

Preliminary Evaluation of a Controlled-Brake Orthosis for FES-Aided Gait

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Abstract—A hybrid functional-electrical stimulation (FES) gait system that incorporates a computer-controlled orthosis system has been developed to address the problems of rapid muscle fatigue and poor movement control that are characteristic of FES-aided gait. The orthosis is a long-leg brace that contains controllable friction brakes at both hip and knee joints. The system achieves desirable limb trajectories by utilizing the stimulated muscles as a source of unregulated power and regulating the power at each joint by computer control of the friction brakes. Muscle fatigue is reduced by locking the controllable brakes to provide the isometric joint torques necessary during stance. The hybrid gait system was evaluated and compared to conventional four channel FES-aided gait using four subjects with paraplegia. The results demonstrated significant reduction in muscle fatigue and improvement in trajectory control when using the orthosis combined with FES compared to using FES alone. Results for distance and speed improvements varied across subjects. Considerable work remains in the design of the hardware before the system is feasible for use outside the laboratory.

Index Terms—Assistive technology, functional-electrical stimulation (FES), hybrid orthosis.

I. INTRODUCTION

A COMMON consequence of spinal-cord injury (SCI) is the loss of mobility resulting from lower limb paralysis. Functional-electrical stimulation (FES) is a means of restoring limited mobility in the vicinity of a wheelchair to some individuals with SCI by using electrical stimulation of motor nerves to elicit muscular contractions [1]–[6]. Two limitations impair the ability of current FES-aided gait systems to restore significant function: 1) rapid muscle fatigue that results from stimulated muscle contraction and limits standing time and walking distance and 2) poor control of joint torques resulting in nonrepeatable steps.

These limitations can be partially overcome with a hybrid system that combines FES with a lower limb orthotic brace. Orthoses can guide or limit the directions in which the limbs move, thus simplifying control problems and orthosis joints may be locked which can reduce the effects of stimulated muscle fatigue.

Several hybrid-FES systems are currently under development. The Louisiana State University (LSU) reciprocating gait orthosis (RGO) locks the knees to provide upright support for standing and couples the hip joints in a reciprocal motion so that hip flexion occurs by extending the contralateral hip [7], [8]. The LSU group has evaluated over 70 paraplegic subjects using the RGO [9]. Other hybrid approaches that lock the knee include the Oswestry Parawalker system [10]–[15], the hip guidance orthosis [16], [17], and the steeper advanced reciprocating gait orthosis (ARGO) [18]–[21]. Mechanical locking of the knee joints can improve the performance of FES-aided walking but lead to a stiff-legged gait with lifting or tilting of the upper body required to provide the swing leg with sufficient ground clearance that, in turn, can lead to increased upper body energy expenditure [22]. Additionally, control of limb trajectories is difficult because the response of muscle to stimulation is not repeatable.

Another hybrid system is the floor reaction ankle-foot orthosis (FRO) developed by Andrews [23], [24]. The FRO is a modified knee-ankle-foot orthosis that provides a rigid ankle support that tilts the SCI individual forward so that the knee joint is stabilized in hyperextension. Strain gage sensors on the FRO detect hyperextensive knee torque and cause the controller to stimulate the quadriceps muscles when the SCI user's center of gravity falls posterior to the knee. The FRO reduced the duty cycle of quadriceps stimulation to 20% during quiet standing, but had less of an effect on duty cycle during gait [24].

Powered orthoses offer more function than purely passive hybrid systems. The hybrid assistive system contains small dc electric motors at one or more joints and was designed for use either with or without supplemental electrical stimulation [25], [26]. Since the stimulated muscle power can be augmented with the motors, these systems need not rely solely on the stimulated muscle to provide the joint torques for gait and, thus, have the potential for being used by a larger segment of the SCI population. However, due to the size and weight of existing dc motors and batteries, self-contained powered orthoses are not likely to be deployed in the near future.

A. Controlled-Brake Orthosis

Our group has developed a hybrid system that addresses the limitations of FES-aided gait by utilizing FES in combination with a controllable passive orthosis [27]. The controlled-brake orthosis (CBO) contains computer-regulated friction brakes at the hip and knee. The brakes can be in the free state, the locked state, or any state in between. By locking the brakes during stance phase and turning off stimulation to the quadriceps,

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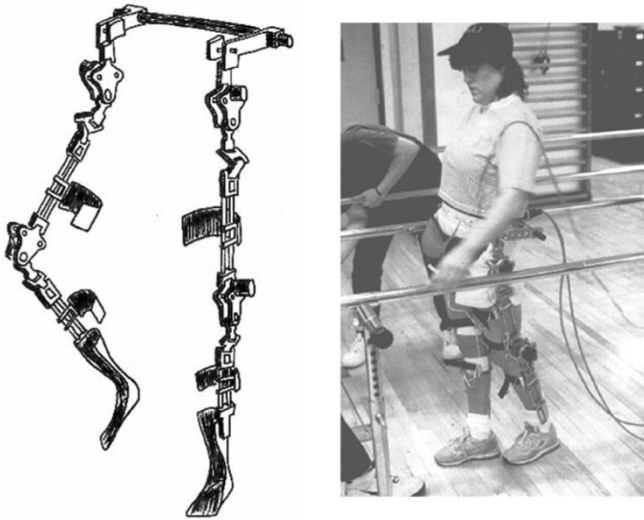


Fig. 1. CBO. FES is combined with a long leg brace that contains computer-controlled brakes at the hip and knee joints. The brakes are used to control limb trajectories and to lock the structure during stance. The device shown is a research version of the CBO that was designed for optimum function with no significant attempts to minimize size, weight, or ease of use. (Right) User who has a complete SCI at T6.

muscle fatigue is reduced. Smooth, repeatable leg motions are achieved during the swing phase by using the stimulated muscle as a source of power and regulating limb motion through continuous computer control of the brakes.

