Pilot Program

A Robotic Hand Device Safety Study for People With Cervical Spinal Cord Injury

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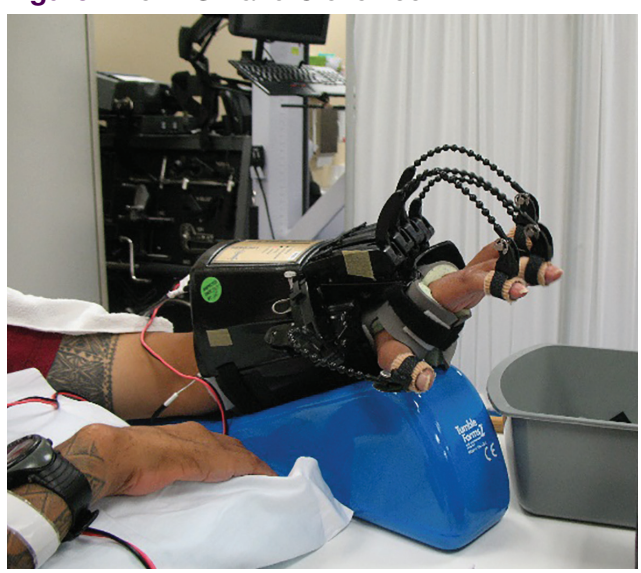
This study of the FES Hand Glove 200 device suggests possible efficacy in enhancing range of motion of various wrist and finger joints.

An estimated 282,000 people in the US are living with spinal cord injury (SCI).[1] Damage to the cervical spinal cord is the most prevalent. Among cervical spinal cord trauma, injury to levels C4, C5, and C6 have the highest occurrence.[1] Damage to these levels has significant implications for functional status. Depending on pathology, patients' functional status can range from requiring assistance for all activities of daily living (ADL) to potentially living independently.

Improving upper-limb function is vital to achieving independence. About half of people with tetraplegia judge hand and arm function to be the top factor that would improve quality of life (QOL).[2] Persons with traumatic cervical SCI may lose the ability to use their hands from motor deficits, sensory dysfunction, proprioception problem, and/or loss of coordination. In addition, they may develop joint contracture, spasticity, pain, and other complications. Thus, their independence and ADL are affected significantly by multiple mechanisms of pathology.

Upper-extremity rehabilitation that emphasizes strengthening and maintaining functional range of motion (ROM) is fundamental to SCI rehabilitation.

Figure. The FES Hand Glove 200



Rehabilitation to restore partial hand function has included ROM exercises, splinting, surgical procedures in the form of tendon transfers and various electrical

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Table 1. Patient Characteristics

Characteristics	No. (%)
Right-hand dominant	14 (100)
Implementation hand	
Left	5 (35.7)
Right	9 (64.3)
Diagnosis	
Central cord	4 (28.6)
Tetraplegia	10 (71.4)
American Spinal Injury Association Impairment Scale (AIS), levels and grades	1 (7.1)
C4 AIS A	2 (14.3)
C4 AIS D	4 (28.6)
C5 AIS A	2 (14.3)
C5 AIS C	2 (14.3)
C5 AIS D	2 (14.3)
C6 AIS C	1 (7.1)
C7 AIS A	
Time post spinal cord injury, y	6.2

stimulation devices, such as implantable neuroprostheses.[2-7] These interventions improve the ability to grasp, hold, and release objects in selected individuals; however, they have not been universally accepted. Traditional modalities, such as active ROM (AROM) and passive ROM (PROM) and electrical stimulation remain highly used in upper-extremity rehabilitation. Devices have been developed to provide either PROM or electrical stimulation to improve hand function and to prevent muscle atrophy. Therapist- and caregiver-directed PROM exercises are time consuming and labor intensive. An innovative therapeutic approach that can provide all these modalities more efficiently is needed in SCI rehabilitation.

Until now, a single device that combines AROM and PROM simultaneously has not been available. A robotic system, the FES Hand Glove 200 (Robotix Hand Therapy Inc, Colorado Springs, CO), was developed to improve hand function (Figure). The device is made of a acrylonitrile butadiene styrene (ABS) plastic clam shell that uses electric motors to assist with both active and passive flexion and extension of the hand and provides PROM to the thumb and fingers 2 to 5 and simultaneous functional electrical stimulation (FES) to corresponding muscles through surface electrodes. Both features are unique to this device and allow the user to provide hundreds of repetitions of robotic-controlled passive motion and simultaneous electrically stimulated muscular-initiated motions during treatment. The goal is to facilitate neural connectivity, restore ROM, improve strength and overall hand function, and increase QOL. This device currently is unavailable commercially, and this study provides an initial evaluation of its safety and tolerability in the clinical setting for patients with tetraplegia from complete or incomplete SCI levels C4 to C8.

