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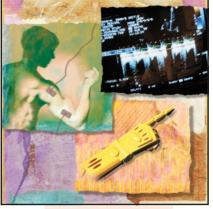
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Surface-Stimulation Technology for Grasping and Walking Neuroprostheses

Improving Quality of Life in Stroke/Spinal Cord Injury Subjects with Rapid Prototyping and Portable FES Systems

n important aspect in the rehabilitation A of stroke and spinal cord injured (SCI) subjects is to help them improve or restore body functions lost as a result of injury or disease as well as help them become as independent as possible [3, 43]. Absence of basic functions such as grasping, walking, breathing, and bladder voiding often renders such subjects dependent on the assistance of others for daily living activities. One way to make these subjects independent is to provide them with assistive devices such as a neuroprosthesis. The neuroprosthesis can help the SCI and stroke subjects regain some lost body functions, such as walking and grasping [43]. A generic neuroprosthesis consists of an electric stimulator, stimulation electrodes, and a variety of sensors, and, in some cases, is used in combination with a mechanical brace [43]. A neuroprosthesis generates a train of short electrical pulses that when applied to a muscle causes it to contract [3, 11] (see Fig. 1). By stimulating properly selected muscles or muscle groups, the neuroprosthesis can enable an SCI or a stroke subject to move an otherwise paralyzed limb or body part.

In this article, portable grasping and walking neuroprostheses, developed by the Automatic Control Laboratory at the Swiss Federal Institute of Technology Zurich (ETHZ) and the Paraplegic Center at the University Hospital Balgrist (ParaCare) are discussed [16, 33, 35]. Both neuroprostheses employ surface stimulation technology (discussed below) and are currently used by a number of subjects in daily living activities.

Functional Electrical Stimulation

Functional electrical stimulation (FES) is a methodology that uses short

bursts of electrical pulses to generate muscle contraction [3, 11]. These pulses generate action potentials in motor-neurons attached to a muscle, which cause that muscle to contract (Fig. 2). A necessary condition to use a neuroprosthesis is that the motor-neurons of the muscles that need to be stimulated are intact; i.e., the muscles should not be "denervated." In order to achieve a continuous muscle contraction (tetanization), the FES system has to induce at least 20 action potentials/s in the motor-neurons [3, 11]. Otherwise, the muscle does not generate a steady output force, but only twitches.

In principle, motor-neurons can be stimulated by both monophasic and biphasic current or voltage pulses [3]. The injected electric charge depolarizes the membrane of the motor-neuron, which causes the generation of an action potential. It is generally believed that the injected charge should be removed from the body and should not be allowed to accumulate over time. In the case of surface-stimulation FES systems, it is also believed that it is often beneficial for both the subject and the stimulation that the positions of the anode and cathode alternate during stimulation. Therefore, the majority of FES systems implement biphasic current pulses, allowing control of the amount of charge delivered to and removed from the body.

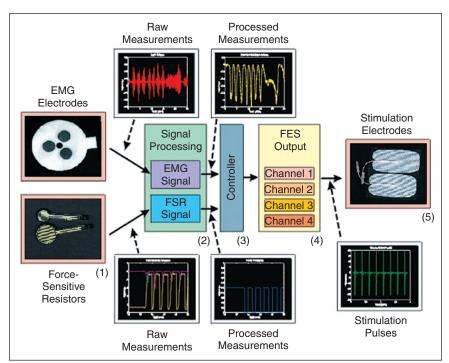
The motor-neurons can be stimulated using either surface (transcutaneous), needle (percutaneous), or implanted electrodes [3]. Transcutaneous stimulation is performed with self-adhesive or nonadhesive electrodes that are placed on the subject's skin, above the motor-neuron [3, 37]. Percutaneous stimulation uses wire electrodes that are introduced into muscles close to the motor-neurons with an epidermal needle [13, 49]. Implanted and thumb electrodes are attached to the motor neurons or the muscles close to the motor neurons [5, 13, 37, 40, 46]. Implanted electrodes and a better muscular selectivity can be achieved, and the risk of infection is reduced compared to percutaneous electrodes [17, 21]. In addition to the stimulation selectivity, one other advantage of an implanted FES system is that once implanted, the stimulator requires less time to put on and take off, compared to a surface-stimulation system. On the other hand, a surface FES system does not require surgical intervention, which some subjects consider very important. In addition, surface FES systems can be applied at a very early stage of the rehabilitation, during the recovery and reorganization period of the central and peripheral nervous systems (plasticity), allowing early benefit for the patient. FES training during recovery may help a subject restore a function to the point that he/she no longer needs a neuroprosthesis. Subjects K.D. and Z.S. in Table 3; and subjects F.M., M.B., and N.S. in Table 4, who participated in our study, all experienced function improvement to the point that they do not need a neuroprosthesis any longer. Similar findings have been previously reported [1, 32]. We believe that the best approach is to start with FES as soon as possible after the injury, using a surface system. In this way, subjects who could benefit from the central and peripheral nervous systems plasticity would be able to recover some functions lost as a result of disease or injury. Other subjects would learn from the very early rehabilitation program to accept the neuroprostheses as devices they need to carry out daily living activities. We believe that subjects should not be advised to have an implanted FES system before he/she is able to successfully use a surface FES system on a daily basis.

