Clinical Evaluation of the Bionic Glove

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ABSTRACT. Popović D, Stojanović A, Pjanović A, Radosavljević S, Popović M, Jović S, Vulović D. Clinical evaluation of the Bionic Glove. Arch Phys Med Rehabil 1999;80:299-304.

Objective: Clinical evaluation of the Bionic Glove, a prototype of a new functional electrical stimulation device designed to improve the function of the paralyzed hand after spinal cord injury.
Patients: Twelve people with spinal cord injury at C5-C7 who had used the device 6 months or more.
Setting: Measurements were made at the Institute "Dr Miroslav Zotović" in Belgrade as a part of a multicenter clinical trial.
Methods: Measures include Upper Extremity Function Test, Functional Independence Measure, and Quadriplegia Index of Function.
Results: The daily use of a Bionic Glove had two major effects: (1) increasing the power grasp; and (2) increasing the range of movements. Active force was significantly greater than passive tenodesis force, as shown in other studies. Most manual tasks improved significantly with the use of the assistive system, as judged by the time needed to complete a task or the subject's qualitative ratings of a task difficulty. Most subjects who retained some dexterity without the assistive system hesitated to use the assistive system to manipulate small objects.
Conclusion: The Bionic Glove can significantly improve independence in people with C5-C7 spinal cord injury if their initial Functional Independence Measure and Quadriplegia Index of Function scores are 20% to 50% of the maximum values.
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FUNCTIONAL ELECTRICAL stimulation (FES) can restore limited control over absent or abnormal hand function in people with cervical spinal cord injury (SCI). The literature describes several feasible solutions to assist grasping: (1) one-to three-channel FES systems with surface electrodes[1-4]; (2) multichannel surface stimulation systems[5,6]; (3) multichannel percutaneous systems with intramuscular electrodes[7-10]; and (4) fully implanted systems with epimysial electrodes.[11,12] A func-tional evaluation of the Case Western Reserve University (CWRU) system[13] showed substantial improvement in simple grasping tasks. More than 25 such systems are in use in North America. The CWRU system is meant for tetraplegic subjects who retain some voluntary elbow flexion and extension, innervation of some forearm and hand muscles, and limited or no wrist control.

This article provides clinical results on the use of a new electrical orthosis, the Bionic Glove,[a] developed by Prochazka and colleagues[1] at the University of Alberta, that improves hand function in people with SCI. This device uses three channels of electrical stimulation to stimulate finger flexors, extensors, and thumb flexors. The control signal comes from a wrist position transducer mounted in the garment. The actual functioning of the device can be described as greatly augmenting tenodesis.[1]

Wrist motion augments the fine motor control of the fingers and hand.[14] Positioning of the wrist in extension puts the digital flexor tendons under tension, flexing the fingers and thumb—this is tenodesis. Conversely, flexion of the wrist puts tension on the long extensors, causing the fingers to extend and automatically open the hand. Wrist extension results from activation of two groups of muscles: (1) extensor carpi radialis longus and brevis (extension of wrist, radial deviation) and (2) extensor carpi ulnaris brevis (extension of wrist, ulnar deviation). The range of wrist movement required for normal functioning is 10° flexion and 35° extension.[15] This range was determined for the following eight functional activities: lift glass to mouth, pour from pitcher, cut with knife, lift fork to mouth, use telephone receiver, dial push-button telephone, read newspaper, and rise from chair. The range was also determined for seven personal care activities: touch of head occiput and vertex, shirt neck, chest, waist, sacrum, and shoe. When the wrist was immobilized the best manual performance was achieved with the wrist in 15° extension.[16]

