Enhanced Functionality Using a Powered Upper Extremity Exoskeleton in Patients With Brachial Plexus Injuries

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***Abstract*— Traumatic brachial plexus injury (BPI) results in significant disability, often hindering functionality in the patient's daily life. Post- surgery, muscle strength recovery can take up to two years, with 40% of patients requiring even longer. A powered elbow orthosis can enhance functionality during activities of daily living (ADLs). This study tested a novel powered myoelectric elbow orthosis (PMEO) during ADLs. Subjects with BPI were fitted with the PMEO and divided into two groups: more impaired (Manual Muscle Test (MMT) < 3, N = 5) and less impaired (MMT≥ 3, N = 4). They performed four ADLs involving full elbow motion, including an activity requiring the subjects to lift a basket with weights. Upper extremity kinematics, electromyographic activity, weight lifted, and subject feedback on the device's form and fit were collected and analyzed. Results showed that the PMEO significantly improved elbow range of motion in the more impaired group (14 ± 23 degrees, p = 0.019) without any additional compensatory motions in the shoulder or trunk. More impaired subjects lifted an average of 1.1 ± 0.6 kg with the PMEO, whereas they could not do so without it (p = 0.011). Subjects appreciated the PMEO's weight, fit, and form. All could don and doff the device with minimal assistance. These findings demonstrate that the PMEO is a viable option to enhance ADL function for patients with BPI.**

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I. Introduction

TRAUMATIC brachial plexus injuries (BPI) are devastating. Treatment may involve complicated surgeries followed by extensive physical rehabilitation and a lengthy healing process. Muscle strength takes up to 2 years to mature [1]. However, surgical interventions do not always restore elbow flexion for patients with traumatic BPI. About 40% of the patients are unable to overcome gravity during elbow flexion after 2 years of recovery [2].

Myoelectric orthoses facilitate movement in the affected limb, assist with functional elbow flexion, and restore independence [3]. Current commercially available powered orthotic devices require sustained activity of the weak elbow flexor's to assist with flexion [4]. Anderson et al. demonstrated, in a series of three case studies, that patients can improve elbow flexion using a commercial myoelectric powered orthosis [5]. Anderson et al. used the myoelectric orthosis for both rehabilitation and daily function. Pulos et al. investigated extended myoelectric orthosis use in nineteen BPI patients in their everyday environment. A review of therapy notes from clinical visits demonstrated that using a myoelectric orthosis improved elbow flexion strength, improved function, and reduced pain in patients with BPI [6]. The orthoses used in these studies, MyoPro, was specifically designed for the stroke population [4] and was used a cross-over application for the BPI population. The MyoPro has been criticized for its bulky form-factor, inducing fatigue and reducing function during use in daily life [7]. The fatigue is caused by the device requiring sustained muscle activity to activate the motorized assistance.

Ögce and Özayçin investigated orthotic technology specific to the BPI population with a lightweight and compact device intended to promote two-handed function [8]. The authors reported that for two case studies, the patients with BPI achieved elbow flexion assisted by the orthosis and two-handed function in activities of daily living. Kubota et al. used a wearable myoelectric robot (upper limb single-joint hybrid assistive limb (HAL)), to provide assisted elbow joint motion to rehabilitate patients with BPI

and demonstrated that using the custom orthosis increased strength, active range of motion, and function at the elbow joint. [9], [10]. Doi et al. evaluated the HAL device as a rehabilitation tool for patients with BPI and compared the results to patients who received electromyographic biofeedback training, allowing for the visualization of the myoelectric activity of the muscles, in a preliminary study [11]. Long-term results for elbow flexion range of motion, elbow flexion power assessed by the manual muscle testing scores (MMT using the modified British Medical Research Council scale [1]), and quantitative dynamometry was similar between the two groups, but the number of rehabilitation sessions was significantly fewer in the HAL group than the biofeedback group. These devices were developed as discrete use rehabilitation tools, and performance evaluation of these BPI specific devices has been limited to case study reports [8], [9], [10] or rehabilitation outcomes [11]. While these rehabilitation devices do show improved outcomes for the BPI population, these devices do not specifically address the limitations of the current commercial myoelectric powered orthosis (such as bulky form-factor, inducing fatigue and reducing function during use in daily life [7]) currently being considered for the BPI population.

