Use of a myoelectric upper limb orthosis for rehabilitation of the upper limb in traumatic brain injury: A case report



Journal of Rehabilitation and Assistive Technologies Engineering Volume 7: 1–11 © The Author(s) 2020 Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/2055668320921067 journals.sagepub.com/home/jrt



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Abstract

Background: Upper limb motor deficits following traumatic brain injury are prevalent and effective therapies are needed. The purpose of this case report was to illustrate response to a novel therapy using a myoelectric orthosis in a person with TBI.

Case description: A 42-year-old female, 29.5 years post-traumatic brain injury with diminished motor control/ coordination, and learned nonuse of the right arm. She also had cognitive deficits and did not spontaneously use her right arm functionally.

Intervention: Study included three phases: baseline data collection/device fabrication (five weeks); in-clinic training $(2 \times / \text{week for nine weeks})$; and home-use phase (nine weeks). The orthosis was incorporated into motor learning-based therapy.

Outcomes: During in-clinic training, active range of motion, tone, muscle power, Fugl-Meyer, box and blocks test, and Chedoke assessment score improved. During the home-use phase, decrease in tone was maintained and all other outcomes declined but were still better upon study completion than baseline. The participant trained with the orthosis 70.12 h, logging over 13,000 repetitions of elbow flexion/extension and hand open/close.

Discussion: Despite long-standing traumatic brain injury, meaningful improvements in motor function were observed and were likely the results of high repetition practice of functional movement delivered over a long duration. Further assessment in a larger cohort is warranted.

Keywords

Traumatic brain injury, rehabilitation, motor learning-based therapy, upper extremity, robotics, myoelectric orthosis, orthotic devices

Date received: 9 August 2019; accepted: 20 March 2020

Introduction

Traumatic brain injury (TBI) affects 1.7 million people in the general US population annually¹ and is one of the most common neurologic disorders causing disability.² Motor deficits are present in 30% of TBI survivors with arm and hand problems occurring in about 17%,³ limiting the ability to perform activities of daily living (ADL). However, there is less research on motor recovery in patients with TBI compared with other neurologic diseases involving the brain, such as stroke.²

Activity-based interventions hope to maximize rehabilitation outcomes and enhance adaptive neural plasticity;³ however, optimal doses and schedules of

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Creative Commons Non Commercial CC BY-NC: This article is distributed under the terms of the Creative Commons Attribution-NonCommercial 4.0 License (https://creativecommons.org/licenses/by-nc/4.0/) which permits non-commercial use, reproduction and distribution of the work without further permission provided the original work is attributed as specified on the SAGE and Open Access pages (https://us. sagepub.com/en-us/nam/open-access-at-sage). training have not been adequately established. Repetition is one parameter important for activitydependent neural plasticity. Studies assessing US rehabilitation found that stroke and TBI survivors receive an average of 32–50 repetitions of upper extremity active and passive movement per therapy session, significantly less than the 400–600 repetitions achieved in animal studies.³ Although persons with TBI benefit from traditional therapy,⁴ it is clear that more is needed to attain full recovery, especially with severely

affected individuals. Consistent with this idea, Krebs and Volpe⁵ argued that the basis of all assistive and therapeutic devices should be to induce the intent to move followed by that movement actually happening, referred to as "intent-driven rehabilitation". One way this can be accomplished is through myoelectric control wherein a weak electromyography (EMG) signal from the muscle of an impaired limb is detected, processed, and used to activate a motor within the orthosis. The motor then assists the user in producing the desired movement. The patient-directed "intentional" action of the device promotes patient engagement as the orthosis will only reward the patient with movement when they use the correct muscles to complete a task. Previous studies of myoelectric driven lab-based robotic interventions⁶ showed improved Fugl-Meyer motor control scores of the upper extremity⁷ and reduced spasticity as assessed by the modified Ashworth scale (MAS).⁸ While demonstrating a benefit of "intentdriven rehabilitation", in-lab robotic intervention restricted the amount of practice because training was restricted to the short lab sessions only and no home practice was possible.⁶

