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Design and Development of a Powered Myoelectric Elbow Orthosis for Neuromuscular Injuries

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ABSTRACT
Introduction:
Recovering from neuromuscular injuries or conditions can be a challenging journey that involves complex surgeries and extensive physical rehabilitation. During this process, individuals often rely on orthotic devices to support and enable movement of the affected limb. However, users have criticized current commercially available powered orthotic devices for their bulky and heavy design. To address these limitations, we developed a novel powered myoelectric elbow orthosis.

Materials and Methods:
The orthosis incorporates 3 mechanisms: a solenoid brake, a Bowden cable-powered constant torque elbow mechanism, and an extension limiter. The device controller and battery are in a backpack to reduce the weight on the affected arm. We performed extensive calculations and testing to ensure that the orthosis could withstand at least 15 Nm of elbow torque. We developed a custom software effectively control the orthosis, enhancing its usability and functionality. A certified orthotist fitted a subject who had undergone a gracilis free functioning muscle transfer surgery with the device. We studied the subject under Mayo clinic IRB no. 20-006849 and obtained objective measurements to assess the orthosis's impact on upper extremity functionality during daily activities.

Results:
The results are promising since the orthosis significantly improved elbow flexion range of motion by 40 and reduced compensatory movements at the shoulder (humerothoracic joint) by 50 . Additionally, the subject was able to perform tasks which were not possible before, such as carrying a basket with weights, highlighting the enhanced functionality provided by the orthosis.

Conclusion:
In brief, by addressing the limitations of existing devices, this novel powered myoelectric elbow orthosis offers individuals with neuromuscular injuries/conditions improved quality of life. Further research will expand the patient population and control mechanisms.

INTRODUCTION

Upper limb injuries are frequently seen in sports[1] and motor vehicle accidents (MVA). Injuries such as peripheral nerve injury (PNI), spinal cord injury (SCI), and brachial plexus injury (BPI) are often debilitating, causing extensive disabilities in the upper extremity (UE). While 5% of all MVAs result in a form of PNI,[2] about 8% of PNI patients have a BPI,[3] which results in severe impairment following penetrating wounds, falls, and motor vehicle accidents or other high-energy trauma. Young male adults comprise a majority among patients with a BPI.[4] MVAs and falls are leading causes of SCI. 38.1% of all SCI were caused by MVAs and 53% by falls between 2010 and 2014.[5] The United States has an estimated annual SCI incidence of 17,000.[6] The National Spinal Cord Injury Statistical Center estimated 282,000 people were living with a SCI in 2016.[7]

Recovery from these injuries/conditions can be an arduous process involving extensive surgeries and physical rehabilitation. Restoring function in the affected limb is the goal of these rehabilitative approaches. Physicians often prescribe an orthotic device to support/enable movement of the affected limb during rehabilitation to individuals affected by these injuries. Presently, the MyoPro (Myomo, Boston, MA, USA) is the most widely used powered elbow orthoses for BPI and PNI. The MyoPro is a myoelectrically controlled, self-contained unit, with the controller, battery, and the motor assembly attached to the affected arm. Myomo describes MyoPro's operation as "the myoelectric arm brace amplifies weak muscle signals to help move the upper limb."[8] The

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MyoPal (Myomo, Boston, MA, USA) is an upcoming orthosis for children, with the battery in a backpack. Myomo states that the MyoPal operates in a similar manner to the MyoPro.