An innovative and lightweight powered myoelectric elbow orthosis (PMEO) developed previously [12], was tested in the current study. This device uses a brake mechanism to hold the elbow at any flexed position, allowing the user to relax their muscle and minimize fatigue in the affected limb. The elbow can extend under gravity once the brake is disengaged. The primary goal of this study was to assess the upper extremity kinematics and strength improvements provided by the PMEO during activities of daily living. The secondary goal was to assess fatigue reduction experienced by the users and their subjective views of the fit and form.

II. Methods

This study tested the effect of a novel PMEO used by patients with a BPI during activities of daily living (ADL) (Fig. 1).

A. Participants

Patients from the Brachial Plexus Injury Clinic at the Mayo Clinic, Rochester, MN were screened for eligibility to participate in the study. Participants included in the study were aged 18 to 65 years and had experienced a traumatic brachial plexus injury that resulted in the loss of elbow flexion, necessitating reconstructive surgeries. They were required to have a functional passive range of motion in the affected upper extremity and the ability to follow simple directions. Exclusion criteria were the presence of a closed head injury that impaired the ability to follow commands, soft tissue or skeletal injuries that would prevent the use of an orthosis, non-functional passive range of motion, neuropathic pain that precluded the use of a powered exoskeleton, and any unwillingness or inability to comply with the test procedures.

Subjects who met the inclusion criteria, regardless of gender, race, or ethnicity, were contacted for recruitment. All enrolled subjects were informed regarding the experiment

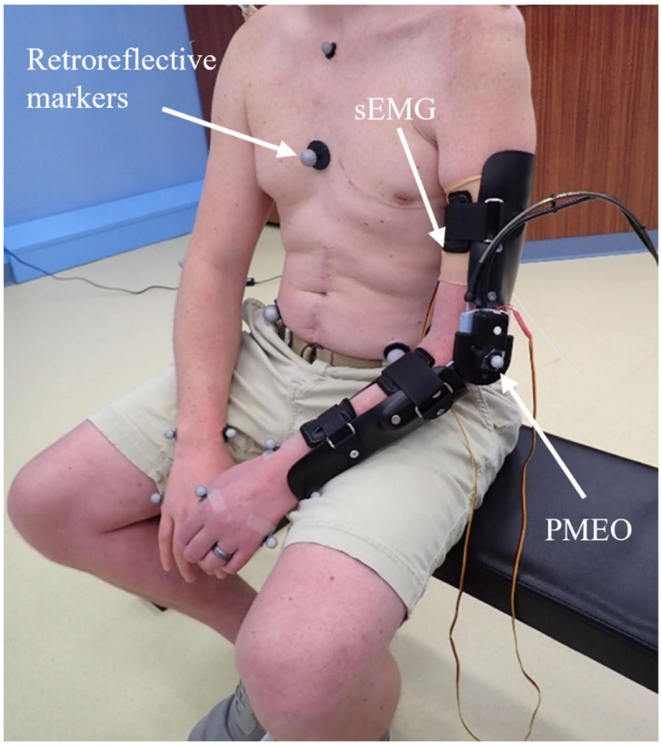

Fig. 1. The powered myoelectric elbow orthosis (PMEO) on the Subject's affected (Left) Arm [12].

and consented under the guidelines set by Mayo Clinic's Institutional Review Board (IRB no. 20-006849) and written informed consent was obtained prior to beginning participation in the study. A board-certified orthotist from Limb Lab, Rochester, MN designed and fit the enrolled subjects with custom orthotic components to attach the PMEO to the subject's arm (Fig. 2 (a)). The orthotist also educated the subjects on properly donning and doffing of the orthosis based on the subject's abilities.