While myolectrically-driven orthotic technology has been in development for many years,⁹⁻¹¹ recent advances have made it more accessible and clinically deployable for rehabilitation. However, initial research has focused on persons with stroke¹²⁻¹⁸ and not TBI. The ability of severely hemiplegic stroke survivors to activate a powered elbow orthosis using myoelectric control has been reported,¹³ along with increased elbow range of motion with orthosis use.¹⁸ Kim et al.¹⁵ reported that after a combined period of training and at home-use of an elbow-only myoelectric orthosis, a statistically significant three-point change in Fugl-Meyer motor control score was found in the upper extremity of nine persons post-stroke. We have recently reported a case series of chronic stroke survivors who used a myoelectric upper limb orthosis over a period of several months and achieved a 9.0 ± 4.8 point improvement in Fugl-Meyer.¹⁹ Since upper limb motor deficits in TBI are a problem that can lead to decreased independence in ADLs and given that there is a lack of effective therapies and supportive devices for upper limb impairment, the purpose of this case report was to illustrate the response to therapy combined with a myoelectric elbow–wrist–hand orthosis in a person with longstanding TBI.

Case description

The protocol described in this case report complies with standards of the Declaration of Helsinki and was approved by the Institutional Review Boards of participating institutions (IRB #16039-H29 and STU00203728) and met the Health Insurance Portability and Accountability Act (HIPAA) requirements for disclosure of protected health information. Written informed consent for participation was obtained from the patient's legal guardian.

The participant was a 42-year-old female who sustained a TBI from being struck by a motor vehicle at age 12. At study entry, she was 29.5 years post injury, dependent on caregivers for most ADL/instrumental activities of daily living (IADLs), used a manual wheelchair for mobility, resided in a group home setting, and required assistance from caregivers to help her make decisions. She attended an adult workshop where she would perform general fitness/mobility activities along with interacting with peers socially, and had done so for several years. As a result of her injury, she had abnormal tone, weakness and dysmetria/ataxia leading to decreased motor control and coordination of the right upper limb. She has avoided using her right (dominant) arm, which has led to learned nonuse of the right arm and overuse of the left arm. Furthermore, she had cognitive, short-term memory, and perceptual deficits. Right visual processing deficits made it difficult for her to read and distinguish color. Her mini mental state exam (MMSE) score at baseline was 15 out of 30. Due to these impairments, she did not spontaneously use her right upper limb functionally. Over the years since her injury, interventions including traditional physical and occupational therapy (functional mobility training, upper limb task practice, aquatic therapy provided by licensed therapists) have been implemented with limited success to increase the use of her right upper limb.

Intervention

The participant underwent casting and a myoelectric elbow–wrist–hand orthosis (MyoPro Motion-G, Myomo Inc., Cambridge, MA) was custom fabricated by a certified and licensed orthotist. The orthosis is intended to help individuals with a weakened or paralyzed arm to complete patient-initiated movements and enhance function (Figure 1).



Figure 1. Functional task practice example. (a) Myoelectric elbow–wrist–hand orthosis custom fabricated to fit the participant using MyoPro Motion G components (Myomo Inc.). When the user tries to move the elbow or grasp objects, sensors in the orthosis detect the myoelectric signal generated by the user's volitional effort, to activate the motor and move the elbow/hand in the desired direction, assisting the user to complete the desired movement. (b) Functional task practice without the orthosis donned to reinforce training. (c) Demonstration of return of functional use showing the participant spontaneously using her impaired limb to feed her pet treats.

Table I.	Types of	practice/training	and hierarc	hy of motor	· control challer	nge that can b	e employed	with the orthosis.
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Less challenging	 a. Single-joint movement practice BICEP TRICEP
	hand OPEN hand CLOSE
\downarrow	 nand CLOSE b. Agonist/antagonist coordination across a single joint (DUAL-mode single-joint practice) BICEP+TRICEP hand OPEN+hand CLOSE c. Individual movement practice across contiguous joints BICEP+ hand CLOSE
	 BICEP+hand OPEN TRICEP+hand CLOSE TRICEP+hand OPEN
More challenging	 d. Agonist/antagonist coordination across contiguous joints DUAL-mode elbow+hand CLOSE DUAL-mode elbow+hand OPEN TRICEP+DUAL-mode hand BICEP+DUAL-mode hand DUAL-mode elbow+DUAL=mode hand

The participant was seen for follow-up to ensure proper orthosis fit and her caregivers were trained in donning/doffing and operation of the orthosis. Study interventions were provided by a licensed physical therapist trained in the use of the orthosis and experienced in the implementation of motor learning-based interventions for individuals with neurological disorders.

