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Combining Functional Electrical Stimulation (FES) to elicit hand movements and a Mechanical Orthosis to passively maintain wrist and fingers position in individuals with Tetraplegia: A Feasibility Test

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Abstract: *We have developed a new approach to assist prehension by combining functional electrical stimulation (FES) and a motorized orthosis: ORTHYB. The aim was to induce movements of fingers, thumb, and wrist joints by activating muscles using surface FES and locking joints in desired positions using electric motors, to reduce muscle fatigue and enable prolonged grasping of objects. Another hypothesis was that the mechanical orthosis would improve grip quality by constraining joint positioning and guiding movements. The functionality and acceptability of this hybrid orthosis were tested on five participants with upper-limb paralysis due to spinal cord injury. The evaluation was carried out by monitoring the quality of grip for 30 seconds on 3 different objects; perceived effort using the Borg RPE (Rating of Perceived Exertion) scale; pain using visual analog scale (VAS); acceptability using QUEST (Quebec User Evaluation of Satisfaction Technology with Assistive Technology) scale and SUS (System Usability Scale). Preliminary results indicate that the hybrid orthosis provides added value compared to FES alone. The scores obtained in terms of functionality were in most of the trials greater than or equal to those obtained with FES alone. Object grasping was possible for 30 seconds without muscular fatigue affecting grip quality.*

Keywords: *upper limb paralysis, exoskeleton, hybrid orthosis, assistive technology*

1. Introduction

The loss of grip function in people with cervical spinal cord injury implies a significant reduction in functionality with consequent dependence on caregivers. The recovery of the function of the upper limbs, especially the hands, is essential for carrying out activities of daily living and should be prioritized [1], [2]. Functional electrical stimulation (FES) can be used to activate muscles to perform grasping tasks in people with

upper limb paralysis [3]. This approach requires low energy consumption and is well integrated by the user [4]. However, the early muscle fatigue induced by FES compared with voluntary muscle activation limits gesture efficiency and duration [5], [6]. In addition, induced gestures may be imprecise, as finger posture may be affected. In the past, a commercial solution was proposed to associate FES with a rigid splint (NESS H200, Bioness Inc) but was usually restricted to rehabilitation training purposes [3]. In more recent years, hybrid orthoses have been developed to combine FES and active mechanical orthoses or exoskeletons [7], [8]. These systems combine the advantages of orthoses in mechanically stabilizing joints with those of functional electrical stimulation in activating paralyzed muscles. Since some of the forces are provided by the actuation, FES does not need to be as intense to produce the same movement, thus reducing muscle fatigue [8], [9]. In addition, FES has the advantage of requiring small batteries to generate high forces compared to motorized exoskeletons or orthoses [9]. It allows the simplification of the mechanical structure and it may result in a portable device that is significantly reduced in size and weight, minimizes power requirements, produces greater force, and more precise control of movement than FES alone by providing movement guidance [7], [9]. The majority of hybrid FES-orthotic systems designed for people with spinal cord injuries use 1) FES to actuate muscles and 2) orthotics to support the action, hold the limb against gravity, provide assistance in reaching movements, lock the joints in the reached position or move joints through the desired range of motion [7]. In most published studies, the proposed hybrid devices that use brakes to lock the joints in the reached position focus on the shoulder and elbow movements [10], [11]. Hybrid devices focusing on wrist and hand movements are lacking [12]. In this paper, we consider people who voluntarily control their shoulder and elbow to perform

extension movements, but are unable to grasp objects. We propose to develop a solution in which wrist and finger movements are induced by electrical stimulation of the forearm muscles, the induced actions are guided by a mechanical structure and once the final grasping posture is reached, the stimulation stops and the joints are passively locked by the mechanical orthosis [13]. The goal is to reduce muscular fatigue when grasping objects compared with using FES alone and to improve the quality of grasping. The objective of the feasibility test was to assess qualitatively and quantitatively a prototype hybrid orthosis (ORTHYB) in participants with upper limb motor impairment due to spinal cord injury.