B. Data Collection

The subjects were studied in the Motion Analysis Laboratory at the Mayo Clinic, Rochester, MN. Prior to data collection, the subjects were asked to don the PMEO independently and assistance was only provided when the subjects requested it. Adjustments were made to the fit and alignment of the PMEO if deemed necessary by the study staff to ensure the components were comfortable for the subject and did not impinge movement. The subject's demographic data (age, height, weight, time since surgery, orthosis side, type of surgery, nerve used, manual muscle testing scores (MMT using the British Medical Research Council scale) were collected.

A calibration procedure was conducted to establish the PMEO's signal activation threshold and operation algorithm inputs, such as a double pulse routine to release the brake mechanism [12], [13](Fig. 2 (b)). The subjects were allowed to become familiar with the device control strategy [12] and operation during the calibration process which lasted about an hour. An sEMG sensor with a built-in amplifier (EMG500, Motion Lab Systems, Inc., Baton Rouge, LA) was positioned on the elbow flexor muscle belly using adhesive tape

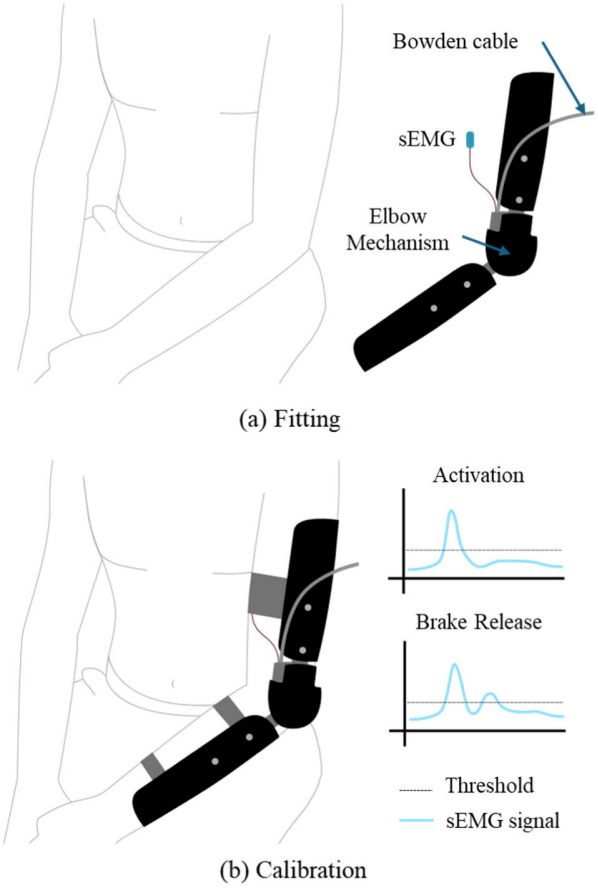

Fig. 2. An illustration describing the initial setup process for the PMEO. (a) The PMEO was fit for each subject by a certified orthotist. The parts attaching the PMEO to the upper and lower arm (black) were vacuum formed using a thermoplastic. (b) A calibration procedure was performed to find the activation threshold and the brake release duration for each subject. (sEMG: surface electromyography sensor).

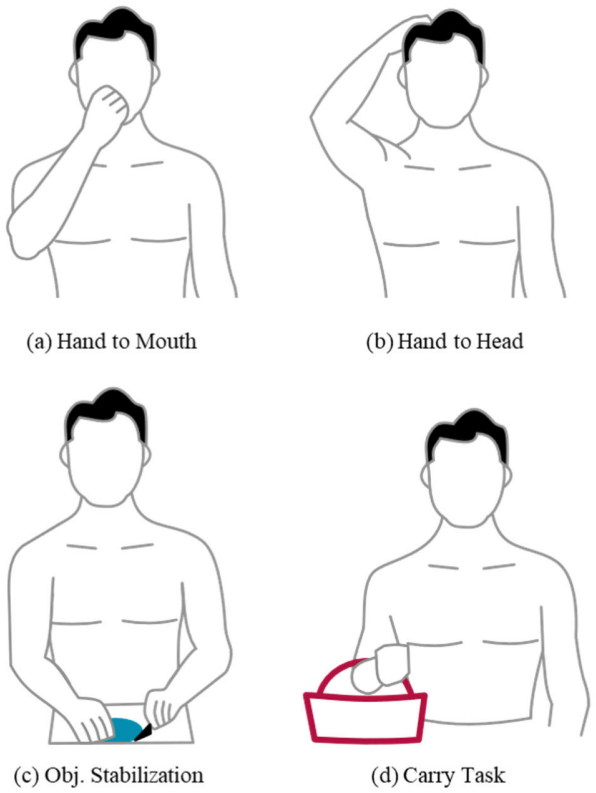

Fig. 3. The four activities of daily living performed by the subjects. (a) hand-to-mouth, (b) hand-to-head, (c) object stabilization, and (d) carry task.