Some tetraplegic individuals retain wrist movement and are able to grasp objects using tenodesis. The grasp generated with tenodesis is rather weak, however, and the handling of heavier objects (eg, opening a door, picking up a camcorder battery or video recorder tape, holding a book, etc) is frequently not feasible. In addition, to hold an object by using tenodesis it is necessary to maintain wrist extension during manipulation, and this is difficult or even impossible. Subjects who are able to use tenodesis for limited grasping typically have innervated finger flexors, but they are not controllable volitionally. The design of the Bionic Glove takes into account the motor control findings described above and applies current technology for surface activation of paralyzed muscles. The prototype Bionic Glove tested in a multicenter trial shows that a rather simple system can improve hand function. The design of the device and preliminary results collected in a multicenter clinical trial of the prototype have been described by Prochazka.[1]

SUBJECTS

Twelve men, age 26.5 ± 8.3 yrs, with SCI between C5 and C7 were included in the evaluation (table 1). The youngest subject was 18, and the oldest 38. Ten subjects had a complete lesion, one a central syndrome (no. 11), and one a Brown-Séquard syndrome (no. 5). The subjects were also classified

Table 1: Subject Characteristics

						Subjects						
	1	2	3	4	5	6	7	8	9	10	11	12
Frankel grade	F_C	F_A	F_A	F_A	F_D	F_A	F_A	F_A	F_A	F_A	F_D	F_A
Age (yrs)	22	19	18	19	34	38	36	18	38	22	31	20
Lesion	C6	C6	C6	C6	C6	C6	C7	C6	C6	C6	C6	C5
Months after injury	>24	>24	>12	>12	>3	>6	>24	>12	>24	>24	>24	>24
Wrist active extension	45°	30°	30°	15°	35°	40°	40°	40°	30°	30°	45°	10°
Wrist extension strength	5	2	2	2	3	3+	4	3+	3	3	4	1+
Wrist active flexion	40°	0	0	0	0	0	40°	0	0	0	40°	0
Wrist flexion strength	4	0	0	0	1	0	2	0	0	0	3	0
Thumb active extension	Full	0	0	0	0	0	0	0	0	0	5°	0
Thumb extension strength	3	0	0	0	1	0	0	0	0	0	1+	0
Thumb active flexion	Full	0	0	0	5°	0	0	0	0	0	5°	0
Thumb flexion strength	3	0	0	0	0	0	0	0	0	0	1+	0
Fingers active extension	50°	0	0	0	0	0	0	0	0	0	Full	3
Fingers extension strength	2	0	0	0	1	0	0	0	0	0	3	0
Fingers active flexion	50°	0	0	0	0	0	0	0	0	0	Full	
Fingers flexion strength	3	0	0	0	1	0	0	0	0	0	3	0

Muscle strength (wrist, thumb, and finger extension and flexion) measured on a scale of 0 to 5.

using a 4-category Frankel classification (F_A to F_D). One patient had an injury at C5 and was classified as F_A, 10 patients had an injury at C6 (7 F_A, 1 F_C, and 2 F_D), and one subject had a C7 lesion (F_A group). Six subjects had received only conservative treatment after their injury, 4 had undergone spinal operations, and 2 had been operated upon and had then received conservative treatment.

At the beginning of the evaluation, postinjury time was more than 24 months for 7 subjects, more than 1 year for 3 subjects, and more than 6 months for 1 subject, and 1 subject was included shortly after injury (3 months). All subjects considered for the evaluation signed the consent information, approved by the local ethics committee before the program began.

PROCEDURES

Before subjects were accepted into the study, their hand and forearm muscle responses to electrical stimulation were tested, as well as their level of tolerance to electrical stimulation. If a good muscle contraction was observed in muscles that are important for grasping, and a subject felt comfortable with the surface FES, he was accepted into the program.

The initial assessment was performed by a clinician. The assessment form included personal data; the level of injury; surgical intervention details (if any); place and discharge dates from rehabilitation; medication; education and employment history/plans; expectations of involvement with FES and cognitive functions in addition to a detailed medical status; physical status; muscle tests; range of movements of the shoulder, elbow, wrist, and finger joints; responsiveness to stimulation; and functional status.