2. Methods

2.1. ORTHYB hybrid orthosis

2.1.1 Structure and function of the mechanical orthosis

A motorized mechanical cable-driven orthosis for the wrist and fingers (Figure 1) was designed and developed (Exo Hand, Aufratech, France) for this study. A prototype was manufactured for the right arm. Adjustable attachments enable the device to be adapted to the arm and finger diameters of different users: 2 attachments on the arm, 1 on the wrist, 3 per long finger, and 2 for the thumb (Figure 1). Cables run along the fingers through adjustable rings and are guided inside a flexible material in the palm. The thumb is held in a functional position by a rigid structure. The rigid components of the orthosis are fabricated using 3D printing technology, incorporating carbon fiber to enhance their mechanical properties. The total weight of the orthosis is 251g excluding the power source and control board which are not embedded presently (around 200g). This weight is lower than observed in other hybrid rehabilitation systems, i.e. Mundos 2.2kg without battery [14], Orthojacket 1.2kg including battery [15], Exoslim 3kg [16] and BCI-Controlled Exoskeleton approximately 1.2kg including battery [17]. It is also important to note that most of these devices include more joints than our prototype. The weight threshold for acceptance for a hand orthosis was identified to be in the range of 400–500g [18]. As a matter of comparison, the mass of the typical human hand is approximately 400g and commercial prosthetic hands range from 460g to 515g (excluding cosmetics and battery) [19], [20]. To accommodate the anatomical differences among participants, certain adjustments to the orthosis were possible. Rings slide along the cables running alongside the fingers and were arranged according to the length of the phalanges, while straps allowed for the adjustment of the ring's diameter. Straps were also used to extend each finger to position the hand at rest in an appropriate posture.

Two drive units are integrated, comprising a 3W DC

motor, a reduction stage, and an encoder. The motor unit associated with the fingers pulls or loosens simultaneously the 5 finger cables and the motor unit associated with the wrist pulls or loosens the wrist cable. This first version of the orthosis is powered from the main supply (14V - 550mA). The reduction ratio of the system is designed to ensure non-back drivability to lock the joints. The sizing of the actuators in this mechanical orthosis has been specifically tailored to work in conjunction with FES. As such, motor units are not designed or sized to generate movement on their own. They require assistance from stimulated muscles or voluntary movements to induce motion. The maximum force exerted on each digit is approximately 10N. The mechanical orthosis is controlled by an Adafruit Feather nrf52840 control board, which is coupled with a DC double-channel driver (L298N). The two encoders of the mechanical orthosis are connected to input pins on the control board to receive signals and are powered by the board itself. To facilitate control and communication, the microcontroller is connected to a computer via a serial communication protocol (serial COM). This allows the mechanical orthosis to be controlled using keyboard inputs. Positions can be set and saved, and the orthosis can be moved to predefined positions or adjusted incrementally.

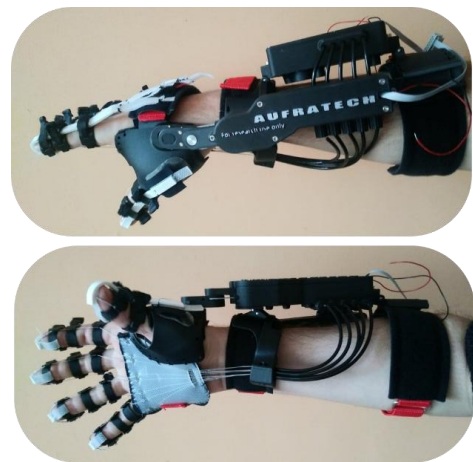


Figure 1: Mechanical orthosis (Exo Hand, Aufratech, France).

One DC motor located on the lateral side of the arm pulls/releases the cable at the wrist. One DC motor located on the dorsal part of the arm pulls/releases the 5 finger cables.

2.1.2 Electrical Stimulation

An electrical stimulator (Phenix Neo©, Montpellier, France) is composed of a base controller connected to a computer and two wireless stimulation units (PODs) featuring 2 stimulation channels each. 3 pairs of surface electrodes were used, for activating (1) extension of the wrist and fingers (2) finger flexion, and (3) thumb flexion [21]. The controller base is connected to the computer with a serial COM.

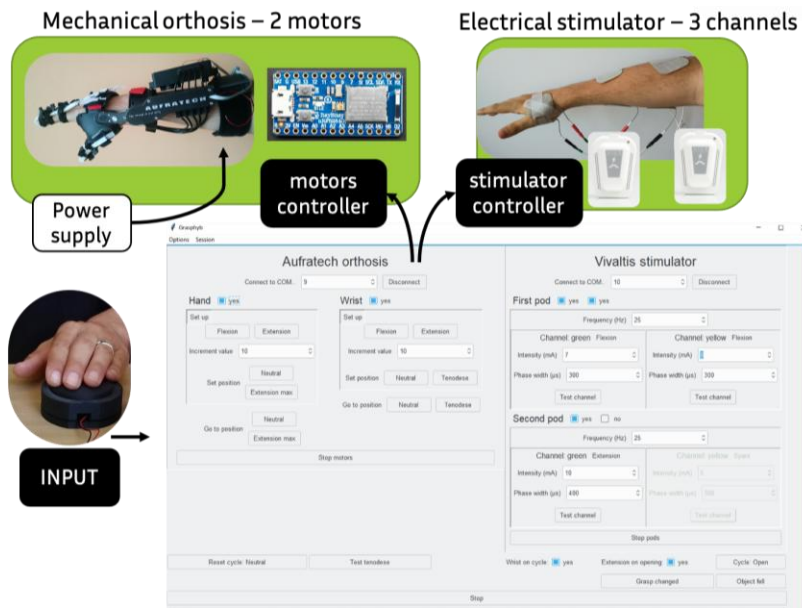


Figure 2: ORTHYB consists of the main controller (GUI in the center) which accepts an input control signal from a switch button to control the 2 motor controllers of the mechanical orthosis and the 3 stimulation channels of the electrical stimulator.