The literature describes many powered orthotic devices for the upper extremity. Cempini et al. and Vitiello et al. developed the NEUROExos for treating patients with a cerebrovascular incident (stroke).[9,10] The orthosis was large, incorporating a stand in its assembly and used a torsional spring at the elbow joint, actuated by motors placed outside the orthosis connected to the elbow joint by Bowden cables. Pylatiuk et al. developed a myoelectric elbow orthosis utilizing a flexible actuator operated via hydraulic pressure.[11] The exoskeleton by Stein et al. utilized 2 Bowden cables to enable flexion and extension of the elbow joint for hemiparetic stroke survivors. The goal of their orthosis was to promote robot-assisted exercise in the patient population; there was no consideration for activities of daily living.[12]

Webber et al. conducted a qualitative study to assess the patient perspectives on their use of a commercially available myoelectric elbow orthosis (MEO).[13] The patient's physician prescribed them the MyoPro elbow orthosis. Webber et al. interviewed the patients 18 months post BPI surgery. Interviewees reported improved functionality of their arm while utilizing the MyoPro for household chores and daily activities. While discussing the rehabilitating aspects of the device, a patient stated, "The best use that I have found for the [MEO] is learning how to use the muscles that have been rewired into me."[13] Other patients complained about the orthosis being "bulky" and that it "got in the way."

Some subjects reported shoulder pain when using the MyoPro, even for short periods of use, requiring a change of posture. Many expressed the need for the device to be lighter and complained about the short battery life. Critical feedback suggested that the device would be more useful if the device could lock in position and support the arm weight without constant muscular activation in the EMG signal. Others felt that locking the arm in a specific position would hinder elbow function.[13]

METHODS

Design and Development

The limitations of the MEO, as described by Webber et al., led to the design goals for the current orthosis.

Design goals

1. Place the motor assembly, controller, and batteries in a backpack to offload the affected arm by transferring weight to a non-affected part of the body.
2. Actuate the elbow mechanism with a Bowden cable system.
3. Eliminate excessive weight from the elbow mechanism.
4. Utilize a solenoid and cam design as a brake system to facilitate holding the elbow at a desired angle.
5. Enable elbow flexion when the brake disengages.
6. Support the weight of the forearm as the brake engages.

Mechanism

Along the design goals stated, we started designing and developing an orthosis. We designed the brake mechanism to maintain the elbow angle independent of a muscle activation signal. The brake mechanism comprises a custom cam-pulley (Fig. 1A.1) and a solenoid pin (Fig. 1A.2). We designed the cam-pulley fixture to enable rotation in the direction linked with elbow flexion, while interaction with the solenoid pin hindered rotation in the elbow extension direction. Upon activation, the solenoid retracts the pin and actuates the primary controller, allowing the motor to flex the elbow or allowing the elbow to extend naturally under gravity. The solenoid could be enabled for automatic locking of the brake mechanism, which would result in reduction of overall energy consumption by the orthosis system and elimination of muscle fatigue by the user.

We designed the elbow mechanism to apply a consistent torque level to the elbow joint, irrespective of its angle. To achieve this, we fixed a pulley to the forearm attachment and used it to guide the Bowden cable. We assumed a weight of 39 N (equivalent to the weight of a gallon of milk) held in the hand (W_o). We obtained other design parameters (weight of forearm [W_f] and length of forearm [l_F]) from previously published literature and calculated the torque required ($F_b \cdot r_{\boxtimes}$) to satisfy the conditions of equilibrium:

$$F_b \cdot r_{\boxtimes} = \left(\frac{W_f}{2} \quad W_o \right) . l_F \tag{1}$$

We designed the constant torque elbow joint to accommodate either right- or left-handed people and provided a routing channel on either side of the mechanism to facilitate reversibility of the joint. We then routed a Bowden cable (Fig. 1L) through the channel and attached it to the barrel pin seat. An absolute angular encoder was inside of the elbow center (Fig. 1H). Two bolt holes on both the forearm and upper arm parts of the orthosis joint provided attachment points for custom-fit orthotics (Fig. 1J and K). The custom-fit orthotic accommodated the patient's specific anatomy.

To actuate the arm, a belt-driven pulley transferred the motor's rotational force to a ball screw, which then converted it into a linear force. The ball screw nut then transferred the force to the Bowden cable, via the unidirectional sled mechanism, which then moved the elbow. The extension of the elbow is achieved by using the weight of the forearm (resisted minimally by the reverse motion of the motor).