Subjects were taught to use the Bionic Glove once the glove was individually tailored and fitted to the forearm and hand.[1] Subjects were instructed in how to set the parameters using the push buttons on the device's control panel. The hysteresis and the maximum level of stimulation was set by a clinician using a PC-based computer setup protocol.[1] An appropriate setting of the hysteresis parameter was crucial for a satisfactory outcome in most patients.

No benefits were guaranteed, but because other studies using FES had demonstrated an increase in muscle bulk and increased blood circulation, the subjects were informed of these results. The expectation of all subjects was that the system would help them in performing simple daily activities and provide more independence. No compensation was given for participation in the study.

The subjects were exposed to some risk of injury from participation. If an injury occurred, treatment was available, at the Institute's expense. We had isolated cases of transitory damage to skin because of misuse of electrodes and the device. It is possible that passive pinch-grip was weakened because of stretching of the web space between thumb and index finger while using the Bionic Glove, but we were not able to measure the change.

The evaluation was done by following the Quadriplegia Index of Function (QIF), the Functional Independence Measure (FIM), the Upper Extremity Function Test (UEFT), and weekly usage log forms. All tests were done at the beginning of the evaluation and after 1, 3, and 6 months of usage. Subjects were asked to complete the weekly log—a form indicating which functions they performed with a assistive system and how long they used the assistive system per day at the beginning and after 1, 3, and 6 months of the study.

The increased tonus of forearm and hand muscles was evaluated by measuring the passive range of movement of fingers while the distal phalange was immobilized with a plastic splint and flexible goniometers were mounted at the proximal phalange. Results are given as a percentage of the full range of movement.

RESULTS

Quadriplegia Index of Function

Selected sections of importance for judging the improvement in hand functions were tested. Attention was paid to feeding, dressing, and grooming. The scoring used the following grades: 4, completely independent, requires no assistive device; 3, independent with an assistive device, requires no human supervision, subject can put on assistive device; 2, requires human supervision only, with or without physical contact, requires no lifting by another person; 1, requires physical contact involving lifting of subject or part of subject's body by one person only; 0, completely dependent patient cannot do activity at all. The grade 9 was applied to a specific comment that cannot be generalized. Feeding was scored to a maximum of 24 points, dressing had a maximum of 20, and grooming a

total of 12 points; hence, the maximum for all activities was 56 points (fig 1).

Functional Independence Measure

FIM included a total of six activities of self care, two of sphincter control, three activities related to mobility, two types of locomotion, two types of communication, and three social cognition elements, for a total of 18 categories. The levels were: 7, complete independence (timely and safely); 6, modified independence (with a device) for activities that do not require helper; 5, supervision (100%); 4, minimal assistance (70%); 3, moderate assistance (50%); 2, maximal assistance (25%); and 1, total assistance (0%). Levels 5, 4, and 3 comprise modified dependence, and levels 2 and 1 comprise complete dependence. The maximum score for FIM is 126 (fig 2).

Upper Extremity Function Test

This test was used to determine differences in the performance of certain activities of daily living while using the Bionic Glove compared with performance of the same tasks done without it.

The tasks tested were: (1) combing hair; (2) using a fork; (3) picking up a VCR tape; (4) picking up a full juice can; (5) picking up a full pop/soda can; (6) writing with a pen; (7) answering the phone; (8) brushing teeth; (9) pouring from a 1-L juice box; (10) drinking from a mug; and (11) handling finger food. The time taken to complete the tasks was noted.