(3M Tegaderm 1624W transparent film dressing frame style tape). An athletic prewrap (Cramer tape, SKU: 214546) securely fastened the sensor to the upper arm. The signal activation threshold value was set higher than the resting level with the arm extended.

Kinematic parameters were obtained using a 12-camera motion capture system (Raptor-12, Motion Analysis Corporation, Santa Rosa, CA). Key anatomical landmarks were marked with retro-reflective markers to model the trunk, as well as the bilateral scapulas, upper arms, forearms, and hands [14].

Three repetitions of four ADLs were performed by the subjects under two conditions, (1) with the PMEO active, donned on the affected arm and (2) without the PMEO donned, to assess the effectiveness of the PMEO. Activities [7] that would elicit full motion and functional capability of the subject's elbow joint were selected. The subject was directed to simulate eating a candy bar with their affected arm (hand to mouth, Fig. 3 (a)), mimic scratching the top of their head with their affected arm (hand to head, Fig. 3 (b)), stabilize a clay ball with their affected arm and slice it like a potato three times with their unaffected arm (object stabilization, Fig. 3 (c)), and lift a basket (containing weights) with their unaffected arm, flex their affected arm, and slide it under the basket handle to carry the basket 10 feet and hand it to the researcher (carry task, Fig. 3 (d)). The carrying task involved progressively increasing weights (in the form of water bottles, each weighing 489 g) in the basket until the subject could no longer lift the basket or experienced discomfort while doing so. The maximum amount of weight lifted by the subjects was recorded for both the conditions. After performing the activities, the subjects completed a patient reported outcome questionnaire, which rated the subjects' experience with the PMEO. A detailed account of the subjects' comments during the data collection was maintained.

C. Data Processing

Commercial biomechanical modeling software (Visual 3D, C-Motion, Inc., Rockville, MD) utilized 3D marker trajectories to create the segment coordinate systems and calculate upper extremity kinematics. Marker trajectories were processed using a generalized cross validatory spline smoothing filter (GCVSPL) within Visual 3D [15]. The segment (forearm, upper arm, and trunk) coordinate systems and the joint angle conventions used to calculate the joint kinematics (elbow and humerothoracic) were defined according to International Society of Biomechanics (ISB) standards [16]. Elbow range of motion for the affected side, the average and standard error for maximum elbow flexion and extension angles, and the maximum and minimum angles of the HT joint and the trunk were calculated for each task and subject.

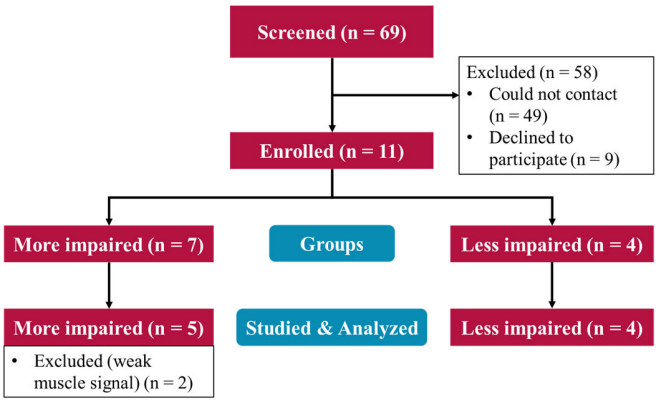

Fig. 4. Consort flow diagram for the cohort study.