The linear force in the Bowden cable during flexion can be expressed as

$$F_b = \frac{2\pi . M_t . k_b . e}{100 . L_s} \tag{2}$$

where M_t was the geared motor torque, k_b was the belt drive reduction ratio, e was the ball screw's percentage efficiency, and L_s was the lead of the ball screw. Hence, using the average

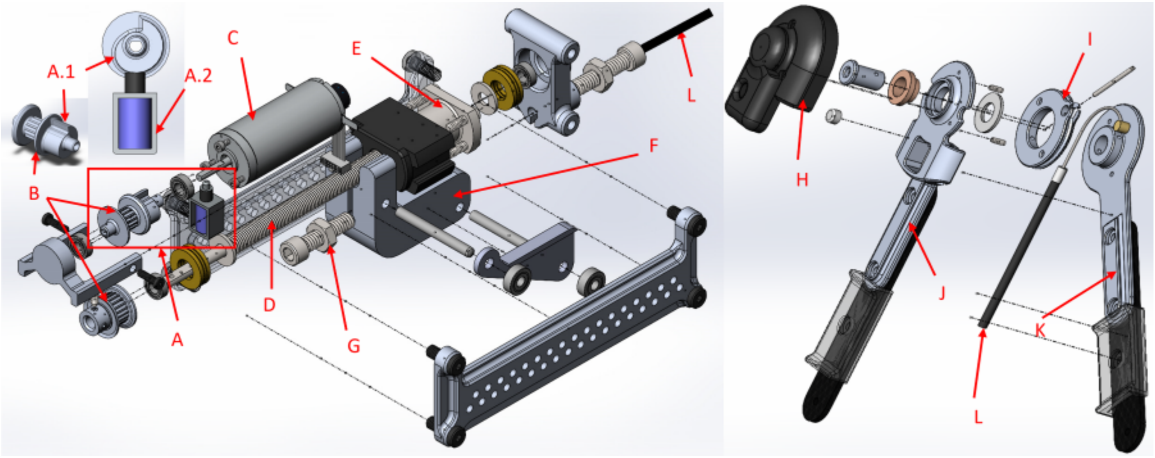

FIGURE 1. Computer-aided 3D model of the orthosis actuator mechanisms. A—brake/cam mechanism; A.1—cam profile; A.2—solenoid; B—belt-driven pulley; C—motor; D—Thomson ball screw; E—ball screw nut; F—sled; G—Bowden cable seat; H—elbow mechanism cover; I—Bowden cable channel; J—upper arm attachment; K—forearm attachment; L—Bowden cable. Image scales vary.

length of a male forearm ($l_F = 0.29$ meter),[14] along with the average weight of a male forearm ($W_f = 19.95$ N)[15,16]:

$$\frac{2\pi.M_t.k_b.e}{100.L_s}.\ r_{\boxtimes} = 15\text{Nm} \tag{3}$$

We selected the geared motor, belt drive, and ball screw to satisfy the equation 3.

The drivetrain of the orthosis comprises a motor (Fig. 1C), the brake mechanism (Fig. 1A), the drive belt (Fig. 1B), and the ball-screw (Fig. 1D). The brake mechanism attached directly to the motor shaft with 2 belt pulleys in line. The belt pulley system (Fig. 1B) connected the motor and ball screw, which reduced the overall drivetrain length. Ball bearings provided smooth rotation of the components.

The transmission mechanism enabled elbow flexion independently of the motor input. This mechanism, named "the sled" (Fig. 1F), allowed the user to flex their elbow while resisting elbow extension below a set angle. The ball screw nut held the sled (Fig. 1E) and stopped motion in one direction, while allowing movement along the ball screw away from the nut. In this manner, the user could flex faster than the motor/transmission if their strength enabled it. Alternatively, if the motor was off, the user could still flex their arm if their strength enabled it. In this case, the fixed brace did not make the user feel stuck. Moreover, if the motor was off, the sled rested against the ball screw and held the arm in a fixed position against gravity. In this situation, the user's input determined the position of the ball screw-nut, limiting extension and acting as an elbow support in conjunction with the brake mechanism. The sled connected to the Bowden cable (Fig. 1L) using the Bowden cable seat (Fig. 1G).