A quantitative measure of the improvement in the time to accomplish selected daily activities is shown in table 2. The average time needed to accomplish the tasks was measured at the end of evaluation. Table 2 shows the average time needed for all 11 tasks when the subjects did not use the assistive system as well as the average time needed to accomplish these tasks with the Bionic Glove. Some of the subjects were not able to accomplish tasks either with or without the assistive system. Subjects 3 and 10 improved their performance by being able to do more with the assistive system than without it, and their
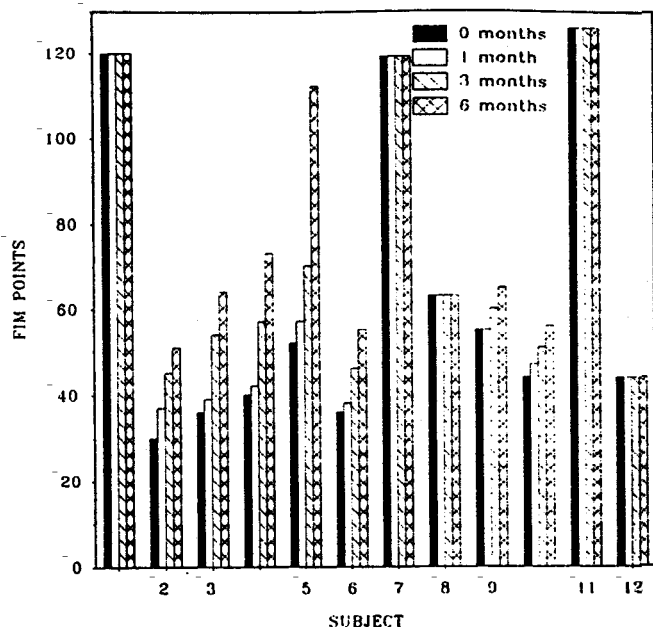

Fig 2. FIM scores for all 12 subjects using the Bionic Glove at the beginning and after 1, 3, and 6 months of evaluation.
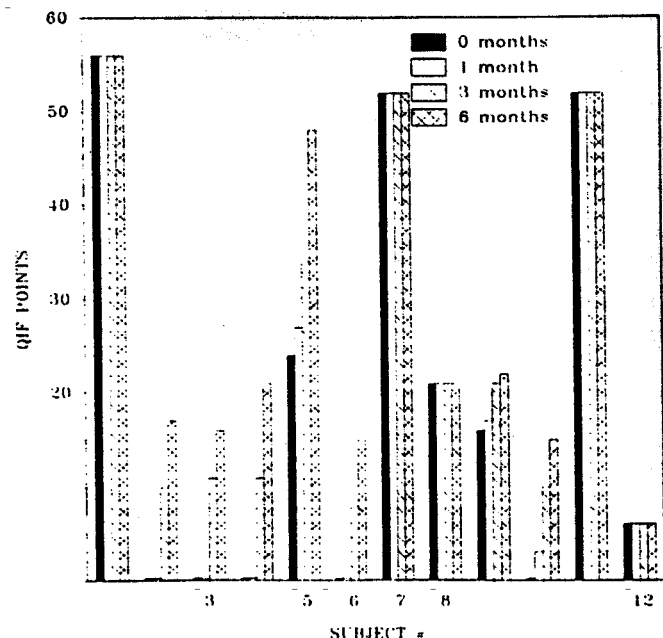
timing was greatly improved. Subject 6 could only grasp a can and use a telephone receiver because he lacked sufficient wrist control. Subject 1 performed much better without the assistive system; he did not practice using it because he could do things without it reasonably fast and safely.

The range of passive movements of fingers was measured to estimate the change in tonic activity caused by the electrical stimulation of the muscles. Those measurements were done to verify whether chronic electrical stimulation decreases spasticity in SCI subjects. Table 3 shows the average range of movements measured before using the assistive system and approximately 30 minutes afterwards. These measurements were taken at the beginning and after 6 months of evaluation.

In the majority of subjects muscle tonus in forearm and hand muscles was decreased; thus, their grasping was greatly improved (table 3). We normalized the range by assigning the value of 100 for normal, maximal range of movements typical for healthy subjects. The average range of movement for all 12 study subjects at the beginning of the evaluation was 63 ± 12 before the stimulation session, increasing to 70 ± 11 after 30 minutes of using the Bionic Glove. After 6 months of participating in the study the average range of movement was 65 ± 13 before using the assistive system and 81 ± 15 afterwards. The average range of movement increased for the whole population by only 2% before the stimulation session, whereas the difference found after using the Bionic Glove of 11% is significant. We measured the joint angle at the elbow of the arm to which the system was applied and no significant difference was noticed, suggesting that FES applied to finger and thumb muscles had local effects.