Study participation was divided into three phases: (1) baseline assessments (week 1 and week 5) and orthosis fitting/fabrication (weeks 1–5), (2) in-clinic training (weeks 5–13), and (3) home-use (weeks 14–22). All study related visits were conducted in the research clinic of the medical center. During the

in-clinic training phase, the participant attended two training sessions per week lasting 1.5h each, for a total of 18 sessions. Additionally, the participant was instructed to complete a customized home exercise program that incorporated the principles from the in-clinic training sessions and was encouraged to use the orthosis to complete functional tasks at home.

Training progression followed a movement hierarchy previously described.²⁰ An adaptation of this hierarchy in use is illustrated in Table 1. The orthosis was used to train a variety of movements across a hierarchy of motor control difficulty as follows: starting with single-joint movement practice, advancing to agonist/

Table 2. Training schedule and progression.

Training schedule (weeks)	5	6	7	8	9	10	11	12	13	16	19	22
training with orthosis												
Hand CLOSE - squeeze sponge						P1						
Elbow BICEP - hand to mouth movement						P1						
Hand OPEN - release of object						P1						
Elbow TRICEP and Hand CLOSE - reach for object												
Elbow DUAL & Hand CLOSE - bilateral task with book												
Elbow TRICEP - reaching for target							Р3					
Elbow DUAL & Hand CLOSE - close chain push/pull with hand holding bar, therapist on the other side						P2						
Elbow BICEP and Hand CLOSE - "eat a banana"												
Elbow DUAL & Hand CLOSE - reach, grasp, then translate to another space and release: "sorting balled up socks"												
Elbow DUAL & Hand DUAL - coordinated elbow and hand movement; pick up objects and place in bowl												
Hand DUAL - rapid alternating of hand opening and closing												
training without orthosis												
forward Reach/grasp/release object												
bilateral forward reach with object												
squeeze putty												
pick up objects with tongs												
writing/drawing												
pick up jar												
reach with hand passively positioned open with paddle												
use right hand to eat with a utensil												
sort/pick up small objects								P4				
wrist extension with 1# weight												
reach for an object sitting in front on a table												
finger abduction/adduction												
passing ball from one hand to the other												
Key												
P1=longer duration of hold												
P2=change in forearm position from pronation to neutral to supination												
P3=change in direction of reach												
P4=varied difficulty by having patient grasp and hold some objects in palm while placing others on the table												
Grey blocks indicate when an activity was added to and retained in the training program.												

antagonist coordination practice across a single joint, then to individual movement practice across contiguous joints, and finally, working on agonist/antagonist coordination across contiguous joints. Motor learningbased therapy in the device was complemented by part and whole task practice without the device with an emphasis on volitional movement as close to normal as possible. High repetition of quality movements were encouraged both within sessions, during home exercise practice, and throughout the home-use phase. The participant was asked to use the device not only for home exercise practice but also during functional task performance. Training was tailored to meet the specific needs of the participant and exercises both with and without the device were selected to address her particular deficits. Detail regarding progression of training employed can be found in Table 2.

Outcome measures were administered longitudinally by the same assessor across the three phases of the study. There were two baseline assessments (weeks 1 and 5), four assessments during in-clinic training (weeks 7, 9, 11, and 13), and three assessments during the home-use phase (weeks 16, 19, and 22).

Impairment was assessed using the following measures. Passive and active range of motion (ROM) of the shoulder, elbow, and wrist were assessed using a goniometer. The MAS, using a 0-5 point ordinal scale, was used to assess muscle tone and spasticity⁸ of the finger flexors/extensors, wrist flexors/extensors, forearm pronators/supinators, elbow flexors/extensors, and shoulder internal rotators. MAS has been widely used to muscle tone following quantify brain injury. Interrater reliability of MAS for arm assessments has been reported as kappa = 0.92 or percent of agreement = 97.4%²¹ Individual muscle tone ratings were then summed to give an overall MAS score. Manual muscle testing (MMT), using a 12-point grading scale (0, 1, 2-, 2, 2+, 3-, 3, 3+, 4-, 4, 4+, 5), was used to assess muscle power.²² Numerical values were then assigned to the grades (i.e. 2 + = 2.33; 3 - = 2.66; and so on) and the overall MMT score was the sum of individual muscle values. The Fugl-Meyer Assessment of Motor Recovery (FM) upper limb subsection is one of the most widely used quantitative measures of motor impairment.²³ The upper limb subsection includes 33 items measuring movement, coordination, and reflex action about the shoulder, elbow, forearm, and wrist with a three-point scale from zero (unable to perform) to two (able to perform) used to score each item for a total score of 66. It has good interrater reliability for use with TBI patients (ICC = 0.97).²⁴