Hardware

The orthosis consisted of a surface electromyography sensor (sEMG) pre-amplified with a gain of 500 (EMG500, Motion Lab Systems Inc., Baton Rouge, LA, USA). To fulfill the power criteria (equation 3), we used the DCX 22 L Maxon motor (Maxon group, Sachseln, Switzerland) along with a PRM 0801 ball screw-nut assembly (Thomson Industries, Radford, Virginia, USA) and a belt drive (Gates corporation, Denver, Colorado, USA). The Maxon motor controller controlled the Maxon motor along with a custom designed commercial grade controller (Robotic Elements LLC, Tempe, AZ, USA) built using a dsPIC33FJ256MC710A microprocessor (Microchip Technology Inc., Chandler, AZ, USA). The sEMG interfaced with an analog-to -digital converter on the controller. The brake mechanism consisted of a cam (described in section "Design and Development") and linear solenoid. To easily display the state of the orthosis control logic, the system had multiple light emitting diodes (LEDs).

Control strategy

The primary input to the controller is the sEMG signal. A threshold value, also used as the activation criteria, was determined for each user (Fig. 2). The orthosis actuated if the sEMG value went above the threshold value, using the motor to flex the arm. Since patients with a free-functioning gracilis transfer have only 1 functioning muscle to move the elbow, a double pulse signaled the return of the arm to a fully extended position. The double pulse routine activated when the sEMG signal rose above the threshold, dropped below the threshold as the user relaxed, and then rose above the threshold again as the user contracted their muscle—all within a precisely defined time period.

Upon powering the system, the orthosis controller entered the "Home" state. The system entered the "Drive Forward" state when the sEMG value was greater than the threshold. In the "Drive Forward" state, the motor activated and engaged the elbow orthosis to flex the user's elbow. In the "Drive Forward" state, if the sEMG fell below the threshold,

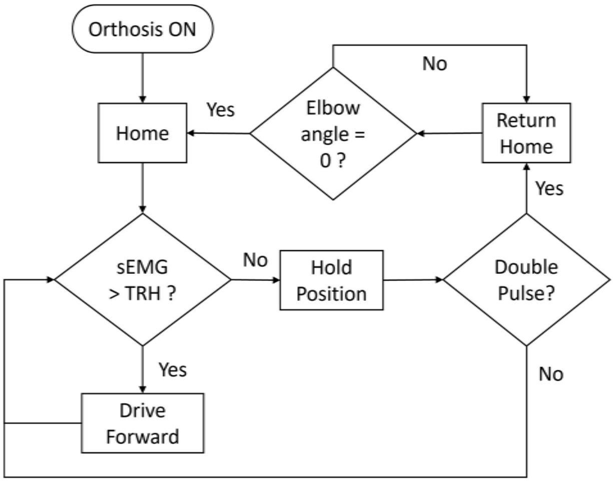

FIGURE 2. Flowchart describing the control strategy (sEMG: surface electromyography, TRH: threshold).

the orthosis entered the "Hold Position" state, and the brake mechanism engaged. In the "Hold Position" state, the system either returned to the "Drive Forward" state if the sEMG went above the threshold again, or the system entered the "Return Home" state if the user performed a double pulse. In the "Drive Forward," "Hold Position," and the "Return Home" states, the system entered the "Safety" state for 5 seconds and then returns to the "Hold Position" state when the system fulfilled the safety criteria.