Six subjects stopped using the assistive system after they completed the study and six continued to use it at home. The main reason for quitting the program was that cost to benefit ratio was too low between using and not using the device. Although subjects 1, 2, 7, 8, 11, and 12 stopped using the Bionic Glove, their QIF (fig 1), FIM (fig 2), UEFT (table 2) and range of movements (table 3) are presented.

Fig 1. QIF scores for 12 subjects using the Bionic Glove at the beginning and after 1, 3, and 6 months of evaluation.

Table 2: Average Time Needed to Accomplish Tasks

	Subjects										
	2	3	4	5	6	7	8	9	10	11	12
Time without glove (sec)	5.14	8.72	21.10	9.33	13.25	90.00	21.90	20.90	15.90	20.00	25.80	14.50
Time with glove (sec)	8.23	8.45	16.11	7.11	10.41	50.00	18.60	18.10	10.80	16.00	21.60	11.10
Difference (%)	−60.1	2.86	23.3	23.8	24.5	44.4	13.7	13.4	32.1	20.0	16.2	23.4
No. of tasks not accomplished without glove	0	0	6	2	3	10	3	0	1	4	3	1
No. of tasks not accomplished with glove	0	0	2	1	2	8	2	0	1	1	2	1

The difference between time without glove and time with glove is reported as a percentage of the time needed without the glove (the longer time for all subjects except subject 1).

DISCUSSION

The analysis of QIF and FIM led to the following conclusions:

(1) The mean QIF was 19.0 ± 6.5 at the beginning and reached 28.4 ± 5.2, an improvement of 49.5%. The maximum possible QIF score is 56; hence, the average was still only about 50% of maximum. When the three subjects with high QIF scores are excluded, the mean value at the beginning was 7.5 ± 3.3 and reached 20.1 ± 3.8 after 6 months, an improvement of 168%, but the final score was still only 36% of the maximum possible. The improvement in QIF is most probably the result of exercising and practice.

(2) The mean FIM value for all 12 subjects increased from 63.8 ± 10.4 at the beginning of the study to 79.0 ± 8.9 after 6 months. When we excluded the three subjects with FIM scores greater than 120, who stopped using the Bionic Glove as a long-term assistive system, the mean value became 44.4 ± 13.5 at the beginning and 64.8 ± 16.6 after 6 months of evaluation, an increase of 20.4 (46%). The maximal FIM score is 126; thus, the final value of 64.8 was only 51% of maximum, indicating that level of independence is lower than desirable. The change, when all subjects were included in analysis, was 23.83%, bringing the average FIM to 63% of maximum. The increase should be associated not only with use of the assistive system, but also with exercise and improvement from practice.

The efficacy of using the assistive system can be analyzed from the difference in QIF and FIM scores for the complete population of 12 subjects (figs 3 and 4).

QIF and FIM increased after treatment with the Bionic Glove for the subjects who started with a lower score. Scores improved by about one class except for one subject (who had Brown-Séquard syndrome) in whom an extraordinarily increased level of independence was not attributed to the Bionic Glove, but rather to natural recovery.

The major change in both QIF and FIM occurred after 3 months. During the first 3 months only one subject improved

his functioning sufficiently to move him one group higher in QIF scoring (fig 3, four groups), and three subjects increased their FIM scores and moved one group higher (fig 4, five groups). The major change occurred during the second 3 months, as can be seen from figures 3 and 4.