Functional task performance without the orthosis was assessed using the following measures. The box and blocks test (BBT) is a standardized assessment of unilateral gross manual dexterity. The participant was seated at a table, facing a rectangular box that was divided into two square compartments of equal dimension by means of a partition. One hundred and fifty colored, wooden 2.5 cm blocks were placed in one of the compartments. The BBT was scored by counting the number of blocks carried over the partition during a one-minute trial. Higher scores on this test indicate better gross manual dexterity. Psychometric properties such as validity and reliability have been wellestablished in numerous populations including TBI.²⁴ Performance of ADLs was assessed using the Chedoke Arm and Hand Activity Inventory, which is suitable for populations with upper limb paresis²⁵ and consists of 13 functional tasks. It is not designed to measure the participant's ability to complete the task using only their unaffected hand, but rather to encourage bilateral function.

Orthosis utilization (i.e. time of use and number of repetitions of elbow flexion/extension and hand open/ close) was recorded by the built-in orthosis software while the participant wore the orthosis for in-clinic training and home-use phase. The orthosis software records the time the orthosis is powered on and off, computing the elapsed time for each activation session. It counts a repetition when the motor activates, generating movement greater than 30° at the elbow or greater than 30% of the preset range of motion at the hand followed by 1s rest or change in direction of motion. Subthreshold movements are not counted, hence unequal values of flexion/extension and open/close can be generated. Data were downloaded from the orthosis periodically during the in-clinic training phase and at each assessment visit conducted during the home-use phase. Caregivers were also asked to record the time the participant spent at home practicing specific exercises from the home program and to report any changes in her function, which were recorded as functional milestones by study staff.

Outcomes

There was a stability of performance on clinical measures between the two baseline assessments. The study protocol was well tolerated, with no adverse or unanticipated events, and the training schedule was appropriately followed with the subject attending all scheduled training and testing sessions.

During the in-clinic training phase, active ROM improved for shoulder, elbow, and wrist, while passive ROM remained essentially unchanged (Figure 2(a)). There was a two-point improvement in summed MAS, while summed MMT increased by 13.98 points (Figure 2(b)). FM improved by 16 points, BBT improved by 5 blocks, and Chedoke improved by 10 points (Figure 2(b)). During the home-use phase,



Figure 2. Change in outcome measures over the study duration: (a) passive and active range of motion at the shoulder, elbow, and wrist; and (b) impairment measures (summed modified Ashworth scale (MAS), summed manual muscle test (MMT), Fugl-Meyer assessment of motor recovery) and functional measures (box and blocks test and Chedoke Arm and Hand Activity Inventory).

passive and active ROM returned to baseline values with the exception of shoulder abductors (Figure 2 (a)) but a summated MAS decrease of two points was maintained (Figure 2(b)).

Over the course of the study, MAS improvements were observed in shoulder internal rotators (from 2 to 1.5), elbow flexors (2 to 1.5), and wrist flexors (from 2 to 1). All other clinical measures retained a gain at the end of study participation, although a decline in some assessments was noted during the home-use phase. For example, there was a seven-point decline in FM score during the home-use phase, but the final assessment was still nine points higher than at baseline. There was a one block decline in the BBT during the home-use phase, but the final assessment was still five blocks higher than at baseline. There was a seven-point decline in Chedoke during the home-use phase, but the final assessment was still three points higher than at baseline (Figure 2(b)).

Over the course of both in-clinic training and homeuse phases, the participant trained with the orthosis a total of 70.12 h and, in total, logged 15,849 repetitions of elbow flexion, 16,859 repetitions of elbow extension, 13,397 repetitions of hand closing, and 13,520 repetitions of hand opening with the orthosis (Figure 3). Through self-report using logs to record home practice time during the in-clinic training and home-use phases, the participant demonstrated consistent practice with assigned exercises/tasks.

Functional milestones were reported by the participant's caregivers (Table 3). Overall, more spontaneous functional use of the right arm was observed during the in-clinic training phase and continued during the homeuse phase. After one month of training, the participant began incorporating her right arm into ADLs, including spontaneously using her right hand for feeding, brushing teeth and manipulating small objects. She also began to incorporate her right arm into bimanual tasks such as maneuvering her wheelchair, which reduced the need to readjust direction when propelling herself independently.