2.1.3 Controller

ORTHYB controller pilots the 3 electrical stimulation channels and the 2 DC motors. A multi-threaded Graphical User Interface (GUI) has been developed in Python. It manages the communication with the motor control board and the stimulator controller through Serial COM. The controller operates as a state machine, allowing independent control of the motors and stimulator, as well as the simultaneous control of both devices based on the selected settings. A push button controlled with the contralateral fist has been developed for the participant to trigger the change of state. The orthosis incorporates two sensors which are rotary encoders, one per actuator. ORTHYB controller continuously estimates the relative position from these input signals. Figure 2 shows in detail all the constituent parts of ORTHYB.

Three states are possible: NEUTRAL, OPEN, and CLOSE. NEUTRAL is associated with a comfortable posture of the fingers and wrist, predefined at the initiation of the session through the GUI. The maximum extension of the fingers is also predefined (OPEN state). The possibility to define a maximum extension of the wrist in the CLOSE state was added as an option to induce a tenodesis effect when the grasp force was low. The push button triggers the event which activates the transition to go from one state to the other. The sequence NEUTRAL > OPEN > CLOSE > OPEN > NEUTRAL always starts from the NEUTRAL: no electrical stimulation is delivered and the 2 motors are in their predefined neutral positions (Fig. 3). Starting from NEUTRAL, when the push button is pressed, the OPEN state is activated: the extension stimulation channel (3) is

triggered and delivers the predefined stimulation parameters while the finger cables are slacked (Motor 1 - fingers) until the movement induced by FES reaches the predefined opening position (fingers maximum extension). The user can then adjust the hand against the object to grasp and press the button again to go to the next state, CLOSE: extension stimulation is stopped and the flexion stimulation channels (1 & 2) are activated. Motor 1 winds the cables to accompany finger flexion around the object to be grasped.

The wrist neutral position is maintained passively to counteract possible wrist flexion induced by FES. Here, a threshold on Motor 1 (fingers) rotational speed is used as the stopping condition. The motor receives a step function in voltage as input, winding the cables until its maximum closure capacity is reached, accommodating objects of diverse shapes and rigidity. When the motor reaches its closure limit, the speed decreases, and once this speed falls below a set threshold, a command to cease winding and stimulation is issued. The hand posture is then maintained passively by the mechanical orthosis. When the button is pressed again the state changes to OPEN to release the object and then go to NEUTRAL.

The activations of FES and motors occur simultaneously when the switch button is pressed. They are controlled in parallel but the motor incremental encoder pilots the stopping time of both.

The following video presents the sequence of the different states: <https://youtu.be/tCz52tDyO6M>

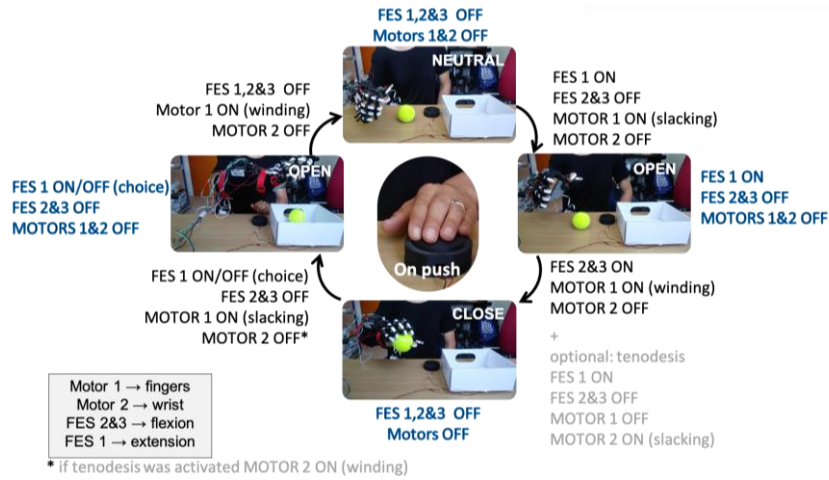


Figure 3: ORTHYB controller relies on a state machine with three states: neutral, open, and closed. Transitions between states occur upon the commands of the switch button.

2.2. Participants

This study was approved by the Institutional Ethics Committee of the Federal University of Minas Gerais (CAAE Registration: 53757521.3.0000.5149) and conducted according to the World Medical Association Declaration of Helsinki. Five participants with spinal cord injury were recruited from rehabilitation centers and hospitals in Belo Horizonte, Minas Gerais, Brazil, and through dissemination of the research on social media. Data collection was carried out at the Bioengineering Laboratory (LABBIO) at the Federal University of Minas Gerais (UFMG).