The raw EMG data was band-pass filtered (4th order Butterworth filter with bandpass filters set at 20 Hz and 450 Hz) and full wave rectified. Fatigue in the elbow flexor during the carry task was studied using the global root mean square of the filtered sEMG amplitude (RMS_{EMG}) and the median power frequency of the filtered sEMG amplitude (MPF_{EMG}) [17]. A fatigued muscle would result in a higher RMS_{EMG} and a lower MPF_{EMG}. All data processing was performed in MATLAB 2021b (The MathWorks, Inc., Natick, MA).

D. Statistical Analysis

The difference between the two PMEO conditions were analyzed for the following data: maximum elbow flexion and extension angles, the range of motion of the HT joint, the range of motion of the trunk, the RMS_{EMG}, the MPF_{EMG}, and the amount of weight lifted. These differences were analyzed using a two-sided student's t-test. Statistical significance was set to $p < 0.05$.

III. Results

In this cohort study, eleven individuals were recruited from the sixty-nine patients screened (Fig. 4). Nine subjects declined to participate, citing their unwillingness to travel to the study site. The enrolled subjects were divided into groups with less impairment (elbow function equal to or greater than 3 on the MMT scale) and more impairment (less than 3 on the MMT scale). Two of the subjects in the more impaired group had a weak muscle activation signal and a high amount of EMG noise, so they were excluded from the study. The final cohort consisted of the more impaired group ($n = 5$) and the less impaired group ($n = 4$) (Table I). All subjects studied were able to operate the PMEO. The less impaired group consisted of 2 subjects with a fused shoulder. All the other subjects had weak shoulder function (MMT grade 2 or lower). All the subjects had a paralyzed hand and wrist.

A. Functional Range of Motion

Using the PMEO, elbow flexion improved in the more impaired group, while the less impaired group were able to extend their elbow better. The more impaired group flexed their elbow 13 ± 23 degrees ($p = 0.019$) more while using

TABLE I
Subject Demographics

	More Impaired	Less Impaired
N	5	4
Height (m)	1.8 ± 0.1	1.8 ± 0
Weight (kg)	97.3 ± 15.1	99.3 ± 27.6
Age (years)	37.6 ± 12.2	27.5 ± 9.3
Time since surgery (months)	43 ± 18.7	44.4 ± 24
Affected side (Right/Left)	1/4	0/4
Type of injury	Upper Trunk: 2; Pan Plexus: 3	Upper Trunk: 0; Pan Plexus: 4
Type of surgery	FFMT: 4; Nerve transfer: 1	FFMT: 3; Nerve transfer: 1
Nerve connected to the elbow flexor	SAN: 3; ICN: 1; Ulnar nerve: 1	SAN: 1; ICN: 2; Ulnar nerve: 1
Orthosis weight on arm (kg)	0.54 ± 0.03	0.53 ± 0.04

FFMT: Free Functioning Muscle Transfer; SAN: Spinal Accessory Nerve; ICN: Intercostal Nerve.

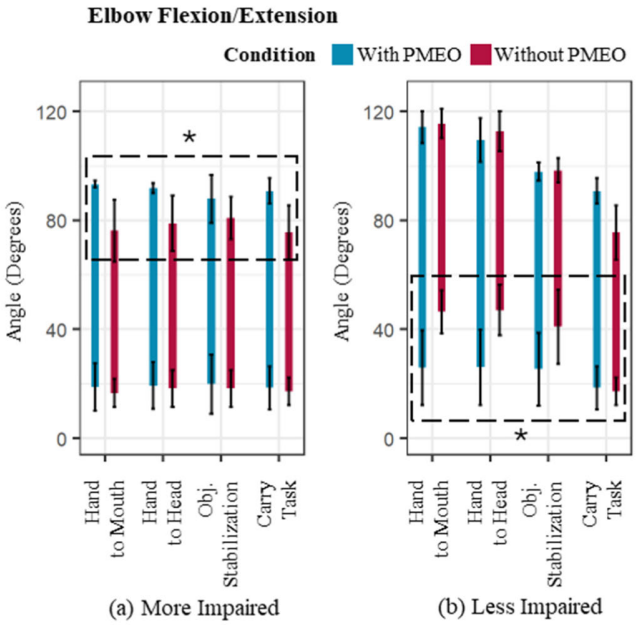

Fig. 5. Elbow range of motion during the activities of daily living for the (a) More impaired group, and the (b) Less impaired group. The error bars are the standard errors. The statistically significant difference between the two conditions is denoted by an asterisk (*).