Figures 1 and 2 and tables 2 and 3 suggest reasons that led some subjects to stop using the assistive system. QIF and FIM remained the same for subjects 7, 8, 11, and 12; therefore, for them, applying the assistive system was just a burden. Although subject 2 improved his functioning greatly (FIM increasing by 21 and QIF by 17), he was not motivated to continue using the system, mainly because he was a computer operator and found that the assistive system reduced his capacity to use a modified keyboard and mouse. Patients 2, 8, and 11 were of the opinion that the assistive system had not met their expectations. Subject 12 was not enthusiastic enough about the assistive system because of the unpleasant sensations and reactions to stimulation and lack of sufficient control of his wrist. Subject 7 experienced technological difficulties because (1) the motor point for finger extension was very proximal and required a very long forearm portion of the garment, and (2) it was extremely difficult to locate a motor point for effective finger flexion without eliciting wrist flexion. Subject 1 was unique in that he had very high FIM and QIF scores throughout the evaluation and his functional performance with the assistive

Table 3: Passive Range of Finger Movement

	Subjects									
	2	3	5	6	7	8	9	10	11	12
At beginning										
Before session	60	75	50	60	80	50	40	70	80	60	65	45
30min after	75	85	70	65	90	60	60	70	80	65	70	50
After 6 months										
Before session	65	75	65	70	90	50	40	70	80	60	65	50
30min after	95	95	100	80	90	60	75	80	80	85	85	50

The numbers reported are based on the assignment of an arbitrary value of 100 for maximum range of movement typically found in able-bodied subjects. Ranges of movement were measured at the beginning and after 6 months of using the Bionic Glove, before and 30 minutes after using it.
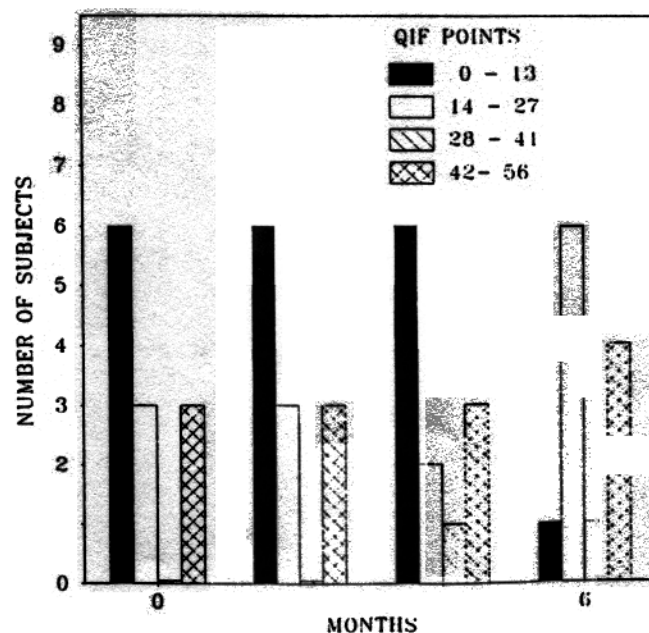

Fig 3. The number of subjects in each of four QIF score groups at the beginning and after 1, 3, and 6 months of evaluation.
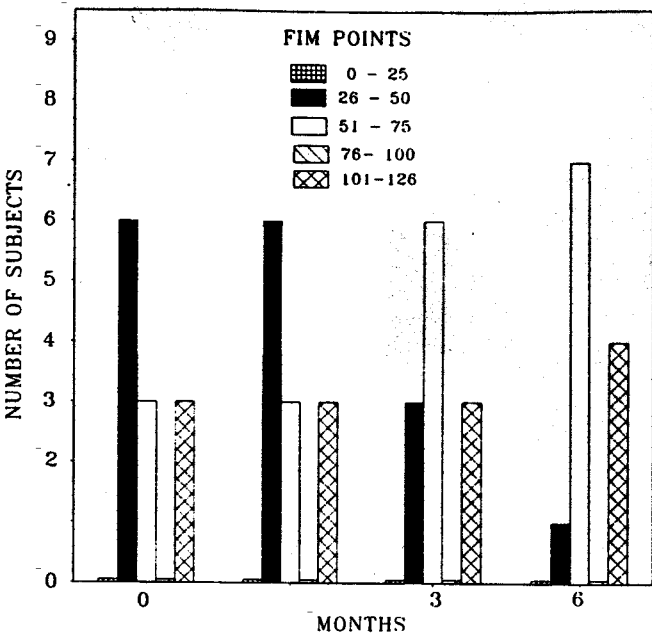
Fig 4. The number of subjects in each of five FIM score groups at the beginning and after 1, 3, and 6 months of evaluation.