2.2.1 Inclusion and exclusion criteria

In this study, the inclusion criteria were: individuals aged 18 years or older, with a spinal cord injury (level C4-C7) for more than 6 months; who do not have active finger flexion and extension movement and which respond positively to electrical stimulation with surface electrodes positioned in the forearm region (flexion and extension of the wrist and fingers). Participants should have a passive range of movement of flexion and extension of the wrist, thumb and fingers preserved (or minimally impacted).

Individuals with other health conditions or comorbidities that made it impossible to carry out clinical tests were excluded from the study, such as signs of medical instability, uncontrolled convulsions; excessive spasticity in the upper limb, considerable increase in muscle tone with difficulty in passive movement or rigid parts in flexion or extension (contracture) (Modified Ashworth Scale ≥ 3) [22]; significant clonus or spasm, neuropathic pain and particularly allodynia.

These criteria are similar to those of functional tendon transfer surgery and it is estimated that 65% to 75% of

patients with cervical spinal cord injuries could benefit from upper extremity tendon transfer surgery [23], [24].

2.3 Outcome Measures

We concentrated the assessment on the holding part of the grasping. A score was given to the quality of hand opening and grasping based on 3 experimenters' visual observation and confirmed, if necessary, by analyzing videos of the session 0: not possible - 1: acceptable (partial success) - 2: successful. The ability to hold the object for 30 seconds was reported and the time when the palmar grasp quality was impacted by fatigue (manifested as relaxation of finger posture) occurrence was based on 2 examiners' visual observations and confirmed, if necessary, by analyzing videos of the session. In addition, the intensity of the physical effort was evaluated by the Borg Rating of Perceived Exertion (RPE) scale. Anatomical adjustments, possible pressure points on the skin, redness, local discomfort, tingling, paresthesia, postural adequacy, safety, and general comfort of each participant were checked after each session. The Visual Analog Scale (VAS) [19] was used to investigate the occurrence of pain and adverse events. The degree of comfort, satisfaction, and acceptance of the user regarding the use of the equipment was assessed through an interview, applying the QUEST and SUS. All participants were evaluated after each session. The QUEST and SUS scales were applied only when the hybrid equipment was used. Participants were also asked to give their feedback in a free manner. The tests were filmed for further analysis from researchers and the exact identification of the main problems to be modified.

2.4 Experimental Protocol

The protocol consisted of 3 sessions. In each session, 3 objects were used to assess palmar grasping function:

ball (50cm-24g), fork adapted with thickener, 50cl water bottle half filled (250g) in a randomly determined order. Several repetitions of opening and closing hand movements and grasping and holding were performed before starting the evaluation tests. In all sessions, the participant remained in front of a table with adjustable height, and the device was attached to right upper limb.

None of the participants had any recent experience (within the last 12 months) with FES. Some had used electrical stimulation during their rehabilitation but at a distance of several years from our experiment. None of them had any experience with exoskeletons. If participants could not open their hands sufficiently with FES, the experimenter was allowed to spread their fingers to insert the object. Similarly, if a too-strong wrist flexion occurred when closing long fingers occurred, the wrist was positioned in a neutral position. The experimenter maintained the wrist to allow holding the object. During the first session, the electrodes were placed on the motor points of the respective muscles to achieve the greatest possible selectivity of stimulation. A photo was taken to ensure the placing of electrodes at the same location in the following sessions. While tetanic contractions can be achieved with a minimum of 20 pulses per second, a pulse frequency of 40Hz is often needed [25]. The current frequency was therefore set to 40Hz and the pulse duration to 500 μ s in all trials. The electrical current amplitude was adjusted individually. Sessions 1 and 3: only FES was used. The ability to hold the 3 different objects for 30 seconds was assessed. The arm was positioned in a comfortable position on a pillow and the experimenter maintained it to have the object in a vertical position to allow it to fall in case the holding force decreased, as can be seen in Figure 4. The experimenter placed the object in the hand and the participants were asked to hold the object 30 seconds before opening the hand and then going back to a neutral state. The manipulation sequence was repeated 3 times for the same object, with a 30 second rest period between each repetition and 2 min between the different objects. The number of successful attempts, the object's manipulation time, the perceived physical effort (Borg RPE scale) [26], and the presence of pain (Visual Analog Scale) were evaluated. Session 2: the hybrid orthosis was used. The same evaluation and training were performed as in the previous session. The same assessments as in Sessions 1 and 3 were carried out. Finally, the acceptability and usability of the device were evaluated using the Quebec User Evaluation of Satisfaction Technology with Assistive Technology (QUEST) [27] and System Usability Scale (SUS) [28] scales. When possible participants were using the control button with their contralateral arm to activate the device state

changes. The orthosis was don and doff by the experimenter as in its current version users with SCI cannot equip themselves independently.