the PMEO, but their elbow extension was similar in both cases across all activities (Fig. 5 (a)). The less impaired group did not show improvement in elbow flexion, but their elbow extension improved by 21 ± 19 degrees ($p < 0.001$) across all activities (Fig. 5 (b)). Hence, the PMEO enhanced the range of motion of the affected arm in all the subjects.

HT joint compensatory motion was similar for both conditions tested. While using the PMEO, the more impaired group's HT joint displayed similar ranges of motion without the PMEO, in the plane of elevation (Fig. 6 (a)) and the elevation angles (Fig. 6 (b)). The more impaired group's

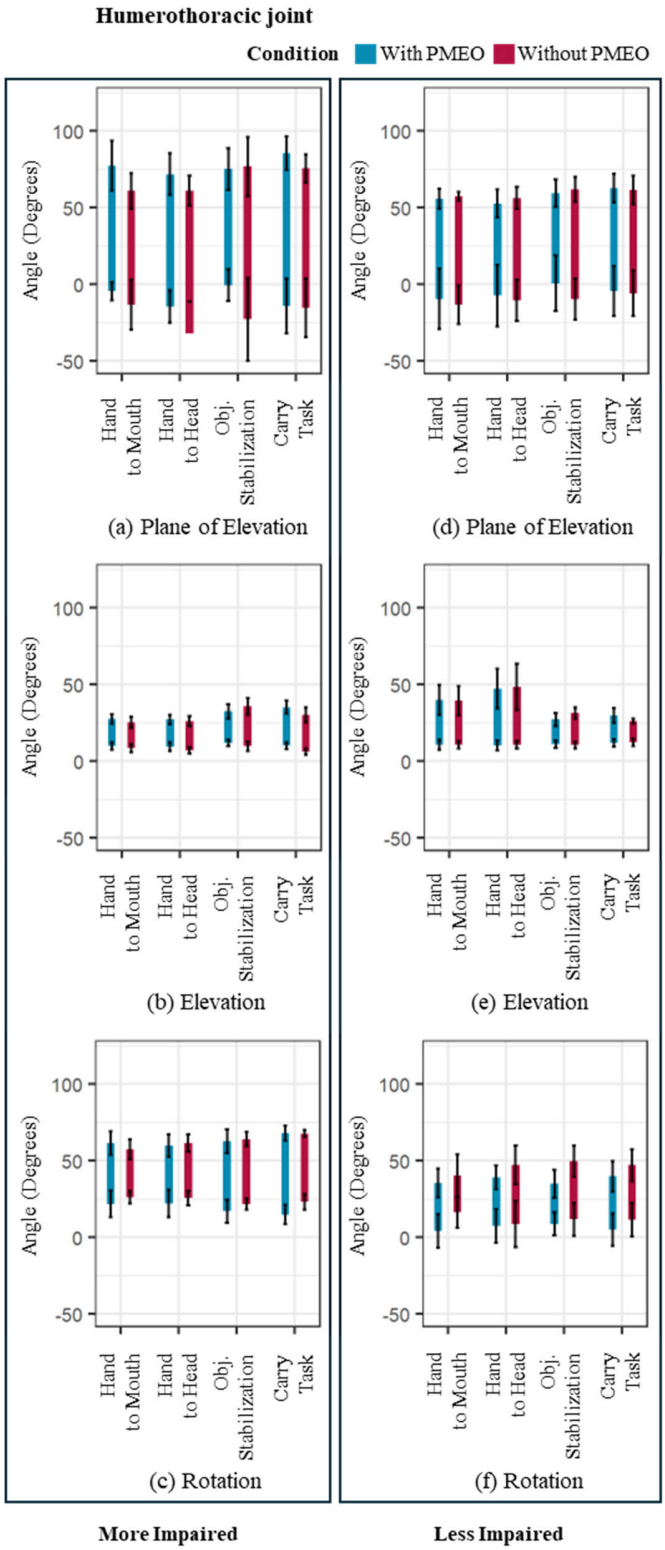

Fig. 6. Humerothoracic joint range of motion for the plane of elevation, elevation and rotation for the more impaired group ((a), (b), (c) respectively) and the less impaired group ((d), (e), and (f) respectively) during the activities of daily living. The error bars are the standard errors. The statistically significant difference between the two conditions is denoted by an asterisk (*).