State of the Art Grasping Neuroprostheses

Grasping neuroprostheses are FES systems designed to restore or improve function in tetraplegic subjects. Some widely known grasping neuroprostheses are the FreeHand system [23, 40, 50], Handmaster [14, 44], Bionic Glove [36], FESmate [52], and the systems developed by Vodovnik, et al. [38] and Popovic, et al. [31]. Except for the FreeHand system, all other devices use surface electrodes. The FreeHand system has eight implanted stimulation electrodes and an implanted stimulator. The stimulation electrodes are used to generate flexion and extension of the fingers. Hand closure and hand opening are commanded by using a position sensor placed on the shoulder of the patient's opposite arm. The subject can choose a shoulder position to command hand opening and one for hand closing. Fast shoulder motions are used to indicate that the current stimulation should remain constant until the next fast shoulder motion ("locking"). The shoulder position sensor and the controller are not implanted. The FreeHand system is the first grasping neuroprosthesis approved by the U.S. Food and Drug Administration (FDA). Thus far, the FreeHand system has been provided to more than 130 subjects.

One of the first grasping neuroprostheses with surface FES technology was developed by Vodovnik, et al. [38]. This system has three stimulation channels (two stimulation electrodes per channel), which are used to generate the grasping function by stimulating the finger flexors, the finger extensors, and the thenar muscle. Although this device was developed more than two decades ago, it is among the few FES systems that allow the subject to control the stimulation train via different sensory interfaces: an EMG sensor, a sliding resistor, and a pressure sensor. As a result, the subject can choose the most appropriate man-machine interface to control (communicate with) the neuroprosthesis. The research group that developed the FreeHand system [12] also tried to use different man-machine interfaces, but these interfaces did not become a standard feature of their system. The option to choose the neuroprosthesis control interface allows tailoring the neuroprosthesis to the patient, rather than forcing the patient to adjust to the system.

The Handmaster [14], also an FDAapproved grasping neuroprosthesis, has three stimulation channels and is used to generate the grasping function in tetraplegic and stroke subjects. Originally, this system was envisioned as an exercise and rehabilitation tool, but it was found to be equally effective as a permanent prosthetic device. The Handmaster is controlled with a push button that triggers the hand opening and closing functions.



1. Schematic diagram of a neuroprosthesis with open hardware and software architecture. Signals from a variety of sensors, such as EMG (eletromyography) electrodes, force-sensitive resistors, and goniometers (1), are inputs to the neuroprosthesis. These signals are processed (2) and provided to the stimulator controller (3). The controller, by way of the stimulator output stage (4), generates a stimulation sequence that is provided to the subject via the surface stimulation electrodes (5). By stimulating properly selected muscles or muscle groups, the neuroprosthesis can enable the patient to move an otherwise paralyzed limb or a body part.

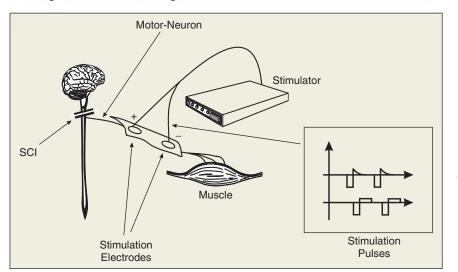
One of the main features of both stimulators is that they can reliably measure muscle EMG activity and use this signal to trigger and control the stimulation

sequences.

With a sliding resistor, the subject can regulate the way in which the thumb flexes, allowing adjustment to the size and the shape of the object being grasped. In addition, the subject can increase or decrease the grasping force by using two push buttons. One of the advantages of the Handmaster is that it is very easy to put on (donning) and to take of (doffing).

The Belgrade Grasping System (BGS), proposed by Popovic et al. [31], is a neuroprosthesis that, in addition to the grasping function, also provides a reaching function. The BGS has four stimulation channels, three of which are used to generate the grasping function, and the fourth channel is used to stimulate the triceps brachii muscle to allow the subject to extend the elbow in order to reach objects otherwise unreachable. The grasping function is controlled via a push button that triggers the hand opening and closing. The reaching function is performed by measuring the subject's shoulder velocity with a goniometer and then stimulating the triceps brachii muscle generating a synergistic elbow motion that resembles normal shoulder-elbow coordination. Similarly, the Cleveland group also combined grasping and reaching functions using their FreeHand system, but they did not replicate an able-bodied subject's shoulder-elbow synergy [10]. Instead, their neuroprosthesis measured the position of the arm in space and, for certain arm positions, automatically triggered stimulation of the triceps brachii muscle. Simultaneously with the triceps brachii muscle stimulation, the subject had to voluntarily contract the biceps muscle to regulate the arm's position.

Finally, we would like to describe the Bionic Glove [36]. This neuroprosthesis was designed to enhance the tenodesis grasp in subjects who have active control of wrist flexion and extension. The system uses a position transducer mounted on the



2. The FES system with surface-stimulation electrodes causes a muscle contraction by electrically stimulating the motor-neurons that are attached to the muscle. The electrical stimulation generates action potentials in the motor-neurons, which propagate along the motor-neurons toward the muscle. When the action potentials reach the muscle, they cause the muscle to contract.

subject's wrist to detect flexion or extension. When the subject flexes the wrist, the finger extensors are stimulated, generating the hand-opening function. When the subject extends the wrist, the finger flexors and the thenar muscles are stimulated, causing hand closure (tenodesis grasp). The Bionic Glove was successfully tested by more than 40 SCI subjects worldwide. Saxena, et al. [39], proposed a grasping system similar to the Bionic Glove, which, instead of a position transducer, uses the EMG signal of the wrist extensor muscle to trigger the onset of the stimulation sequence.