Figure 3. Orthosis utilization was recorded while the participant used the device for in-clinic training, home-use and during functional task performance assessment. The orthosis software recorded the date/time the device was worn and number of repetitions of elbow flexion/extension and hand opening/closing. The number of repetitions includes full and partial completion of movement.

Table 3. Self-reported and observed functional milestones.

Week 9	Increased use of right upper limb for ADLs with occasional cuing (i.e. brushing teeth, eating with utensil, answering phone, feeding dog treats with precision pinch).
Week 10	More independent initiation of functional tasks with right upper limb (i.e. picking up toothbrush; feeding herself finger foods spontaneously); participant manipulated object into a functional position in her hand during testing.
Week 11	Initiated self-feeding with utensil without cuing (i.e. was "eating macaroni salad at a picnic" using a spoon in the right hand).
Week 12	Eating finger foods with her right hand without cuing; increased precision with pincer grasp when feeding the dog or picking up small objects; ate a small pastry with her right hand in therapy; stacked three checkers during therapy.
Week 13	Increased awareness of the right upper limb, states she has been "using her left hand too much in the past and needs to use her right hand more". Caregivers note she can reach out further in front of her to use her right upper limb.
Week 14	Able to pick up very small pieces of dog treat with the device and feed them to her dog.
Week 15	Using right upper extremity more evenly during wheelchair mobility. Able to maneuver her wheelchair in her home without having to readjust/reposition as often.
Week 19	Continues to use her right upper extremity more spontaneously and maneuvers her wheelchair more independently.

Discussion

This case report demonstrates the potential benefit of using a myoelectric elbow–wrist–hand orthosis in motor learning-based rehabilitation of upper limb deficits in an individual with chronic severe brain injury. The participant demonstrated gains on measures of motor impairment and function, and caregivers reported functional improvement in her home setting in response to the intervention. Importantly, meaningful changes in motor performance were observed 30 years after initial neurological injury suggesting that patients with chronic severe TBI have the potential to improve in response to training.

The use of myoelectric orthoses may have a therapeutic effect in addition to previously demonstrated orthotic effect.²⁶ Therapeutic effect refers to improvements in impairment, defined by the International Classification of Functioning, Disability and Health (ICF) framework as changes related to "problems in body function and structure".²⁷ Orthotic effect refers to functional improvements that are possible while wearing the orthosis that increase activity and participation. Activity and participation are defined by the ICF as "execution of a task or action" and "involvement in life situations", respectively.²⁷ We observed a therapeutic effect according to several measures of both impairment (MAS, MMT, FM) and function (Chedoke, BBT) of upper limb motor performance. The basis for a therapeutic benefit of the intent-triggered myoelectric devices likely rests in the encouragement and reinforcement of coordinated volitional practice of motor control⁵ and the ability to gradually progress the training. Use of the device motivates practice and allows appropriate progression of therapy as the EMG threshold that triggers mechanical motion is gradually increased requiring the user to elicit greater volitional muscle activation and reciprocal agonist/antagonist activity. Thus, myoelectric orthoses provide the opportunity to engage and build on small residual volitional muscle activation, and through the application of motor-learning principles can be used to treat upper limb motor impairment for individuals with brain injury.

The design and implementation of efficacious training methods for individuals with neurological dysfunction is challenging. Treatment approaches based on motor learning theory are currently the prevailing choice in neurorehabilitation²⁸ and have been shown to improve impairment, function and quality of life in the setting of chronic neurological disease.^{20,29–31} Common across motor-learning based approaches are the application of critical motor learning principles. These principles include high repetition of functionally relevant movement performed as close to normal as possible; feedback on performance (i.e. knowledge of results or knowledge of performance); part versus whole task practice; massed versus distributed practice; and practice variability to ensure transfer to novel tasks.³² However, the current healthcare environment does not support implementation of these timeintensive yet critical motor learning principles in the traditional rehabilitation clinic. First, treatment duration is considerably short and patients have limited access to skilled care. In a recent study of outpatient therapy utilization 1-3 months post-stroke, patients attended on average only 24 outpatient therapy sessions in the first year, which equates to less than one therapy session every two weeks.³³ In chronic stages after brain injury, there is even more limited or no access to rehabilitation services. Second, typical outpatient upper limb rehabilitation provides insufficient repetition of arm movement that is an order of magnitude below numbers needed for effective neuroplasticity.34 Individuals perform an average of 32-50 repetitions of upper extremity practice per therapy session while animal studies report 400-600 repetitions per session are required to induce neuroplasticity.³ Even though high dose has been identified as a crucial ingredient to induce neuroplasticity, it is not being accomplished adequately in the clinical setting. Third, there is a need to ensure high quality practice of adequately challenging patient-driven functional movement. When under the skilled supervision of a therapist, motor performance can be closely monitored and progressed incrementally with clinically significant results.^{19,20,31} However, in-clinic training needs to be supplemented with home practice. Unfortunately, inhome practice usually lacks quality, capacity to progress and sufficient adherence.³⁵ Therefore, portable devices that are used in both clinical and home settings have the potential to allow for this critical repetition of quality practice to occur. The biofeedback technology employed by myoelectric orthoses such as the Myopro, ensures that training is patient-driven in that the patient must activate the correct muscle(s) in order to experience the desired movement. Training complexity can be progressed from single joint to multijoint movement and, very early on in training, functionally relevant tasks can be practiced.