Software

We developed the firmware using a Simulink model (MATLAB 2021b, MathWorks, Natick, MA, USA) provided by Robotic Elements (Tempe, AZ, USA). We programmed the microprocessor using MPLAB libraries along with the Simulink coder and compiler. The model developed to execute the control strategy utilized a fourth-order Butterworth low pass filter, cutoff at 4 Hz, to obtain the EMG envelope from the sEMG signal. Safety measures were programmed into the model to prevent over-extension. The safety measures also included accommodations to limit the flexion velocity of the elbow and the current drawn by the motor.

Subject Testing

The muscle characteristics of a restored and reinnervated muscle were different than a healthy muscle.[17,18] Hence, we tested the prototype on a subject with a BPI.

Participant

We recruited the subject and informed them about the experiment under the guidelines set by Mayo Clinic's Institutional Review Board (IRB no. 20-006849). The subject (male, 30 yr., Body Mass Index 26.6 kg.m^{-2}, 3.5 years post-surgery) had a gracilis free-functioning muscle transfer surgery with a spinal accessory nerve as the donor nerve to restore elbow flexion. The patient could not flex his arm against gravity but could flex his elbow in a gravity-eliminated position (with the arm resting horizontally on a table).

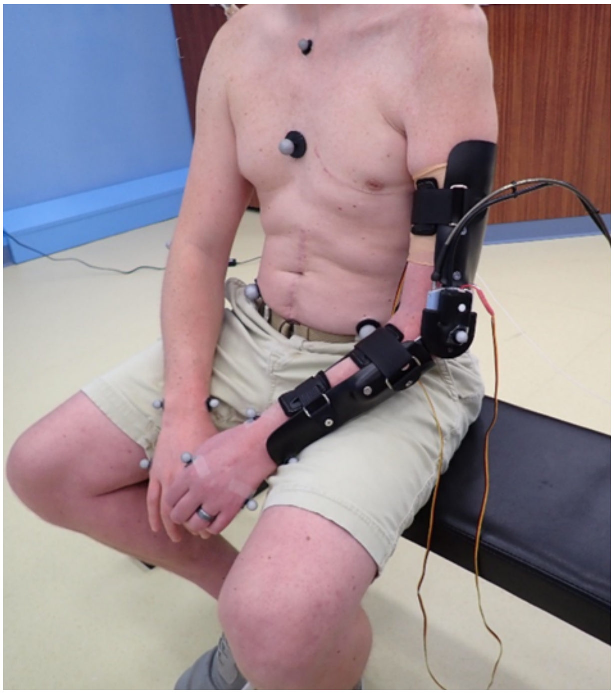

FIGURE 3. The subject with the orthosis on his affected (left) arm.

Data collection methods

Prior to using the orthosis, a calibration routine established the signal activation threshold and algorithm inputs. A board-certified orthotist (Limb Lab, Rochester, MN) fitted the subject with a custom orthosis that attached the subject's upper arm and forearm to the orthosis. The elbow mechanism acted as the elbow joint (Fig. 3). We placed an sEMG sensor on the gracilis muscle via palpation (elbow flexor for the subject) on the muscle belly using an adhesive tape (3 meter Tegaderm 1624 W transparent film dressing frame style tape). An athletic prewrap (Cramer tape, SKU: 214546) firmly secured the sensor to the upper arm. The threshold value was set above the quiescent level.

Retro-reflective markers were placed on key anatomical landmarks to model the trunk, and bilateral scapulas, upper arms, forearms, and hands.[19] A 12-camera motion capture system (Raptor-12, Motion Analysis Corporation, Santa Rosa, CA) obtained the kinematic parameters. The 3D marker trajectories input into a commercial biomechanical modeling software (Visual 3D, C-Motion, Inc., Rockville, MD) created the segment coordinate systems and calculated the subsequent rigid body upper extremity kinematics at the affected elbow.