Walking Neuroprostheses

The first walking neuroprosthesis was proposed in 1961 by Liberson and his colleagues [20]. This system was developed to compensate for the "drop foot" problem in hemiplegic subjects (a subject with "drop foot" problem often has control of one leg, but poor or no control over the other leg. The subject cannot flex or extend the ankle of the disabled leg and also has reduced control over the hip and the knee joints of the disabled leg). By stimulating the peroneal nerve, the prosthesis elicits a flexion reflex that generates simultaneous hip, knee, and ankle flexion, allowing the subject to take a step with the disabled leg. Since 1961, a number of walking neuroprostheses have been designed and tested with various subjects. The widely known walking neuroprostheses are Fepa [47]; MikroFES [22]; Parastep [8, 9]; LARSI [51]; FESmate [52]; HAS [30]; WalkAid [48]; RGO [41, 42]; Praxis24 [7]; Odstock 2 [45]; the system proposed by Kralj, et al. [19]; and the implanted FES system proposed by Kobetic, et al. [17, 18]. These devices can be divided into the systems that are designed mainly to compensate for the "drop foot" problem, such as Fepa, MikroFES, WalkAid and Odstock 2, and the systems that facilitate walking in subjects who have both legs paralyzed, such as the Parastep, RGO, HAS, and Praxis24.

The Fepa, MikroFES, WalkAid, and Odstock 2 systems use surface stimulation (one generation of the Fepa system had an implanted electrode, but this idea was abandoned in favor of surface stimulation [47]) with one or at most two stimulation channels. The stimulation sequences are triggered with a push button, foot switch, or a pendulum resistor. These FES devices are most frequently used for short-term therapeutic treatment in the clinical environment, although some subjects use them as permanent orthotic devices [2]. All of these systems are small, fairly reliable, and simple to use. Some of them, such as the Odstock 2 and the MikroFES, have been fitted to more than 500 subjects. Thus far, only the WalkAid has been FDA approved.

The walking FES systems such as the Parastep, HAS, RGO, Praxis24, and the systems proposed by Kobetic, et al. [17,18] and Kralj, et al. [19], were designed for subjects who have both legs paralyzed. Parastep and the system proposed by Kralj, et al., are walking FES systems with six stimulation channels. Two channels are used to stimulate the peroneal nerves bilaterally, two channels to the quadriceps muscles bilaterally, and two channels to stimulate the paraspinals or the gluteus maximus/minimus muscles bilaterally [9]. The last two channels are used with subjects who cannot voluntarily extend the lower back. The quadriceps muscles are stimulated during standing up and during the stance to provide body support. The peroneal nerve stimulation is used to generate simultaneous hip, knee, and ankle flexion, allowing the subject to take a step. The stimulation sequences are triggered with a push button, which is attached to the walker or crutches. The Parastep system was successfully applied to more than 400 subjects and is the first FDA-approved

FES system. The system proposed by Kralj, et al., was also successfully used with more than 50 subjects.

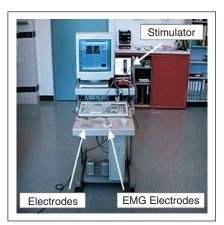
The FESmate and the system proposed by Kobetic, et al., are implanted FES systems with 24 and 32 electrodes, respectively. They are used to restore walking in paraplegic subjects. Besides walking, the Praxis24 system also provides bladder-voiding function, which is not discussed in this article. Both of these systems were designed to perform the walking and standing functions, similar to the functions generated by surface-stimulation systems mentioned above. The only difference is that these two systems are implanted and therefore should provide better stimulation selectivity and a more natural walking pattern; both are still in the development phase.

The HAS and the RGO walking neuroprostheses are devices that, in addition to using surface FES, also apply active and passive braces, respectively. The braces were introduced to reduce the high metabolic rate observed in subjects during FES walking [9] and to provide additional stability during standing and walking [29]. Thus far, the RGO system has been successfully applied to more than 40 subjects.

ETHZ-ParaCare Functional Electrical Stimulators

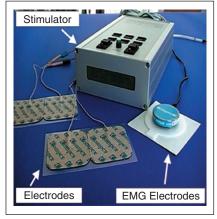
Prior to developing a neuroprosthesis, one has to select a stimulator to be used as the hardware platform. In 1995, when our

project was initiated, a portable and programmable surface stimulator that satisfies the requirements for EMG controlled neuroprostheses was not available on the market. Therefore, our team, which intended to develop an EMG-controlled grasping neuroprosthesis, had to design its own stimulator. As a result, in 1998, two different stimulators were developed by our group: a system for rapid prototyping of the neuroprosthesis [15,35], and a portable FES system that subjects can use at home in daily living activities [16, 33, 35]. The rapid prototyping system (RPS) consists of a data acquisition system (LabPC+ board from National Instruments), a constant current electrical stimulator, a custom made software written using LabView 5.1 from National In-