Figure 4: Position of the arm and object being held during the clinical test.

3. Results

The average age of participants (N=5, two males) was 52 years, ranging from 28 years to 73 years (Table 1). Participant 3 was unable to take part in the last session (FES only) for personal reasons beyond the control of the experimenter. Participant 5 did not respond sufficiently to the FES to be able to perform the object entry tasks, therefore we decided not to ask the participant to come for the third session. The required stimulation intensity varied for different movements: 15-28mA for finger flexion, 8-26mA for thumb flexion, and 12-20mA for wrist and finger extension. The current intensity was the same throughout each session. For all participants, the finger flexor muscles were activated to produce a visible movement (Table 2). As the current amplitude increased, the wrist flexors were systematically activated, except for P1, who had active wrist extension. Thus, for all participants, the experimenter needed to maintain the wrist in a neutral position to counteract the wrist flexion accompanying finger flexion. For all participants, the wrist extensor muscles were activated in such a way as to produce a visible movement. For P1 and P5, however, it was not possible to activate the finger extensor muscles because the muscles were not responsive to stimulation. In participant P5, it was not possible to trigger a clear movement of the thumb flexors either (atrophy of the thenar eminence). Table 3 summarizes the quality of functional gestures obtained in the FES condition (FES only) or using the hybrid orthosis (ORTHYB) and indicates the active movement without using any assistive device (no aid). We analyzed the opening gesture separately from the actual grasping of the object. The notation used is 0 when the movement was not possible at all and 2 when the movement obtained was correct. When movement was partially achieved, for example when the hand opening was insufficient to accommodate the object and the experimenter had to

spread the fingers slightly, or when grasping of the object was achieved but imperfectly, the score used was 1.

Table 1: Participant characteristics

	NLI*	AIS**	Time (years)* **	Wrist active extension	Dominant hand****	Upper limb active movements
P1	C6	D	20	YES	Right	scapular elevation, shoulder flexion, shoulder abduction to 90 degrees, internal and external rotation of the shoulder, elbow flexion, pronation and supination of the forearm, and wrist extension.
P2	C5	C	16	NO	Right	scapular elevation, shoulder flexion, shoulder abduction to 90 degrees, internal and external rotation of the shoulder, elbow flexion, and supination of the forearm
P3	C5	D	1	NO	Right	scapular elevation, shoulder flexion, shoulder abduction to 90 degrees, internal and external rotation of the shoulder, elbow flexion, and supination of the forearm.
P4	C4	D	9	NO	Right	scapular elevation
P5	C5	A	2	NO	Right	scapular elevation, shoulder flexion, shoulder abduction to 90 degrees, and elbow flexion.

* Neurological Level of Injury, ** ASIA impairment score (AIS) ***Time since the onset of the SCI, ****Right hand was equipped

The scores for hand opening using the ORTHYB were all greater than or equal to those obtained with the FES only, except bottle for P2 and ball for P4 for which the opening was less satisfactory with ORTHYB than using FES only. The scores for grasping obtained with the ORTHYB condition were all greater than or equal to those obtained with the FES only, except bottle grasping for P2. For participant P5 it was not possible to produce sufficient movements via the FES to either open the hand or tighten it around the various objects whereas with ORTHYB, the task was achieved for ball and fork.

Table 2: Movements elicited by FES

	FES channel 1		FES channel 2		FES channel 3
	Finger extension	Wrist extension	Long fingers flexion	Wrist flexion	Thumb flexion
P1	No	Yes	Yes	Yes	Yes
P2	Yes	Yes	Yes	Yes	Yes
P3	Yes	Yes	Yes	Yes	Yes
P4	Yes	Yes	Yes	Yes	Yes
P5	No	Yes	Yes	Yes	No

The task consisted of holding the object in the hand for

30 sec. and 2 observers reported the relaxation of finger posture around the object characteristic of the onset of muscle fatigue. Similarly, if the object fell, the corresponding time was recorded. Figure 5 shows these two items of information for each condition and each object. Participant P3 was not able to participate in the third session as discussed earlier. The order of the objects that appear in the figure corresponds to the order that was used during the test. As already indicated in Table 3, participant P2 was unable to perform the bottle grasp with the hybrid orthosis whereas he was able to do so in the FES-only condition. Conversely, P3 failed to grasp the bottle with FES only but succeeded with the orthosis.

For P5, no task was possible with FES only, but the orthosis enabled the participant to grasp the ball and the fork. In the ORTHYB condition, participants were able to hold objects in their hand for 30 seconds without relaxation of the finger posture, except P2 for whom in one of the 3 fork trials the object fell after 20 seconds due to a bad initial positioning of the object in the hand. In the FES-only condition, participants were able to hold certain objects for 30 seconds, but in each trial, we observed evidence of muscle fatigue inducing a decrease in finger grasping quality.

