

Clinical Data Summary

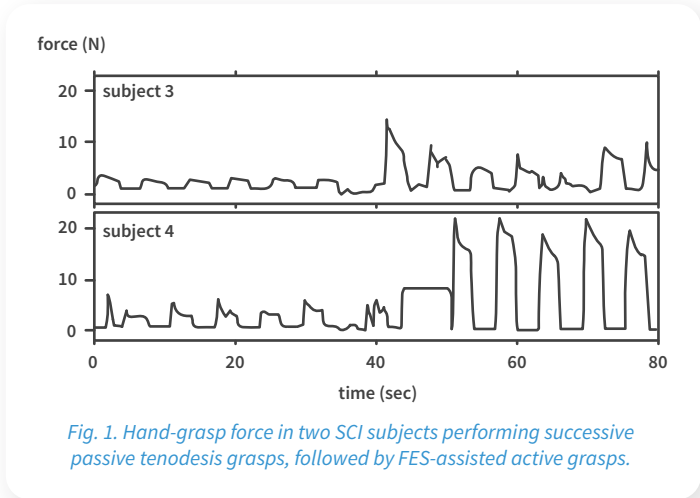
Overview:

The Bionic Glove is a functional electrical stimulation (FES) device intended to improve the function of paralyzed hands after spinal cord injury (SCI) or stroke. The Bionic Glove is a forerunner of the ReGrasp, it comprised a garment with internal panels that connected to self-adhesive electrodes on the forearm. A sensor in the glove detected voluntary wrist movements, allowing users to control FES of muscles to open and close their hand. Two studies were conducted to clinically evaluate the effectiveness of the Bionic Glove as an assistive device for SCI patients. Twenty-one patients with C5-C7 SCI used the glove daily for a period of up to 3 months or more to assist in activities of daily life.

Results:

Bionic Glove Increases Grip Strength¹

Passive and active (FES-assisted) tenodesis grasp forces were measured across nine C6-C7 SCI patients. Their average hand grasp force increased by more than four times, increasing from 2.6N (passive) to 11.3N (active, FES-assisted) (Table 1). All patients were asked to first perform passive grasping, followed by FES-assisted active grasping after approximately 35 seconds. Figure 1 shows the graphical hand-grasp force output for subjects three and four only.



Bionic Glove Decreases Spasticity²

The range of passive movements of fingers was measured before and after 6 months of daily Bionic Glove use in twelve C5-C7 SCI patients. The numbers reported in Table 2 are based on the assignment of an arbitrary value of 100 for maximum range of movement typically found in able-bodied subjects. At the end of the study, the average range of movement increased by 11% following the stimulation session. The results reported in table 2 show that chronic electrical stimulation was able to decrease spasticity and improve finger range of motion.

Subject	Passive Force (N) 1st Grasp		Active Force (N)			
	Onset	5sec	1st Grasp		5th Grasp	
	Onset	5sec	Onset	5sec	Onset	5sec
1	0.7	0.5	4.0	1.9	3.8	2.7
2	1.3	0.5	6.4	5.3	6.2	3.2
3	3.0	2.0	12.4	7.7	8.1	5.9
4	4.8	2.2	21.4	15.0	18.8	14.2
5	0.3	0.2	5.3	5.3	4.9	4.9
6	0.1	0.1	17.0	14.0	11.5	9.8
7	0.7	0.7	8.5	7.7	6.9	6.5
8	11.9	3.1	22.6	17.3	19.2	11.9
9	0.3	0.3	3.9	3.5	3.2	2.5
Mean	2.6	1.1	11.3	8.6	9.2	6.8
SD	3.8	1.1	7.4	5.5	6.1	4.2

Table 1. Peak Hand-Grasp Force at Onset of Grasp and After 5 Seconds of Maintained Grasp

As seen in Table 1, active grasp force was significantly greater than passive grasp force even when muscles were fatigued after repetitive grasp-release cycles.

	Subjects											
	1	2	3	4	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	70
After 6 months												
Before session	65	75	85	70	90	50	40	70	80	60	65	50
30min after	95	95	100	80	90	60	75	80	80	85	85	50

Table 2. Passive Range of Finger Movement

ReGrasp Improves ADL Performance, Efficiency, and Functional Independence²

Twelve C5-C7 SCI patients used the Bionic Glove daily for a period of 6 months. Their paralyzed hand function was evaluated at intervals of 0, 1, 3, and 6 months using the following assessments: the Quadriplegia Index of Function (QIF), the Functional Independence Measure (FIM), and an Upper Extremity Function Test (UEFT).