3. Neuroprosthesis rapid prototyping system (RPS).

Table 1. Data Sheets for the Rapid Prototyping and Portable FES Systems						
Parameters	Rapid Prototyping System	Portable System				
Stimulation Channels	4 channels: • current regulated • pulse frequency 20-50 Hz • pulse amplitude 0-100 mA • pulse width 0-500 μs	4 channels: • current regulated • pulse frequency 20-50Hz • pulse amplitude 0-100 mA • pulse width 0-500 μs				
Analog Input Channels	 8 channels: for EMG, FSR, goniometer, inclinometer and other sensors 8 channels multiplexed with maximum sampling frequency of 64 kHz 	6 channels: • for EMG, FSR, goniometer, inclinometer and other sensors				
Controller	LabView programmable: • for custom made applications • control frequency 25 Hz	Assembler programmable: • for custom made applications • control frequency 200 Hz				
Work Station	200 MHz Pentium PC					
Power Source	110/220 VAC and 4 Ah/8.4 VDC NC battery (12 h of stimulation)	2.8 Ah/7.2 VDC Li-ion battery (8 h of stimu- lation)				
Dimensions	Standard PC	200 mm \times 120 mm \times 56 mm				



4. Portable FES system.

struments, and a personal computer (PC), which combines these elements into an integrated system (Fig. 3 and Table 1). The electrical stimulator consists of four multiplexed stimulation channels (separated by an Hewlett Packard 2630 optocoupler) that are controlled with a Motorola HC11 microcontroller. The stimulator communicates with the PC via galvanically separated digital ports and is battery powered for safety. The RPS was developed as a tool to rapidly design custom-made neuroprostheses. With this system, in a matter of minutes, one can program the neuroprosthesis stimulation sequences and the stimulation parameters such as pulse amplitude, pulse width, and pulse frequency. In addition, one can choose a sensor the subject can use to interact (communicate) with the neuroprosthesis, such as EMG sensor, push button, accelerometer, etc. The RPS is used to assess which functions can be improved or restored in the patient, to identify which muscles and muscle groups can be stimulated to restore the desired function, to test different stimulation electrode configurations, to identify the best stimulation sequence and control strategy for the proposed neuroprosthesis, and to test the prosthesis.

Once the neuroprosthesis is developed using RPS, the software from this system is transferred to the portable stimulator to provide a neuroprosthesis the subject can take home. The portable system, shown in Fig. 4 and discussed in Table 1, has identical stimulation characteristics to the RPS. The only difference is that once the prosthesis program is downloaded into the portable stimulator, it cannot be changed as readily as is possible with the RPS. On the other hand, the portable system is significantly smaller and can be used in daily living activities, unlike the RPS (Table 1).

As mentioned above, one of the main features of both stimulators is that they can reliably measure muscle EMG activity and use this signal to trigger and control the stimulation sequences. The concept of using the EMG signal for triggering purposes is not new, and some devices that perform this task were patented 20 years ago (Hodgson - UK patent GB2098489). Today, advanced arm prostheses for amputees, such as the Boston Elbow, Utah Arm, and the Otto Bock arm, apply either a proportional EMG control strategy or use the EMG activity of a muscle to generate ON and OFF commands for the prosthesis. In the case of the proportional EMG control, the prosthesis joint moves only when the muscle, which is instrumented with the EMG sensor, is contracted. The second control strategy uses the onset of the EMG activity to trigger the joint motion, and the second onset of EMG activity of the same muscle to terminate the motion.

There is a fundamental difference in measuring EMG activity for a prosthesis for amputees and for a neuroprosthesis. Due to the electrical stimulation, the subject with the neuroprosthesis has an induced voltage noise in his/her body, with magnitude often significantly larger than that of the EMG signal. The EMG signal of a healthy muscle is usually in the range of 10 to 1000 µV (in SCI subjects, the EMG amplitude is often lower) while the stimulation artifacts can easily reach 5 to 10 V. (Our most difficult case thus far, but also successful, was stimulation of the wrist extensor muscle, with 80 V, distance between the stimulation electrodes of 12 cm, the EMG electrodes placed on the same wrist extensor muscle between the stimulation electrodes, and the distance between EMG electrodes at 2 cm.)

In order to measure reliably voluntary EMG activity of a muscle that is stimulated, we had to develop a real-time signal processing routine that discriminates voluntary EMG activity from stimulation artifacts. We have developed a software routine that eliminates the stimulation artifacts from the measured EMG signals by blanking the EMG signals for 2 ms following the stimulation pulse. The EMG signal is measured using a "Biofeedback Sensor" (Model 2M4456, Compex SA, Ecublens, Switzerland) (gain 1400; high-pass cut-off frequency 300 Hz; low-pass cut-off frequency 4 kHz) [4]. The measured EMG signal is further rectified and filtered using a 1.5 Hz lowpass filter. Our grasping neuroprosthesis can

Table 2. Examples of the SCI Disability Classification					
C5 Complete SCI Sub	C5 Complete SCI Subject				
Injury:	intact sensory and motor neurons coming out of the spine above cervical vertebra No.5; sensory and motor neurons coming out of the spine below cervical vertebra No.5 are affected by the injury				
Symptoms:	subject is unable to perform finger flexion and extension, wrist flexion and extension, shoulder extension, supination, pronation and elbow extension; as a result the subject cannot grasp objects using a single hand and can grasp only few objects using both hands				
C7 Incomplete SCI Su	C7 Incomplete SCI Subject				
Injury:	intact sensory and motor neurons coming out of the spine above cervical vertebra No.7; sensory and motor neurons coming out of the spine below cervical vertebra No.7 are partially affected by the injury				
Symptoms:	<i>the worst case scenario:</i> the subject would have a disability similar to C7 complete SCI subject: unable to per- form finger abduction and adduction, thumb flexion and adduction. The subject could have difficulties performing finger extension, wrist extension and pronation; as a result the subject would have rudimentary grasp but would not be able to perform fine object manipulation <i>the best case scenario:</i> the subject would have few disabilities and would be able to perform almost all functions as the able-bodied subject				

thus be controlled using EMG control strategies, as discussed below.