After each of the 9 trials in each condition, we asked participants to rate their perceived exertion when completing the task on a scale from 6 to 20 (BORG Scale) (Figure 6). For all tasks, this score never exceeded 16 (difficult). P1 and P4 indicated a moderate effort for their first session (FES only) (score 11), then an extremely light effort for the other two sessions (score 6). Participant P2 gave a score of 2 points higher when using

the orthosis than when using electrical stimulation. For P3, the use of the orthosis was perceived as requiring slightly less effort than electrical stimulation.

Table 3: Functional movements assessment in the different conditions (no aid, FES only, and ORTHYB) and with the different objects (ball, fork, bottle).

		NO AID		FES ONLY		ORTHYB	
		Open Hand	Grasp	Open Hand	Grasp	Open Hand	Grasp
P1	Ball	0	1	0	2	1	2
	Fork	0	0	1	2	2	2
	Bottle	0	0	0	2	1	2
P2	Ball	0	1	2	2	2	2
	Fork	0	0	2	2	2	2
	Bottle	0	0	2	2	1	0
P3	Ball	0	NA	2	2	2	2
	Fork	0	0	2	1	2	2
	Bottle	0	0	2	0	2	2
P4	Ball	0	0	2	2	1	2
	Fork	0	0	1	1	1	2
	Bottle	0	0	1	0	1	2
P5	Ball	0	0	0	0	1	2
	Fork	0	0	0	0	1	1
	Bottle	0	0	0	0	0	0

0: the movement was not possible (white) - 1: the movement obtained was partially achieved (yellow) - 2: the movement obtained was correct (green). NA: not applicable

■ No fatigue observed
■ Fatigue observed

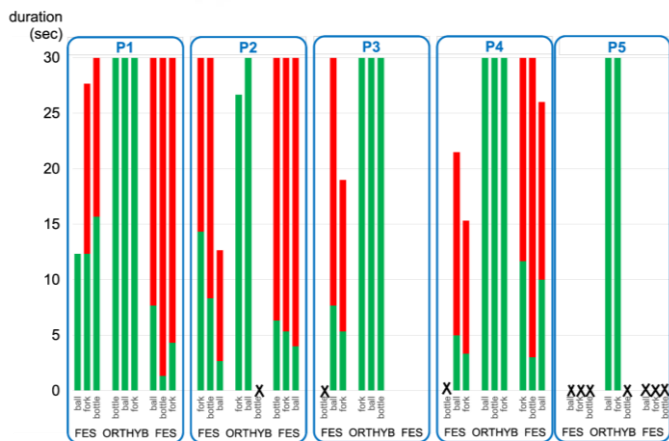


Figure 5: Holding times: average over the 3 trials for the 3 different objects during the 3 sessions (FES / ORTHYB / FES). All movements that were not possible to perform were marked with an "X".

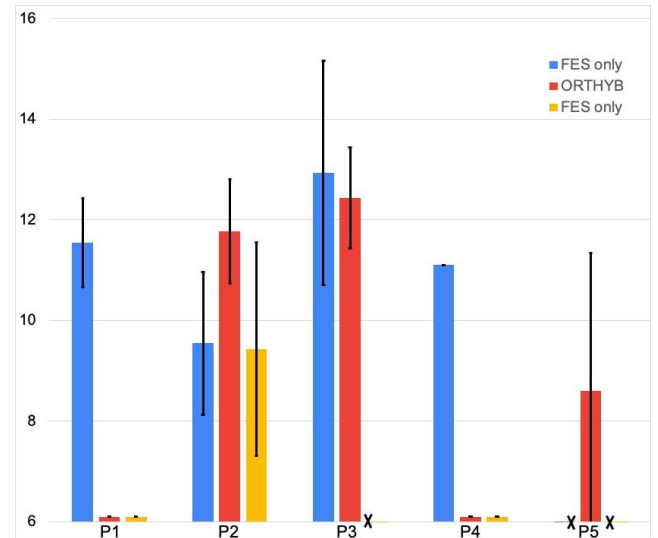


Figure 6: BORG RPE (Rating of Perceived Exertion) scale from 6 to 20 (6 = "no exertion at all" and 20= "maximal exertion" of effort): average and standard deviation scores over the 9 trials (3 trials per object) performed during the 3 sessions (FES only / ORTHYB/FES only) by the 5 participants.

The ORTHYB solution, albeit in a prototype form, was evaluated using the QUEST questionnaire, taking into account only the device scores (Table 4). The results obtained were 4.1 ± 0.43 i.e. quite satisfactory. The highest scores were attributed to weight, safety, security, and durability. The lowest scores were attributed to ease of adjusting, ease of use, comfort, and effectiveness. The System usability scale (SUS) is composed of 10 statements with responses ranging from 1 (strongly disagree) to 5 (strongly agree). The scores (Table 5) can be used to construct the satisfaction score in the user experience with the ORTHYB prototype. The average of the scores obtained was $76 \pm 13,98$ ("Good"). P1, P2, and P5 considered their use experience as "very good". P3 and P4 gave a score corresponding to a moderate experience.