HT rotation range of motion was 6 ± 9 degrees higher with the PMEO compared to without the PMEO ($p = 0.013$) (Fig. 6 (c)). The less impaired group's HT joint displayed similar ranges of motion in all three planes (Fig. 6 (d), (e), (f)). The ranges of motion in the trunk were similar with and without the PMEO for all subjects. Therefore, use of the PMEO did not induce any compensatory movements in the subjects while performing ADLs.

B. Fatigue and Functional Strength

The subjects in the more impaired group were able to perform tasks which were not possible without the PMEO. These subjects carried a basket with an average weight of 1.14 ± 0.57 kg while being unable to lift any weight without the PMEO ($p = 0.011$). The less impaired group lifted similar amounts of weights with and without the PMEO (Δweight = 0.51 kg; $p = 0.33$). Hence, the PMEO enhanced the functional strength of the affected arm in the more impaired subjects.

Neuromuscular fatigue induced during the carry task was similar between the with and without PMEO conditions. The MMT ≥ 3 group's MPF_{EMG} with the PMEO (0.83 ± 0.24 Hz) was similar to that without the PMEO (4.08 ± 4.45 Hz) ($p = 0.22$) and their RMS_{EMG} with the PMEO (0.044 ± 0.047 V) was similar to that without the PMEO (0.05 ± 0.043 V) ($p = 0.83$).

C. Patient Reported Outcomes

The subjects reported favorable results after using the orthosis. Most of the subjects reported needing no assistance when donning (5 out of 9) and doffing (6 out of 9) the PMEO. Two subjects reported needing minimal assistance while both donning and doffing the PMEO. Seven subjects reported that the PMEO felt lightweight on their affected side, while the other two subjects declined to answer. The subjects were also pleased with the form and fit of the PMEO (3 subjects said the device was excellent; 6 subjects said the device was acceptable). None of subjects reported any discomfort during the PMEO use.

IV. Discussion

The study showed that the PMEO was able to provide functional assistance to the subjects. The PMEO improved elbow flexion. The PMEO also enhanced the functional strength in the subjects with a higher level of impairment, without inducing additional fatigue in the elbow flexor. Lastly, the form and fit of the PMEO were acceptable to the subjects. They were able to don and doff the device without external assistance.

The PMEO provided enhanced function by improving the amount of elbow flexion of the affected arm. The ability to position and orient the hand using proximal joints (elbow and shoulder) is critical to the successful completion of ADLs [18]. Restricted elbow range of motion results in increased time to complete tasks and outright impairment [19]. Oosterwijk et al.'s review stated that a majority of ADLs require the elbow to flex above 90 degrees [20]. The more impaired subjects studied in the current study were able to flex their elbow above 90 degrees with the PMEO, while being unable to do so on their own. In their study, Vasen et al. restricted elbow flexion in healthy individuals

during ADLs. They reported that no impairments, and the subjects successfully performed ADLs with an elbow range of motion of 75 to 120 degrees [21]. In the current study, the PMEO did not hinder elbow flexion in the less impaired subjects, who were able to flex their elbow to a maximum of 120 degrees with the PMEO. Hence, the function of the affected limb was improved by the PMEO.

The less impaired subjects were able to extend their elbow better with the PMEO than without the PMEO. The less impaired subjects in Barrie et al.'s study had an average elbow extension deficit of 27 degrees [22]. Less impaired subjects are capable of opposing gravity during elbow flexion as compared to the more impaired subjects [22]. Post-surgery, the patients with a BPI generally have a higher passive range of motion compared to their active range of motion. Therefore, the elbow should extend further with a weight attached to it. The PMEO and the carry task exerted an external weight on the subjects affected arm. The elbow extended further in both those cases. Therefore, it can be argued that the PMEO helped extend the elbow further in the less impaired subjects, thereby improving the range of motion.