Since January 1999, our team has been collaborating with the company Compex SA. located in Ecublens, Switzerland, which is one of the leading manufacturers of electrical stimulators for medical and sports applications worldwide. The objective of this collaboration is to develop a new portable electrical stimulator with surface stimulation electrodes. The stimulator will be used for various neuroprosthetic, rehabilitation, and scientific applications, and will be programmed with a Windows-based graphical user interface. The dimensions of the new stimulator are $148 \times 85 \times 30$ mm, and weight 420 g.

Grasping Neuroprosthesis

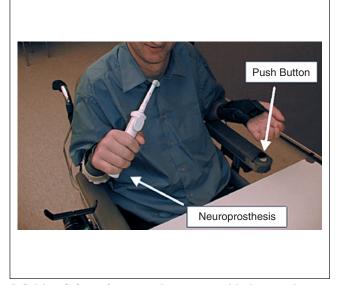
The grasping neuroprosthesis, developed using the above rapid prototyping and portable FES systems (see above), was designed to improve or restore the grasping function in complete high lesioned SCI subjects [16, 33, 35]. In this article, the term "high lesioned SCI subjects" is used to describe C5 SCI subjects [25] (see Table 2). If the part of the spinal cord below the lesion is completely disconnected from the upper part, this lesion is called *complete*. All other lesions are called incomplete. Although the grasping neuroprosthesis was designed for C5 complete SCI subjects, it can also be used by subjects with lower level lesions, such as C6 and C7 complete SCI subjects; or C5 and lower lesion incomplete SCI subjects.

The ETHZ-ParaCare grasping neuroprosthesis is designed to generate either a palmar or a lateral grasp, but not both. The palmar grasp is used to grasp bigger and heavier objects such as cans, bottles, and an electrical razor (Fig. 5). The lateral grasp is used to grasp smaller and thinner objects such as keys, paper sheets, and floppy disks. A pinch grasp, which is used to hold a pen, is obtained using the lateral grasp strategy (Fig. 6). The lateral grasp is generated by first flexing the fingers, followed by the thumb flexion. The palmar grasp is generated by simultaneous flexion of both the thumb and the fingers. Finger flexion is performed by stimulating the flexor digitorum superficialis and the flexor digitorum profundus. Thumb flexion is performed by stimulating the thenar muscle of the thumb or the median nerve. Finger extension is performed by stimulating the extensor digitorum.

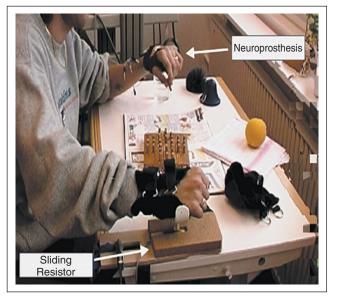
The proposed grasping neuroprosthesis consists of the portable stimulator (see above), three pairs of the Compex self-adhesive surface stimulation electrodes (5052MID [6]), a wrist retainer/splint, and the Compex EMG sensor "Biofeedback Sensor" (2M4456 [4]). One pair of surface stimulation electrodes is placed on the subject's skin above the flexor digitorum superficialis and the flexor digitorum profundus muscles to generate finger flexion. The second pair of electrodes is placed on the subject's skin, above the median nerve, to generate thumb flexion. The third pair of The ETHZ-ParaCare grasping neuroprosthesis is des igned to generate either a palmar or a la teral grasp, but not both.

electrodes is placed on the subject's skin, above the extensor digitorum muscle, to generate finger extension. The current pulse amplitudes and widths generated by the grasping neuroprosthesis are in the range of 16 to 40 mA and 0 to 250 (s, respectively. The wrist splint is used to stabilize the wrist and to provide support during grasping. The EMG electrodes are used to monitor the subject's voluntary muscle activity.