The QIF is a functional assessment designed for individuals with tetraplegia due to SCI. It is useful for documenting small but clinically significant gains made by quadriplegics throughout their rehabilitation. The patients in this study were assessed on their hand-function performance in the following categories of ADLs: feeding, dressing, and grooming. The average QIF score across all patients improved by 49.5% after 6 months of daily Bionic Glove use (Fig 3).

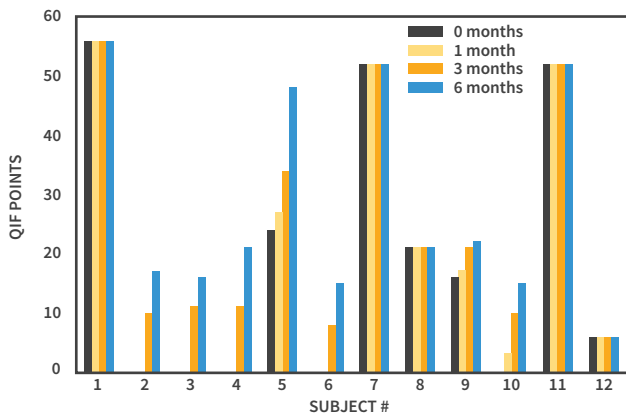


Fig. 3. QIF scores for all 12 subjects using the Bionic Glove after 0, 1, 3, and 6 months after evaluation. Maximum QIF score is 56.

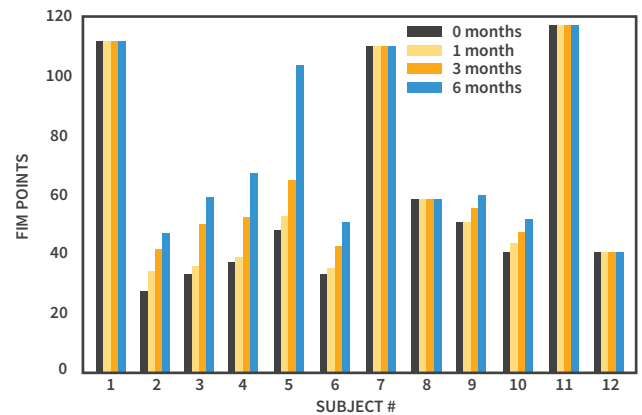


Fig. 4. FIM scores for all 12 subjects using the Bionic Glove after 0, 1, 3, and 6 months after evaluation. Maximum FIM score is 126.

The FIM is a uniform assessment tool for indicating how much assistance is required for an individual to carry out ADLs. The average FIM score across all patients improved by 23.8% after 6 months of daily Bionic Glove use (Fig 4).

The UEFT used as part of this study included 11 various ADLs performed both with and without the assistance of the Bionic Glove. Each ADL incorporated the use of hand function. All patients were able to perform the same number of tasks or more with the use of the glove, and all but one were more efficient with the glove vs. without* (Table 3).

	Subjects											
	1	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	25.90	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

* Subject 1 did not practice using the Bionic Glove because he could do things without it reasonably fast and safely

Table 3. Average Time Needed to Accomplish Tasks

Conclusion:

- ✓ Major improvements in hand function were first seen after 3 months of daily Bionic Glove use.
- ✓ The Bionic Glove enhances grip strength, improving power grasp and handling of bigger objects.
- ✓ The Bionic Glove decreased spasticity and improved finger range of motion after 6 months of daily use.
- ✓ Functional status of the user is an important factor in determining candidacy for the Bionic Glove. Patients who have minor independence with FIM and QIF scores of 20-50% maximum values saw the most benefit.

References:

1. PROCHAZKA, A., GAUTHIER, M., WIELER, M. & KENWELL, Z. (1997) The Bionic Glove: an electrical stimulator garment that provides controlled grasp and hand opening in quadriplegia. *Archives of Physical Medicine and Rehabilitation*. 78, 608.
2. POPOVIĆ, D., STOJANOVIĆ, A., PJANOVIĆ, A., RADOSAVLJEVIĆ, S., POPOVIĆ, M., JOVIĆ, S., VULOVIĆ, D. (1999) Clinical evaluation of the bionic glove. *Archives of Physical Medicine and Rehabilitation*. 80, 299-304.