system was worse than without it. He reported that he used the assistive system as a therapy on average 3 days per week. In his case the assistive system worked therapeutically.

The comparison of efficacy in daily living activities when using the Bionic Glove with respect to functioning without the assistive system also included subjective assessment (table 4). Subjects were asked to categorize change in functioning as follows: better, 1; no difference, 0; and worse, −1. The 11 tasks tested included use of the following: (1) a comb; (2) a fork; (3) a VCR tape; (4) a soda can; (5) a small can; (6) a pen for writing; (7) a telephone receiver; (8) a toothbrush; (9) a 1-L package of juice (to pour the contents into the glass); (10) a mug, to drink; and (11) finger food. Table 4 summarizes the assessments of the glove's effect on task performance by six subjects who continued to use it, as well as the average computed from all task assessments for each of the six subjects. The average was calculated using only the functions accomplished (eg, all tasks for subject 4, but only three tasks for subject 6). The average for the whole group was .745, suggesting that 75% of functions were better performed with the Bionic Glove in subjects who continued using the assistive system. Table 4 shows that subjects assigned ratings of −1 four times and 0 seven times, and for 11 trials an "NT" was assigned, indicating that the

Table 4: Subjective Assessments of Functioning by 6 Subjects

| Subject | Tasks | | | | | | | | | | Average |
	2	3	4	5	6	7	8	9	10	11	
	1	1	1	1	1	NT	0	1	NT	−1	1
	1	1	1	0	0	0	1	1	0	1	1
	1	1	1	0	1	1	0	1	NT	1	−1
	NT	NT	NT	1	1	NT	1	NT	NT	NT	NT
9	1	1	1	1	1	1	1	1	1	1	−1
10	1	1	1	1	1	1	1	1	0	0	−1

Subjective assessment categories: 1, better; 0, no difference; −1, worse; NT, not tested because subject not functional for that task. The average assessment value for all tasks was calculated only from tasks that could be accomplished.

function could not be tested. This total of 22 suggests that in about one third of individual trials the goal was not completely achieved.

An additional result of the evaluation was obtained from the daily and weekly log reports (table 5). The weekly log reflects the number of hours that a subject used the Bionic Glove for all six users who continued to use the system after the 6 months of evaluation. The number of hours that subjects used the system generally increased by approximately three times, indicating its usefulness in assistance with daily living.

The strength of grasping was increased in all subjects,[1] which allowed subjects to handle heavier and bigger objects. The manipulation of bigger objects was enhanced greatly with the Bionic Glove, but only after subjects developed tricks in how to reach and begin the hand-opening and grasping motions.

Subjects complained of difficulties in donning and doffing the system. A particular difficulty was in getting the thumb and fingers through the openings of the glove. Four of six users were able to put the assistive system on independently, one with some assistance, and one needed major assistance. The electrodes in some cases were too big, and therefore the stimulation spread to muscles that should not have been activated, which was counterproductive. The positioning of the electrodes in these cases was difficult because with a small shift the function changed dramatically. In some cases the position of the mesh (metal contact with the back of electrode) was not ideal after prolonged use of the system and it was difficult to ensure good contact between the mesh and the electrode. In other cases the mesh touched the skin, which must be avoided to minimize skin irritation and, in rare cases, skin burns.