The proposed grasping neuroprosthesis offers four different control strategies:



5. Subject S.O. performs a palmar grasp with the grasping neuroprosthesis.



6. Subject D.K. performs a pinch grasp with the grasping neuroprosthesis.

- Proportional EMG control can be used by SCI subjects who can voluntarily, selectively, and gradually contract the anterior and posterior branches of their deltoid muscle. Two EMG sensors are placed on the anterior and posterior branches of the deltoid muscle on the arm opposite to the one instrumented with the neuroprosthesis. By contracting the anterior side of the deltoid muscle, the SCI subject commands finger extension (hand opening), and by contracting the posterior side of the deltoid muscle, the subject commands fingers and thumb flexion (hand closing and grasping). The subject has to keep the anterior branch of the deltoid muscle continuously contracted during the time he/she wants the hand to be open. Similarly, the subject has to keep the posterior branch of the deltoid muscle continuously contracted during the time he/she wants the hand to be closed. The amplitude of the difference between the anterior and the posterior EMG signals is used to control the force exerted by the subject's hand during grasp.
- Discrete EMG control can be used by subjects who can voluntarily contract a muscle but cannot contract it gradually or cannot maintain the muscle contraction for prolonged periods of time. Such subjects generate on and off commands similar to Morse code by contracting and relaxing a muscle. These commands are interpreted by the prosthesis, which in turn generates an appropriate stimulation sequence. For example, our C6 complete SCI subject K.D. (see Table 3), who has voluntary control of the wrist extensor muscle on the stimulated arm, used two rapid contractions of this wrist

extensor muscle to trigger hand closing. The neuroprosthesis responded to this command by opening the hand, keeping it open for two seconds, and closing it automatically. The hand remained closed until the subject contracted the wrist extension muscle once again and kept it contracted for at least 2 s without a break. This is the hand opening command to which the prosthesis reacted by opening the hand, maintaining it open for two seconds, and then ceasing stimulation, which caused the hand to relax. When the subject needed his hand to be open longer than 2 s prior to grasping, he had to issue the hand-closing command every second for as long as he needed the hand to be open. Once the subject ceased to generate the hand-closing command, the hand closed automatically after 2 s and remained closed until the hand-opening command was issued again.

• **Push button control** can be used by an SCI subject who cannot or does not want to use the EMG control strategies. By pressing a push button, the subject initiates the hand-closing function, discussed above under the discrete EMG control strategy. The hand remains closed until the subject presses the push button once again. By pressing the push button for the second time, the hand opening function described under the discrete EMG control strategy (Fig. 5) is initiated. In order to keep the hand open longer than 2 s prior to grasping, the subject has to press the push button every second after he/she has already issued the hand-closing command. The subject has to press the button repetitively for as long as the hand is to remain open. The push The walking neuroprosthesis can enable a subject with the "drop foot" problem to walk or to improve walking by generating a gait sequence in the impaired leg.

button control is less attractive than the discrete EMG control strategy, since the subject needs more time to press the push button than to generate an EMG signal.

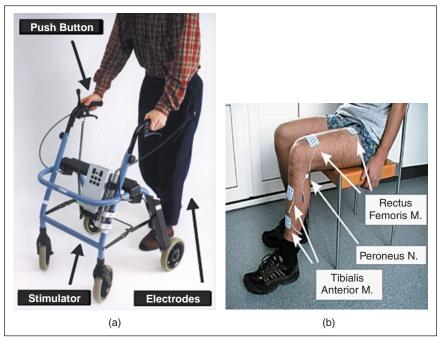
• Sliding potentiometer control is similar to the proportional EMG control strategy. By sliding the potentiometer in one direction, the subject generates finger extension (hand opening), and by sliding it in the opposite direction, finger and thumb flexion are generated (hand closing). The resistance of the potentiometer (i.e., excursion of the slider) is used to control the grasping force generated by the prosthesis (Fig. 6).

Table 3. Experimental Results with the Grasping Neuroprosthesis							
Subject	Sex	Born	Disability	Arm	After Injury	Control Strategy	Outcome
M.T.	М	1962	C5 complete	Right	8 months	Proport. EMG	Accepted
A.M.	М	1979	C4 incomplete	Right	3 months	Slding resistor	Accepted
С.К.	F	1959	C5 complete	Right	5 years	Push button	Accepted
S.O.	М	1966	C4-C5 complete	Right	2 months	Push button	Accepted
Z.S.	F	1928	C6 incomplete	Right	2 months	Push button	Rejected
K.D.	М	1977	C6 incomplete	Left	7 months	Dscrete EMG	Rejected
H.R.	М	1983	C5-C6 complete	Right	4 months	Push button	Rejected
B.R.	М	1935	C3 incomplete	Right	2 months	Push button	Rejected

Results and Patient Acceptance

The ETHZ-ParaCare grasping neuroprosthesis was tested with eight SCI subjects (see Table 3), four of whom accepted the prosthesis. The term accepted is used to indicate that the neuroprosthesis was able to generate the desired function and that the subject adopted the prosthesis and used it to perform daily living functions. When it is stated that the system was rejected, this means that the FES system could not generate the desired function due to physiological reasons, or the subject refused to use the prosthesis despite the fact that it performed successfully, or the subject recovered to the point that he/she could generate the desired function without using the neuroprosthesis. The grasping neuroprosthesis was rejected by four subjects for the following reasons. Subject H.R. was emotionally unstable and refused to collaborate with our group. Subject B.R. already had a good tenodesis grasp and did not benefit much from the neuroprosthesis. As for subjects K.D. and Z.S., they improved their grasp during FES training to the point that they did not need the neuroprosthesis any longer. Our tests have shown that the best candidates for the proposed grasping neuroprosthesis are subjects with C4-C5 or C5 complete SCI lesions, or equivalent. Subjects with lower lesion levels, such as C6 complete SCI, or incomplete SCI, could also benefit from the grasping neuroprosthesis, but the success rate is much lower since these subjects often have a partially functional grasp.