A generalized cross-validatory spline smoothing filter was applied to the collected data in Visual 3D.[20] International Society of Biomechanics (ISB) standards defined the elbow and humerothoracic (HT) (shoulder) coordinate systems.[21]

We calculated the elbow range of motion and the average and SE for the maximum elbow flexion and extension angles along with the compensatory movement of the HT joint for each task.

The subject performed 3 repetitions of 4 activities of daily living (ADLs), with and without the orthosis, to evaluate the utility of the powered orthosis. These activities generated full motion and functional capability of the subject's involved limb at the elbow joint. The subject was instructed to (a) move his affected arm as if he was going to eat a granola bar, (b) move his affected arm as if he was going to scratch the top of his head, (c) stabilize an object (a clay ball) with his affected arm and slice it like a potato 3 times with his unaffected arm, and (d) pick up the basket (with weights in it) with his unaffected arm, flex his affected arm, and slide it under the basket handle to carry the basket 10 feet and hand it to the researcher. The subject performed the carrying task with increasing weights (in the form of water bottles = 489 g each) in the basket until the subject could not lift the basket or felt discomfort while lifting the basket.

RESULTS

The orthosis, along with the custom-fit attachment, weighed 0.536 kg, while the controller and battery unit weighed 1.473 kg. For comparison, the MyoPro weighs 1.8 kg and is entirely supported by the affected arm.[22] The subject initially felt that the elbow mechanism of the orthosis was heavy, but quickly adjusted to its weight soon after data collection began. He successfully wore the orthosis with minimal assistance and found it comfortable throughout the study.

While the subject had no voluntary flexion in his affected arm, he could flex his elbow by using the compensatory movements in the HT joint. Hence, we asked him to do his best while performing the hand-to-mouth and hand-to-top-of-head tasks without the orthosis. He was able to successfully flex his elbow using the orthosis. For the hand-to-mouth task, the subject achieved an average flexion of 97 with the orthosis, while without the orthosis the average flexion was 57. The compensatory movement in the HT joint's plane of elevation was reduced, on average, by 15 in flexion and 46 in extension (Fig. 4A).

During the hand-to-top-of-head task, the subject exhibited an average flexion of 94 while wearing the orthosis, compared to an average flexion of 62 without the orthosis. With the orthosis, compensatory movements in the plane of elevation of the HT joint were reduced by an average of 13 in flexion and 50 in extension (Fig. 4B). The HT elevation and rotation motions were similar for both the orthosis and no orthosis condition during the hand-to-mouth and hand-to-top-of-head tasks.

The subject used his unaffected arm while performing the stabilization task to position their affected arm onto the object without the orthosis. Average elbow flexion with the orthosis was 33 better than without the orthosis. The HT plane of elevation improved by 24 in flexion and 7 in extension.