Table 4: Quebec User Evaluation of Satisfaction Technology with Assistive Technology (QUEST)
Device scores (1-low, 5-high)

	P1	P2	P3	P4	P5	Mn (sd)
Dimensions	5	5	3	4	5	4,4 (±0,89)
Weight	4	5	5	5	4	4,6 (±0,54)
Ease in adjusting	3	5	3	4	3	3,6 (±0,89)
Safe and secure	3	5	5	4	5	4,4 (±0,89)
Durability	4	5	4	5	4	4,4 (±0,54)
Easy to use	4	5	3	4	3	3,8 (±0,83)
Comfortable	3	5	3	4	3	3,6 (±0,89)
Effective	4	3	4	4	4	3,8 (±0,44)

Total	3,75	4,75	3,75	4,25	3,87	4,07 (±0,42)
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Mn= average sd = standard deviation

Table 5: System usability scale (SUS) questionnaire, composed of 10 statements with responses ranging from 1 (strongly disagree) to 5 (strongly agree).

	P1	P2	P3	P4	P5
1. I think that I would like to use this system frequently	4	5	4	4	4
2. I found the system unnecessarily complex	2	1	2	2	2
3. I thought the system was easy to use	4	5	3	2	4
4. I think I would need support of a technical person to be able to use this system	4	1	5	2	2
5. I found the various functions in this system were well-integrated	4	5	4	4	4
6. I thought there was too much inconsistency in this system	2	1	2	2	2
7. I would imagine that most people would learn to use this system very quickly	4	5	5	4	4
8. I found the system very cumbersome to use	2	1	3	3	2
9. I felt very confident using the system	4	5	5	4	4
10. I needed to learn a lot of things before I could get going with this system	1	1	3	2	2
Total	72,5	100	65	67,5	75

We also asked participants, at the end of each trial, to rate the pain perceived during the test using the visual analog scale (VAS) between 0 “no pain” to 10 “worst pain”. 4 participants systematically gave the score 0 to their experience in both FES and ORTHYB conditions. Participant P3, who already had a pain level of 4 and 5 at baseline, scored between 8 and 9 in the trials with the orthosis. He stated that the level of pain increased due to the pressure exerted by the orthosis on his arm, as his pain level usually increased when his arm was touched.

4. Discussion

The results obtained in this study, although preliminary, are very promising. The use of the hybrid orthosis generally improved the quality of object grasping in most trials compared with the use of electrical stimulation alone (Table 3 – Fig. 5). The hybrid device did not show any evidence of muscle fatigue (finger posture relaxation) compared to the FES-only condition, allowing for longer grasping of objects. The global approach proposed appeared to be feasible and was well-

perceived by the participants (Table 4) despite the need to improve the design (Table 5). The BORG Rating of Perceived Exertion scale (Fig. 6) remains a subjective measure that can be biased, as it is sometimes difficult for participants to fully understand. Nevertheless, it remains an interesting indicator, and its low to moderate value in our case indicates that the proposed approach was well tolerated. VAS indicated that, except for participant P3, whose profile was peculiar in terms of pain, the use of the FES and the orthosis did not induce any pain or discomfort, and we noted no support lesions apart from some temporary redness at the pressure points of the orthosis, which disappeared within 30 minutes of testing. The participants had no experience of assisted grasping with FES and no training in functional electrical stimulation. Good results with FES alone would require regular practice to achieve better contraction performance and fatigue resistance. Overall, for the 2 conditions (FES only and ORTHYB), we can assume that with practice, functional performance would increase (Table 3). Despite these considerations, and bearing in mind that the results presented in this article are still preliminary, certain difficulties encountered may allow us to draw some conclusions.

Activation of the forearm muscles to induce functional movements, particularly in cases of hypotrophy, is difficult. And some of the participants also possibly have lower motor neuron damage. Activating sufficient finger flexion to support the weight of objects without activating wrist flexion is hardly possible with conventional surface electrodes when the participant has no active extension of the wrist. The quality of object grasping with the FES alone was not satisfactory in several participants, and the wrist had to be positioned in a neutral position, particularly for heavier objects (bottle). On the contrary, the mechanical orthosis limited wrist support by the experimenter and ensured that the long fingers were guided around the objects. Extension of the long fingers was also a problem in several subjects using only the FES, as the experimenter had to spread their fingers to insert the object, whereas the mechanical structure of the orthosis enabled us to adjust the extension in several cases.