The PMEO also improved function by allowing the more impaired subjects to lift weights. Positive correlation between muscle strength and better ADL outcomes have been observed [23]. Miller et al. observed that function and quality of life improved with an increase in strength in patients with a BPI [24]. The more impaired subjects in the current study were studied about 4 years post-surgery. These subjects did not have the ability to oppose gravity with their elbow flexor. Hence, using a PMEO would improve their capability to perform ADLs.

The PMEO did not induce any compensatory movements in the subjects. Several researchers have reported compensatory movements in the proximal joints due to an orthosis/prosthesis on the distal joint [25], [26], [27]. The PMEO only induced an additional 6 degrees of HT joint rotation in the more impaired subjects, with a similar range of movements in all other planes with and without the PMEO. Vasen et al. reported the need for compensatory movements in adjacent joints during ADLs with a limited elbow range of motion [21]. Fradet et al. noted that compensatory movements were induced in both the shoulder and trunk during ADLs when the elbow range of motion was limited between 60 to 100 degrees [28]. Both studies suggest a reduction in shoulder and trunk compensatory movement with an improvement in the elbow range of motion. Although the PMEO use did not increase compensatory movements, it also did not result in a reduction of movements. A possible explanation of this phenomenon could be the limited amount of orthosis training provided to the subjects. Further studies including a longer training duration, and an at-home data collection protocol are underway.

Despite a mechanism to hold the user's arm without any muscle activation, the metrics indicating fatigue in the elbow flexor did not improve while using the PMEO. This could be attributed to the lack of orthotic training the subjects underwent prior to data collection. In their study, de Araújo et al. showed a better EMG amplitude for subjects who received training with their orthosis for 8 weeks, indicating better neuromuscular control [29]. Hammelef et al. reported that after an 8 week period, their subjects were able to successfully incorporate their orthotic device in ADLs [30]. Vanderniepen et al. stated that a training session duration of longer than 1.5 hour would result in a better outcomes with an orthosis [31]. It was also observed that patients with a BPI were able to get used to an elbow orthosis after prolonged use [6]. The subjects in the current study were allowed to use the PMEO for less than an hour before data collection. Hence, it is believed that the subjects might be less fatigued using the PMEO for ADLs with further training.

The subjects found the PMEO acceptable to wear. In a prior study by Webber et al., the subjects reported that the commercially available device, MyoPro, was useful during rehabilitation, but not during ADLs [6]. They also commented on the bulk of the MyoPro causing fatigue and pain in the affected arm. The PMEO was designed to be light weight and have a low profile such that it could worn under clothing. None of the subjects reported any pain during the data collection. The subject's stated that the PMEO was light weight and was easy to don and doff.

The study described in the article has certain limitations. Marker-based motion capture kinematics were utilized to compare the with and without PMEO conditions. In the without PMEO condition, the distal upper arm and the proximal forearm segments were defined with a marker placed directly on the lateral elbow epicondyle. While in the with PMEO condition, these segments were defined by a virtual marker created from the measured offset between the marker placed on the PMEO and the lateral elbow epicondyle. Extreme care was taken to align the PMEO with the subject-specific elbow joint axis to minimize the differences between the marker placed on the PMEO and the lateral elbow epicondyle. The PMEO was not tested on a large cohort. However, BPI is a rare injury and prior studies on this patient population also have had a small sample size [32], [33], [34], [35]. The subjects were not allowed a lengthy accommodation prior to beginning the study. The data collection was performed in a controlled laboratory setting. Performance of the PMEO in the user's home environment over a longer period of time would provide a better understanding of the benefits of the device. A future clinical trial is planned to address these limitations.

V. Conclusion

The study showed that the PMEO improved the functional capability of the user's affected arm. Improvements were pronounced in the more impaired subjects, allowing them to perform more ADLs. A longer training period may lead to even better fatigue outcomes.

Acknowledgment

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