In our case, the participant practiced an array of exercises and functional tasks that were progressed during the in-clinic training sessions and reinforced in the assigned home practice. Indeed, utilization data reported for this participant supports that much of the training occurred in her home setting. She performed several thousands of volitional muscle activations at home over the course of study participation. Early in treatment, functional task performance both with and without the orthosis was encouraged and assigned as part of her home practice. For example, since our study participant enjoyed the companionship of her pet, she was highly motivated to practice the functional activity of "feeding treats to her pet," thus reinforcing use of her impaired right upper limb. This motivation resulted in adherence to high quality repeated practice.

It is compelling that meaningful changes in motor performance were achieved in response to training many years after injury, and after demonstration of a stable baseline. According to her caregivers, the participant had many opportunities following her injury to rehabilitate use of her right arm; however, success was limited. From initial assessment, it was apparent that although she had motor impairments that affected her right arm, they were not sufficiently severe to preclude movement of the arm. She had weakness of her right upper limb but was able to move against gravity; increased tone but was still able to move her joints through partial range; decreased coordination but had the ability to move out of stereotypical synergy patterns. Despite this, she avoided using her right arm and did not attempt to incorporate it into everyday function. Working with the myoelectric orthosis allowed her to overcome the barrier of decreased attention to her right arm as the orthosis produced large arm movements in response to her activating the appropriate muscle. By focusing the training on the right upper limb through both volitional and orthosis-driven exercises, the patient was being guided to use the right limb in a coordinated way. High repetition and the introduction of meaningful functional task performance further reinforced use of her right arm. Minimal clinically important difference (MCID) and minimal detectable change values (MDC) of the measures used in this study have not been established for TBI; however, values have been reported for chronic stroke. When considering these values, the effects of training produced robust improvement on the FM (16-point increase during in-clinic phase; nine points increase overall at conclusion of home phase) exceeding the MCID range of 4.25-7.25 for chronic moderate stroke.³⁶ The score for box and block test improved by 5, a result that is close to the MDC reported for chronic stroke population (5.5–6 blocks/min).³⁷ For the Chedoke Arm and Hand Activity Inventory, she exceeded the 6.3-point MDC for chronic stroke (10point increase after the in-clinic phase; three points at conclusion of the home phase).^{38,39}

In conclusion, for this case of an individual with long-standing TBI and motor deficits of the right upper limb, motor function improvements were observed in response to training with a myoelectric elbow–wrist–hand orthosis combined with motor learning-based therapy. Meaningful improvements on study measures and self-reported function were observed 30 years after initial injury. It may be that the combination of motor learning and the reinforced use of an impaired limb through high repetition practice of functional movement that was delivered over a long duration led to these results. Further assessment in a larger cohort of TBI patients is warranted.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: SK is an employee of the manufacturer of the myoelectric orthosis used in this case report. Other authors have no conflicts of interest to declare. All authors are co-investigators on the following grant which funded this work. The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. Opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the Office of Secretary of Defense for Health Affairs, through the Orthotics and Prosthetics Outcomes Research Program, Orthotics Outcomes Research Award under Award No. W81XWH-16-1-0733. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

Guarantor

SP.

Contributorship

SF, SP, and SK researched literature and conceived the study. SF, SK, JM, and MS were involved in protocol development, gaining ethical approval, patient recruitment, and data analysis. SF wrote the first draft of the article. All authors reviewed and edited the article and approved the final version of the article.

Acknowledgements

Portions of the work presented in this article were previously presented at the American Academy of Orthotists and Prosthetists Annual Scientific Meeting held in New Orleans, LA, 14–17 February 2018.

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