METHODS

This prospective safety study evaluated the occurrence of adverse effects (AEs) associated with the use of the FES Hand Glove 200. The study was performed in the Occupational Therapy Section of the Spinal Cord Injury Center at the James A. Haley Veterans' Hospital (JAHVH) and approved by the JAHVH Research and Development Committee as well as the University of South Florida Investigational Review Board. For recruitment, the goals of the study as well as the inclusion and exclusion criteria were presented to the Spinal Cord Injury Center health care providers. Potential candidates of the study were referred to the study team from these providers.

Screening of the referred candidates was conducted by physicians during inpatient evaluations. All subjects signed a consent form. Participants included active-duty military or veterans with traumatic SCI at levels C4 to C8 and American Spinal Injury Association Impairment Scale (AIS) grades A, B, C, and D. Participants were aged 18 to 60 years, at least 1-month post-SCI, medically stable, and had impairments in upper-extremities strength and ROM or function, including hand.

Subjects were excluded if any of the following were present: seizure within 3 months of study; active cancer; heterotopic ossification below the shoulder; new acute hand injuries of the study limb; unhealed fractures of the study limb; myocardial infarction within 12 months; severe cognitive impairment determined by a Modified Rancho Score below VI[8]; severe aphasia; pregnancy; skin irritations or open wounds in the study limb; fixed contractures of > 40° of the metacarpophalangeal (MP) or proximal interphalangeal (PIP) joints of the study hand; unwillingness to perform all of the therapies and assessments required for the study; active implant device (eg, pacemaker, implanted cardiac defibrillator, neurostimulator or drug infusion device); major psychological disorder; severe residual spasticity despite maximal medical therapy; muscle power grade of more than 3+ on wrist and finger extensors and flexors of the study limb; recent or current participation in research that could influence study response; pain that prevents participation in the study; or

Table 2. Participants Primary Outcomes

Participant	Skin Integrity		Wrist/Finger Joints Deformity		Pain at Intervention Hand, Scale 0-10 (Location)		Occurrence of Autonomic Dysreflexia
	Initial	Wk 6	Initial	Wk 6	Initial	Wk 6	Initial to Wk 6
1	Intact	Intact	None	None	0	0	None
2	Ecchymosis right dorsal elbow	Intact	None	None	0	0	None
3	Intact	Intact	None	None	0	0	None
4	Intact	N/A[a]	None	N/A[a]	0	N/A[a]	N/A[a]
5	Discoloration right dorsal hand	Intact	None	None	3 (wrist)	2 (wrist)	None
6	Ecchymosis	Intact	None	None	0	0	None
7	Healed scars on hand	Unchanged	None	None	0	0	None
8	Scab on thumb	Intact	None	None	0	0	None
9	Intact	Intact	None	None	0	0	None
10	Intact	N/A[a]	None	N/A[a]	5 (elbow)	N/A[a]	N/A[a]
11	Intact	Intact	None	None	0	0	None
12	Right elbow wound 0.5 cm	Unchanged	None	None	0	0	None
13	Erythema right elbow	Intact	None	None	2 (thenar)	4 (wrist)	None
14	Intact	N/A[a]	None	N/A[a]	0	N/A[a]	N/A[a]

[a]Participant did not complete the 6-week intervention protocol.

concurrent use of transcutaneous electrical stimulation on the study arm.

The following data were documented: level of SCI, AIS-score; complete medical history; physical examination (including skin integrity); and vital signs of bilateral upper extremities. A nurse practitioner (NP) certified in Functional Independent Measure (FIM) conducted chart reviews and/or in-person interviews of each subject to establish a FIM score before and after 6 weeks of research treatment. Two experienced occupational therapists (OTs) conducted detailed hand evaluations before the research treatment interventions. An OT provided subjects with education on the use, care, and precautions of the FES Hand Glove 200. The OT adjusted the device on the subject's hand for proper fitting, including initial available PROM, and optimal muscle stimulation.

The OT then implemented the treatment protocol using the FES Hand Glove 200 in 1 hand per the subjects' preference. The subjects received 30 minutes of PROM only on the FES Hand Glove 200, followed by an additional 30 minutes of PROM with FES for 1 hour of therapy per session. The study participants were treated 4 times per week for 6 weeks. Before and after each session, OTs evaluated and documented any loss of skin integrity and pain. Autonomic dysreflexia occurred when systolic BP increased > 20 to 30 mm Hg with symptoms such as headache, profuse sweating, or blurred vision was reported.[9] The FES Hand Glove 200 was set up for PROM to the thumb and to digits 2 to 5 and for

Table 3. Functional Independence Measure Scores[a]

Participant	Initial	Wk 6	Change
1	63	63	0
2	105	107	2
3	62	62	0
4	70	N/A[b]	N/A[b]
5	107	111	4
6	63	63	0
7	63	70	7
8	71	104	33
9	59	68	9
10	52	N/A[b]	N/A[b]
11	115	124	9
12	62	62	0
13	47	52	5
14	56	N/A[b]	N/A[b]
Total Change (n = 11)			
Min-Max	0-33		
Mean (SD)	6.27 (9.55)		
Median (IQR)	4.00 (9.00) *P* = .02		

[a]Functional Independence Measure (FIM) score provides a measurement of disability and level of assistance required. An increase in the FIM score indicates improvement in function.
[b]Subject did not complete the intervention course.

electrical muscle stimulation of the finger extensors and flexors. No other therapeutic exercise was performed during the study period on the other extremity. Primary and secondary outcomes were collected at the end of the 6-week intervention.