As already commented, only one version of the hybrid orthosis was available, which posed certain limitations in terms of adaptation to larger and smaller hands and the needed time to adjust the orthosis to the hand. This is one of the criticisms that emerges clearly in QUEST (Table 4). This makes the fitting time a little long and tedious (10 to 15 minutes to position the mechanical orthosis only). In addition, the rigid support around the thumb, for example, interfered with the application of force to the objects, particularly when P2 and P5 were gripping the bottle, as their hands were rather small. In addition to disrupting the grasping of larger objects, the opening of

the hand was also impacted by this volume of rigid material, which restricted the space available for inserting objects such as the ball and bottle. The flexible material positioned against the palm for the passage of the finger cables was in some cases too large for certain hand sizes and interfered with the flexion of fingers as it spilled over the base of the fingers. Several sizes of the device would be needed to fit each hand properly. In the future, we will study the ergonomics of the orthosis to adapt it to individual profiles and to facilitate the fitting and removal of the device. Recent studies have presented 3D printing as a possible means of low-cost production of flexible, customized orthoses [29].

The SUS scale (Table 5) is designed to reflect the relationship between trust and the perceived usability of a prototypical device. It is part of the ISO 9241-11 standard and, together with the Quest, helps to reflect the potential usability of a technological assistive device. SUS scores higher than 68 can be considered above average and scores lower than 68, are below average [26]. Two out of the five participants with a score ≥ 75 expressed strong support. The other 3, with respectable scores between 65 and 75, expressed their support, with a nuance for certain items relating to the ease of use and cumbersomeness of the device (items 3 and 8), and to learning and mastering the device before acquiring it (items 4 and 10). They all approached the device with confidence (item 9), and paradoxically asserted that once technological maturity is achieved, users would learn to use it quickly and successfully (item 7). This analysis underlines the importance of this feedback in the co-design process, and the active and constructive involvement of the user in developing an orthosis that they feel will be useful to them. The prototype was not offered in a wearable version, as not all the elements were embedded yet, which certainly made it difficult to project it for autonomous use in everyday life. The aim here was to test the feasibility of the proposed approach. The integration of the various components is still necessary to propose a more mature solution. At present, the electric motors are powered by an external energy source, and the switch to batteries has yet to be made. The electrical stimulator and motor controllers are not embedded in the orthosis but in external boxes. Surveys of upper extremity amputees [19] report that a hand prosthesis should be capable of operating for a full day between battery charges, and a majority of amputees use their prostheses more than 8 hours per day. As such, a battery charge should provide for at least 12 hours of use. Considering an amount of 3800 daily grasps [30] and 3 seconds of motor activation per grasp, a 2A.h 14V battery (motors, driver, Adafruit card) would be sufficient for a full day of autonomy, this would represent 136g. Only participants P1 and P3 were able to use the control

button correctly. Different modalities will be proposed in the future to trigger events for the state machine, including voice control, detection of voluntary movements, etc. [29], [31].

The majority of hybrid orthoses presented in literature predominantly target lower limb assistance during walking, benefiting from the periodic nature of this activity, which allows for predicted commands based on a cycle. For this preliminary study, we have chosen a simple activation mode, although it acknowledges room for improvement in this aspect. To facilitate various gripping phases with a single command, a state machine is employed. This machine encompasses three states: neutral, open, and closed, forming a cycle similar to those observed in other hybrid orthoses. However, unlike automated systems, the transition between states in this machine occurs upon the user's request (push button). The technological maturity of such an orthosis has yet to be confirmed, but it opens up prospects for use in spinal cord injured patients: (1) in the sub-acute period, to rapidly initiate synergistic contraction of muscles essential for grasping and releasing objects, (2) in the chronic period, to prepare the hand and wrist to integrate new motor activation synergies that will subsequently be generated by functional tendon transfer surgery or implanted neurostimulation. It also opens up the possibility of providing stroke patients with a demonstration of functionally useful motor activity in their hemiplegic hand. We are also considering the use of such an orthosis in the context of implanted electrical stimulation [32]. While it's conceivable to sustain stimulation during closure to enhance muscle strengthening, this wasn't the primary focus of our approach. Exploring the ability to customize the balance of effort between motorization and FES could be an interesting avenue for future research.

5. Conclusion

We proposed a novel approach utilizing a hybrid orthosis that integrates electrical stimulation targeting both the extensor and flexor muscles of the fingers, thumb, and wrist, alongside a mechanical framework equipped with low-power motors. This hybrid design is intended to synchronize the FES-induced movements with the sustainment of achieved positions through passive motor properties, aiming to develop a lightweight orthosis facilitating effective object grasping. Our objective is to ensure a stable grip over prolonged periods, minimizing the risk of object slippage. To assess feasibility, we engineered a prototype. Subsequently, we conducted trials involving five individuals with tetraplegia, comparing the efficacy of grasping three objects (ball, fork, bottle) using our hybrid device versus functional electrical stimulation (FES) alone. The preliminary

results show the superiority of our orthosis over FES alone, as it enables sustained object grasping for up to 30 seconds without succumbing to muscular fatigue. A study with a larger number of participants is necessary to allow statistical analysis.

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