Successful use of the system required good control of the wrist joint, and in some cases the manipulation of heavier and bigger objects was compromised because the hand opened when the external load to the hand flexed the wrist (eg, subjects 6, 7, and 12). Some subjects found that the assistive system decreased their ability to grasp and handle smaller objects (eg, manipulation of small objects, finger food) and they preferred not to use the assistive system for those tasks. The main problem was the rigidity of the hand portion of the assistive system for those fine movements.

CONCLUSION

Some people with C6-C7 lesions may benefit from using the Bionic Glove (fig 5). The benefits can be valuable enough to make the Bionic Glove a daily used assistive device. Technical improvements, specifically related to cosmetics, positioning of the electrodes, and donning/doffing, should increase the number of regular users.

Power grasp and handling of bigger objects was greatly improved (eg, pouring from a container, using a telephone receiver, handling videotapes). Slipping of objects remained a problem in most subjects even after prolonged use. We did not noticed a change in skin texture after the study, and the friction coefficient remained very low (not measured).

It is clear that the functional status of the potential user is the

Table 5: Hours Per Week of Glove Use by 6 Subjects at 1, 3, and 6 Months of Use
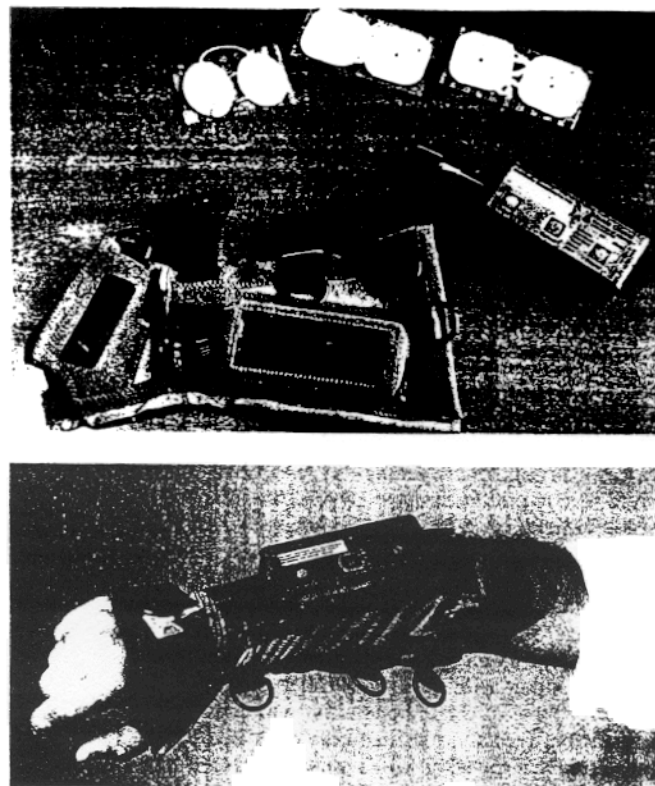
| Hours Per Week | No. of Subjects Using the Glove | | |
	1mo	3mo	6mo

4

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Fig 5. The prototype of the Bionic Glove used for the evaluation.

most important factor in deciding whether the assistive system should be used in the long term. Subjects who are fairly independent without the assistive system are more reluctant to put up with additional hardware for tasks that they can do anyway, compared with the people who gain an increased level of independence when using the system.

The general conclusion is that the best candidates for using the the Bionic Glove are individuals with complete C6-C7 tetraplegia with an FIM score between 25 and 50, eventually up to 75 (of 126), and a QIF between 0 and 13, eventually up to 27 (of 56). The second criterion deals with the motivation to become independent, being almost proportional to the efficiency of grasping.

The overall impression is that the assistive system mostly contributes to improved grasping as a therapeutic aid. Functioning without the assistive system after 6 months was very much improved when compared with the increased grasping with the Bionic Glove during the 6-month evaluation. There are subjects, however, in whom the assistive system as an orthosis is instrumental, but based on this study the number of these people is small.