Primary outcomes included complications from the use of FES Hand Glove 200, including skin integrity and any joint deformity as drawn on a figure, changes of pain level by visual analog scale (VAS), and total number of autonomic dyreflexia episodes. Secondary measured outcomes included changes in PROM and AROM of wrist, metacarpal joint and interphalangeal joints of thumbs and digits 2 to 5 ≥ 10°; hand and pinch strength decline of > 1 lb; decline in manual muscle test, and FIM score, which is a validated measurement of disability and the level of assistance required for ADL.[10]

Statistical analyses were performed using SAS version 4 (Cary, NC) to assess the degree of change in the improvement score, which was defined as the postintervention score minus the preintervention score. However, because of the large standard error due to small sample sizes, the normality assumption was not satisfied for all the outcomes considered.

RESULTS

Of the 20 participants screened, 14 men aged between 19 and 66 years with cervical SCI level of C4 to C6 AIS grades A to D were enrolled in the study. Three did not complete the 6-week trial due to SCI-related medical complications, which were unrelated to the use of the FES Hand Glove 200. They continued with regular OT treatment or self-directed home exercises after they were seen by the treating physician. (Table 1)

Skin integrity of all subjects was maintained throughout the study. One subject had a right-elbow wound before the intervention, which was unchanged at the end of the study. After 6 weeks of experimental intervention, there was no wrist or finger joint deformity noted and no increase in pain level except for 1 subject who reported increased pain that was unrelated to use of the device. No occurrence of autonomic dysreflexia was recorded during the use of FES Hand Glove 200 (Table 2).

For the secondary outcomes, there was no significant decrease in AROM or PROM ≥ 10° in forearm, wrist, or finger joints in any participants. There was no loss of strength > 1 lb as measured by gross grasp, pinch tip, 3-point, or lateral grip. There was no decline in motor strength per manual muscle testing. No worsening of FIM score was noted (Table 3).

Although this was not an efficacy study primarily, participants improved in several areas. Improvements included active and passive movements in the forearm, wrist, and hand. There also was significant improvement in strength of the extensor digitorum communis (EDC) muscle. Data are available on request to the authors.

DISCUSSION

Passive ROM and AROM exercises and FES are common strategies to improve certain hand functions in people with cervical SCI. Many people, however, may experience limited duration or efficiency of rehabilitation secondary to lack of resources. Technologic advancement

allowed the combination of PROM exercise and FES using the FES Hand Glove 200 device. The eventual goal of using this device is to enhance QOL by improving upper-extremity function. Because this device is not commercially available, its safety and tolerability are being tested prior to clinical use. Although 3 subjects withdrew from the study due to nondevice-related medical reasons, 11 subjects completed the study. Potential AEs included skin wounds, burns, tendon sprain or rupture, edema, and pain. At the end of the 6-week study period, there was no loss of skin integrity, no joint deformity, and no increase in hand or finger edema in all subjects. Increase in pain level at 6 weeks was noted in only 1 subject.

One concern was that overuse of such devices could potentially cause muscle fatigue, leading to decreased strength. Pinch grasp and manual muscle testing were evaluated, and no decrease in any of these parameters was noted at the end of study. Although this was not an efficacy study, there was some evidence of improved ROM of multiple wrist and finger joints as well as the EDC muscle strength.

Limitations

Limitations of the study included the duration of treatment of eight 30-minute sessions per week over a 6-week period. A longer treatment duration could result in repetition-related injuries and should be tested in future trials. Finally, the sample size of this study was relatively small. Future studies of different treatment frequency, longer duration of use and monitoring, and using a larger sample size are suggested. An efficacy study of this device using a randomized controlled design is indicated. As people with cervical SCI rank upper-extremity dysfunction as one of the top impairments that negatively impacts QOL, rehabilitation strategy to improve such functions should continue to be a research priority.[2]

CONCLUSION

This study supports the safety and tolerability of a 6-week course using FES Hand Glove 200 in traumatic SCI tetraplegic subjects. Additionally, data from this study suggest possible efficacy in enhancing ROM of various wrist and finger joints as well as certain muscle group. Further studies of efficacy with larger numbers of subjects are warranted.

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Disclaimer

The opinions expressed herein are those of the authors and do not necessarily reflect those of Federal Practitioner, *Frontline Medical Communications Inc., the US Government, or any of its agencies.*

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