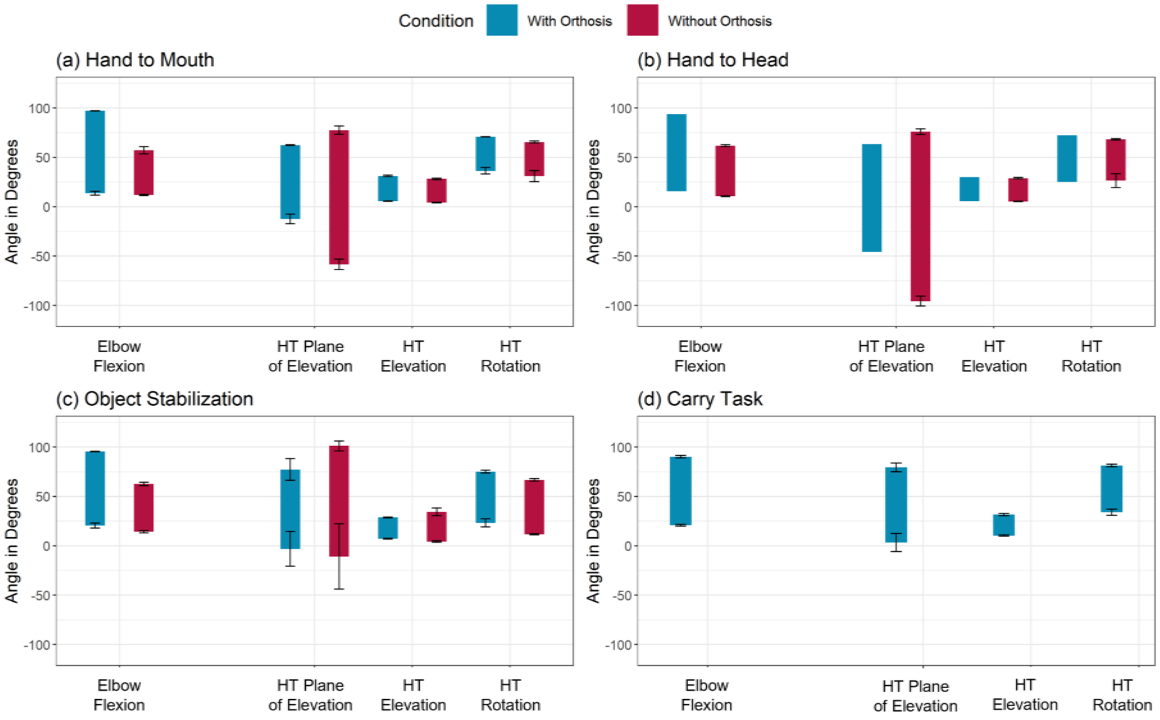

FIGURE 4. Range of motion for the elbow and humerothoracic (HT) joints during the (A) hand to mouth task, (B) hand to head task, (C) object stabilization task, and (D) carry task. Whiskers represent SE.

The rotation for the HT joint improved by 9 in internal rotation and 12 in external rotation (Fig. 4C). HT elevation was similar for the 2 conditions.

The subject was not able to carry the basket without the orthosis. The subject could lift the basket with 3 water bottles (1.47 kg) with the orthosis. The subject expressed a lack of fatigue, made possible by the brake mechanism present in the novel orthosis. In contrast, MyoPro requires the user to maintain contraction to hold the forearm in a flexed position. The subject flexed their elbow up to 90 , while compensating with their HT joint by 79 plane of elevation flexion (Fig. 4D). We did not add more weight to the basket considering the subject's shoulder strength.

CONCLUSION

We successfully designed and tested an advanced myoelectric elbow orthosis. The powered orthosis resulted in noteworthy enhancements to both the range of motion and task performance by the subject. The orthosis enabled the subject to proficiently execute tasks that were previously arduous or unattainable without its assistance. Notably, the subject achieved the remarkable capacity to lift a weight of 1.47 kg while wearing the orthosis, unequivocally illustrating its significant functional advantages.

We are currently recruiting subjects (a total of 11 patients with a BPI) to obtain supplementary data and substantiate the performance of the orthosis across a broader spectrum of activities and conditions. Consequently, these findings have promising implications for the future development and implementation of orthotic devices for enhanced motor rehabilitation and functional assistance.

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INSTITUTIONAL REVIEW BOARD

The authors followed the guidelines set by Mayo Clinic's Institutional Review Board (IRB no. 20-006849).

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Not applicable.

INDIVIDUAL AUTHOR CONTRIBUTION STATEMENT

CV and SGB contributed to this work equally in terms of analysis and writing the manuscript. KH, PK, EM, and WBM designed and prototyped the orthosis. SGB and EM developed the control system and collected the data. AYS, TGS, and KRK designed this research, reviewed, and edited the manuscript. All authors read and approved the final manuscript.

INSTITUTIONAL CLEARANCE

Does not apply.

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CONFLICT OF INTEREST STATEMENT

The authors have no competing interest to disclose.

DATA AVAILABILITY

The data underlying this article will be shared upon reasonable request to the corresponding author.

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