Some of the tasks the subjects (Table 3) were able to perform with the grasping neuroprosthesis were: (1) to grasp, to lift, and to place a variety of objects (up to 3)



7. (a) Walking neuroprosthesis for hemiplegic subjects and subjects with unilateral paraplegia. (b) Placement of the stimulation electrodes for the subject in (a).

kg); (2) to lift a telephone receiver, to dial a number, to maintain a conversation, and to hang up; (3) to pour a liquid from a bottle into a glass and to drink it from the glass; (4) to grasp a fork or a spoon and eat with it; (5) to grasp an apple and eat it; (6)to grasp a pencil and write with it; (7) to brush the teeth; and (8) to shave using an electrical or a manual razor. Currently, subjects A.M., S.O. and C.K. use the grasping neuroprosthesis in daily living activities (A.M. - two years, S.O. - seven months, and C.K. - six months). Subject M.T. was released from our hospital in early 1997, before we were able to provide him with the portable FES system.

Walking Neuroprostheses

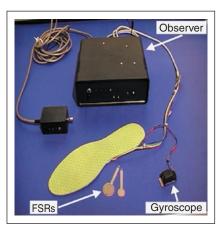
The ETHZ-ParaCare walking neuroprosthesis was also developed using the above rapid prototyping and portable FES systems (see above). This neuroprosthesis was designed to improve or restore the walking function in incomplete SCI and stroke subjects who had good control of one leg but have poor or no control over the other leg [33, 35] (see Fig. 7). These subjects are typically wheelchair users or slow walkers who cannot flex or extend the ankle joint (the "drop foot" problem) and have poor control over the hip and knee joints. However, to benefit from the walking neuroprosthesis, they

Table 4. Experimental Results with the Walking Neuroprosthesis							
Subject	Sex	Born	Disability	Leg	After Injury	Control Strategy	Outcome
D.B.	М	1972	C6-C7 incomplete	Right	2 years	Push button	Accepted
M.A.	М	1940	C4 incomplete equivalent	Left		Push button	Accepted
R.C.	М	1921	T4 incomplete equivalent	Left	10 years	Push button	Rejected
D.G.	М	1975	T8 incomplete	Right	9 months	Push button	Rejected
A.H.	М	1965	Lock in syndrome	Right	9 months	Push button	Rejected
F.M.	М	1955	C7 incomplete equivalent	Right	4 months	Foot switch	Rejected
M.B.	М	1956	C5-C6 incomplete equivalent	Right	1 month	Foot switch	Rejected
N.S.	F	1970	Tumor on the spine	Left	1 month	Foot switch	Rejected

Rapid prototyping FES is an ideal tool to design a neuroprosthesis and to immediately assess its effectiveness.

must have a good sense of balance and must be able to stand safely using a support structure such as walker or crutches.

The walking neuroprosthesis can enable a subject with the "drop foot" problem to walk or to improve walking by generating a gait sequence in the impaired leg. In most cases, a movement that is similar to the swing phase of the natural walking cycle can be evoked by stimulating the peroneal nerve, which elicits a flexion reflex. This reflex activates a simultaneous contraction of the hip, knee, and ankle flexor muscles that lift the leg off the ground. The subject's forward movement of the upper body, combined with the flexion reflex, generates the desired stepping motion. Besides peroneal nerve stimulation, the following muscles and muscle groups can be stimulated to provide additional support or smoother movement of the impaired leg during walking: tibialis anterior, gastrocnemius, rectus femoris,



8. Gait phase identification sensor.

biceps femoris, vastus lateralis, vastus medialis, and semitendinosus.

The walking neuroprosthesis consists of the stimulator unit (see above), up to four pairs of Compex self-adhesive surface-stimulation electrodes [6], and either a push button, a foot switch, or a gait phase recognition sensor [34] used to trigger the stimulation sequences.

The proposed walking neuroprosthesis offers three different triggering strategies to control the prosthesis:

- Push button control strategy was used by the majority of the subjects listed in Table 4. By pressing a push button, which is attached to a walker [Fig. 7(a)], the subject triggers the onset of the stimulation sequences that cause the impaired leg to move. After a few hours of walking with the prosthesis, all subjects learned how to use this control strategy without consciously thinking about it.
- Foot switch control strategy is very similar to the push button control strategy. Instead of the subject pressing the push button, the foot switch, which is located in the shoe sole under the heel, automatically triggers the stimulation sequence each time the subject lifts the heel. This control strategy is also intuitive and easy to implement, similar to the push button control strategy. The disadvantage of this strategy is that the foot switch often generates erroneous triggering signals, due to weight shifting or foot sliding during standing [26, 34].
- Gait phase recognition sensor consists of three force-sensitive resistors (FSRs), a gyroscope, and a rule-based observer [34] (Fig. 8). The gait phase recognition sensor identifies four gait phases during walking: heel-off, swing phase, heel-strike, and mid stance, with a reliability greater than 99% [27,28,34]. The sensor is integrated into the shoe sole of the disabled leg and initiates stimulation each time the disabled leg is in the heel-off gait phase. In order to bring the disabled leg into the heel-off phase, the subject has to take a step forward with the healthy leg. Once the healthy leg is in mid-stance gait phase and the weight is shifted to it, the disabled leg goes into the heel-off gait phase. Unlike the foot switch [26] and other available gait phase sensors [24], our sensor is capable of distinguishing true walking sequences from weight shifting during standing, and it does not give false gait annunciation

when the instrumented foot is sliding during standing. This control strategy is still being tested, and the test results will be made available at the end of this year.

