance to prosthetics. New York: Intercontinental Book
- Corp. 1973:77-99. 6. Vavken E, Jeglic A. Application of an implantable stimulator in
 - the rehabilitation of paraplegic patients. Int Surg 1976;61:335-43.
- 7. Thoma H. Frey M, Holle J, Kern H, Mayr W, Schwanda G, et al. Functional neurostimulation to substitute locomotion in paraplegia
 - patients. In: Adrarde JD, editor. Artificial organs. New York: VCH Publishers Inc, 1987:515-29.
- 8. Vodovnik L, Crochetiere WJ, Reswick JB. Control of a skeletal

 - joint by electrical stimulation of antagonists. Med Biol Eng 1967; 5:97-109.
- 9. Rebersek S, Vodovnik L. Proportionally controlled functional electrical stimulation of hand. Arch Phys Med Rehabil 1973;54:378-
- 10. Peckham PH, Marsolais EB, Mortimer JT. Restoration of key grip and release in the C6 tetraplegic patient through functional electrical
- stimulation. J Hand Surg 1980;5:462-9. 11. Vodovnik L. Therapeutic effects of functional electrical stimulation of extremities. Med Biol Eng Comput 1981; 19:470-8.
- tem for tetraplegics. J Rehabil Res Develop 1995;32:17-24. 13. Merletti R, Acimovic R, Grobelnik S. Cvilak G. Electrophysiological orthosis for the upper extremity in hemiplegia: feasibility study. Arch Phys Med Rehabil 1975; 56:507-13. 14. Waters R, Bowman B, Baker L, Benton L, Meadows P. Treatment of hemiplegic upper extremity using electrical stimulation and bio-

12. Saxena S, Nikolic S, Popovic D. An EMG-controlled grasping sys-

- feedback training. In: Popovic D, editor. Advances in external control of human extremities 7. Belgrade: Yugoslav Committee for Electronics and Automation, 1981:251-66. 15. Teeter JO. Kantor C, Brown DL. Functional electrical stimulation
- (FES) resource guide. Cleveland: FES Information Center. 1995. 16. Marsolais EB, Kobetic R. Functional walking in paralysed patients
- by means of electrical stimulation. Clin Orthop Rel Res 1983;175: 17. Marsolais EB, Kobetic R, Functional electrical stimulation for walking in paraplegia. J Bone Joint Surg 1987;69A:728-33. 18. Marsolais EB. Kobetic R. Implantation techniques and experience
 - with percutaneous intramuscular electrode in the lower extremities.
- J Rehabil Res 1987;23:1-8. 19. Kilgore KL. Peckham PH. Keith MW, Bryden AM. Wuolle KS. Restoration of grasp and release with an implanted neuroprosthesis (abstract). First annual conference of the International FES Society: 1996 May 14-16; Cleveland (OH). Cleveland: Case Western Re-

serve University.

22. Nathan RH, Ohry A. Upper limb functions regained in quadriplegia:

21. Baker L, Yeh C, Wilson D, Waters RL. Electrical stimulation of

wrist and fingers for hemiplegic patients. Phys Ther 1979;59:1495-

- a hybrid computerized neuromuscular stimulation system. Arch Phys Med Rehabil 1990;71:415-21. 23. Nathan RH. Functional electrical stimulation of the upper limb: charting the forearm surface. Med Biol Eng Comput 1979; 17:729-
- 24. Nathan RH. Device for generating hand function. US Patent No. 5,330,516, 1994. 25. Prochazka A, Wieler M, Kenwell Z. Garment for applying con-

hand. Arch Phys Med Rehabil 1963;44:499-503.

- trolled electrical stimulation to restore motor function. US patent No. 08/408828, 1995. 26. Wieler M, Prochazka A, Kenwell Z, Gauthier M, Isaacson G. Multi-
- centre trials of the Bionic Glove: using electrical stimulation to improve hand closing and opening in people with spinal cord injury. Proceedings of the 12th International Congress of World Confedera-
- tion for Physical Therapy: 1995 June 25-30; Washington (DC): Washington, American Physical Therapy Association. 27. Burke RE, Levine DN, Zajac FC, Tsairis P, Engel WK. Mammalian
- motor units: physiological-histochemical correlation in three types in cat gastrocnemius. Science 1971;174:709-12. 28. Wuolle KS, Van Doren CL, Thrope GB, Keith MW, Peckham PH. Development of a quantitative hand grasp and release test for pa
 - tients with tetraplegia using a hand neuroprosthesis. J Hand Surg 1994; 2:209-18.
- 29. Loeb GE, Zamin CJ. Schulman JH, Troyk PR. Injectable microstimulator for functional electrical stimulation. Med Biol Eng Comput
- 1991; 29:NS13-NS19. 30. Waters RL. The enigma of "carry-over." Int Rehabil Med 1984:
- 31. Hines AE. Crago PE. Billian C. Hand opening by electrical stimulation in patients with spastic hemiplegia. IEEE Trans Rehab Eng
- 1995; 3:193-204. 32. Javidan M, Elek J, Prochazka A. Attenuation of pathological tremors by functional electrical stimulation: II. Clinical application. Ann Biomed Eng 1992: 20:225-36.

33. Prochazka A. Elek J. Javidan M. Attenuation of pathological trem-

ors by functional electrical stimulation: I. Technique. Ann Biomed

Eng 1992: 20:205-24. Suppliers a. SPSS Inc., 44 North Michigan Avenue, Chicago. IL 60611.

b. Neuromotion Inc., Suite 201, College Plaza Professional Building.

- 8215-112 St., Edmonton. Alberta, T6G 2C8 Canada.