Results and Patient Acceptance

The ETHZ-ParaCare walking neuroprosthesis was tested with the eight subjects listed in Table 4, two of whom successfully used the prosthesis (i.e., accepted the system). The prosthesis was rejected by six subjects for the following reasons: For subjects R.C. and D.G., we were unable to successfully stimulate the peroneal nerve. Subject A.H. had both legs disabled due to the lock-in syndrome, and our walking neuroprosthesis, which is designed to compensate for the drop foot problem, could not help restore walking. Subjects F.M., M.B., and N.S., after extensive physiotherapy and training with the walking neuroprosthesis, were able to restore normal walking function and did not need the neuroprosthesis any longer. The tests performed by our group have shown that subjects who can benefit longterm from the walking neuroprosthesis are those for whom gait cannot be restored by other means and who have a good response to peroneal nerve stimulation.

Some of the tasks the subjects (Table 4) were able to perform with the walking neuroprosthesis are: (1) to walk safely using a walker; (2) to walk up to 500 m without halting, at an average speed of 1.5 km/h; and (3) to walk uphill and downhill. Currently, subject M.A. has used the walking neuroprosthesis for more that 12 months in daily living activities. Subject D.B. was released from our hospital in early 1997, before we were able to provide him with the portable FES system.

Conclusions

The walking and grasping neuroprostheses developed by the Swiss Federal Institute of Technology Zurich and the University Hospital Balgrist represent advanced surface stimulation FES systems that can be used by SCI and stroke subjects to improve or restore the walking and grasping functions. The grasping neuroprosthesis is used to restore palmar or lateral grasp in high lesioned SCI subjects. The grasping neuroprosthesis can be tailored to fit the subjects' needs, and it can be controlled with one of the following strategies: proportional EMG, discrete EMG, push button, and sliding resistor. Based on our experience, the best candidates for the grasping neuroprosthesis are subjects with C4-C5 or C5 complete spinal cord lesion, or equivalent. Subjects with lower level lesions, such as complete C6 or lower level SCI, or incomplete SCI, could also benefit from the grasping neuroprosthesis, but the success rate is much less, since these subjects often have a partially functional grasp.

The walking neuroprosthesis is used most frequently to compensate for the "drop foot" problem in incomplete SCI and stroke subjects. According to the subjects' needs and preferences, the neuroprosthesis can be controlled either by push button, foot switch, or the phase detection sensor. Our experiments have shown that only subjects who are motivated and whose gait can be significantly improved with electrical stimulation can benefit from the neuroprosthesis.

After five years of experimenting with the walking and grasping neuroprostheses, we conclude that these systems can significantly improve the quality of life for stroke and SCI subjects. These devices can be used for either permanent prosthetic or rehabilitation purposes. For both devices, we have observed that the sooner the subject starts training, the faster and the better recovery tends to be. Also, the subject who starts training with the FES system early after the injury can potentially benefit from the positive effect that FES training has on the plasticity of the central nervous system. Some subjects can recover enough due to FES training that they do not need the neuroprosthesis any longer. Since the surface FES systems can be applied to subjects almost immediately after the injury, they are ideal for such rehabilitation applications. If the subject cannot recover function through FES training, which happens more frequently, then the system is used as a neuroprosthesis. For these subjects, it was also observed that the sooner use of the neuroprosthesis starts (and the more often it is used), the higher the acceptance rate is. An early start with FES training also prevents loss of muscle volume, shortening of tendons, and joint contractures. The subjects are generally more motivated to learn "FES skills" in the early stage after the injury, rather than later, when they have become accustomed to daily living routines. We believe that a subject prior to deciding to have an implanted FES system should first learn to use a surface FES system in daily living activities. Subjects who are motivated and in good psychological condition are more likely to accept and benefit from the neuroprosthesis.

Most of the existing FES systems were developed with a specific application in mind. As a result, their hardware-software architectures have limited flexibility, and a subject often has to adjust to the system instead of the system being adjusted to the subject. We believe that FES systems must be flexible and suitable for a wide range of applications. The FES system should be able to adjust to different subjects with their specific needs as well as be controlled by various man-machine interfaces.

The man-machine interfaces and the stimulators must be robust, reliable, easy to implement, and appealing to the subjects. The rapid prototyping and the portable FES systems discussed in this article were designed to provide greater hardware and software flexibility, and to provide the subjects with the option to use different man-machine interfaces to control the neuroprosthesis. Although the systems developed could be further simplified and improved, they clearly showed that rapid prototyping FES is an ideal tool to design a neuroprosthesis and to immediately assess its effectiveness. In addition, the flexibility of the systems allows the use of any sensor the subject finds convenient to control the neuroprosthesis. Capability to download the neuroprosthesis developed with the rapid prototyping system into the portable FES system further minimizes prosthesis development time and ensures that every subject has a system specifically designed to meet his/her needs.

Our current efforts are aimed at designing a new generation of the portable electrical stimulator with surface-stimulation electrodes. This project is being carried out in collaboration with Swiss company Compex SA from Ecublens. This stimulator will be suitable for various neuroprosthetic, rehabilitation and scientific applications.

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