A laboratory-based version of the CBO was designed and built to evaluate the concept (Fig. 1) [27]. The laboratory CBO weighs 6 kg. One half of the orthosis weight is located on the pelvis resulting in rotational inertia and gravitational loading of the brace that is less than 10% of the equivalent loading provided by the limbs. The CBO joints were designed to be back-driveable and the resulting friction and damping of the device is small when compared to the passive compliance and damping of the natural joints. The flexion and extension axes of the hip and knee joints contain magnetic particle brakes that enable controllable braking torques of up to $50 \text{ N} \cdot \text{m}$ at the knees and $30 \text{ N} \cdot \text{m}$ at the hips. The hip and knee joints also contain position and torque sensors to enable feedback control. In addition to the controlled joints, the CBO allows limited flexion and extension of the ankle as well as abduction of the hip to enable relatively unrestricted walking. A limit stop on hip adduction prevents the scissoring of one leg in front of the other that can occur during FES-aided gait.

To determine the feasibility of the CBO concept, a series of experiments were undertaken to evaluate the ambulation performance of SCI subjects wearing the CBO. The experiments were done under controlled laboratory conditions and compared gait using traditional, four-channel FES alone (referred to as “FES gait” in this paper) with hybrid gait that combined FES with the CBO (“CBO gait”). The objective of the study was to determine if the CBO approach resulted in lower muscle fatigue, longer walking distances, faster speeds, and more repeatable trajectory control during stepping. The purpose of conducting the study was to determine if further engineering development of the CBO concept is warranted.

TABLE I
SUBJECTS

ID	Sex	Age	Injury level	Yrs post-injury	Notes
AA	F	26	T6	2	Motor/sensory complete
BB	M	36	T6	13	Motor/sensory complete
CC	F	36	T6/T7	10	Motor/sensory complete
DD	M	44	T8	10	Incomplete

II. METHODS

A. Subjects

Evaluation of the CBO system was conducted using four individuals with paraplegia resulting from SCI (Table I). All had motor and sensory complete injuries except for subject DD who had some sensation and could achieve brief periods of unassisted standing in a walker or parallel bars. This subject was included to determine if the CBO system was applicable to a wider population of users than just those with complete injuries.

Subjects were admitted to the study after passing a screening examination that included checks for excessive osteoporosis, spasticity, cardiovascular complications, or abnormal autonomic system response to stimulation. Before participating in the gait experiments, subjects strengthened their quadriceps at home with a daily program of stimulation using a commercial neuromuscular stimulation unit (Empi FOCUS), and in the lab using an ERGYS 1 electrical stimulation bicycle (Therapeutic Alliances, Inc.). The strengthening program typically took four to six weeks before the subjects were cleared for standing and gait. Study protocols were approved by the appropriate Institutional Review Boards.

B. Instrumentation

Electrical stimulation was applied through self-stick surface electrodes (Model BG1062, American Supply, Minneapolis MN) with a pair of $7.6 \times 4.4 \text{ cm}$ electrodes over each quadriceps and $4.4 \times 4.4 \text{ cm}$ electrodes over the peroneal nerve to elicit a flexion withdrawal reflex for stepping. For the latter, one electrode was placed directly over or slightly posterior to the head of the fibula with the return electrode placed just above the medial posterior crease formed at the knee joint when sitting. The stimulator produced asymmetric, biphasic, current-controlled pulses with amplitudes that could be varied between zero and 150 mA under computer control. Pulses applied to the quadriceps were at 25 Hz and $300\text{-}\mu\text{s}$ width, while those to the peroneal nerve were at 50 Hz and $350 \mu\text{s}$.

Gait occurred on a step-by-step basis with each step being initiated through a keystroke on the control computer upon a voice command by the subject. To implement a step, the stimulus controller turned off the ipsilateral quadriceps and excited the peroneal nerve to elicit a withdrawal reflex that flexed the hip, knee and ankle. After a controlled pause, the quadriceps was turned on to extend the leg in preparation for return to double-support stance. During CBO gait, the controller sensed the hip and knee joint positions and actively controlled the braking command signals and the level of stimulation to track a prescribed stepping trajectory. Detailed descriptions of the control algorithms can be found in [27].

Quadriceps muscle fatigue was characterized by measurement of the isometric recruitment curve (IRC). The IRC, which

represents the nonlinear static gain between stimulation level input and muscle force output, was measured via the torque sensors on the orthosis using the input–output cross-correlation technique developed by Beck and Durfee [28]. The effectiveness of swing-phase trajectory control was evaluated by examining step-to-step variation in joint angle trajectory records that were sampled during gait.

The level of exertion during gait was estimated by measuring heart rate and blood pressure. Heart rate was measured by a manual pulse count or using an exercise heart rate monitor (Polar Beat Model 1901201, Polar Electro, Inc., Port Washington, NY). Blood pressure was measured manually using a standard sphygmomanometer or automatically with a digital blood pressure monitor (Model HEM-704C, Omron Corporation). The relationship between heart rate and O₂ uptake is typically linear for nondiseased hearts which means that heart rate can be used as a rough estimator of work load [29], [30]. One must be cautious in assigning too much significance to this indicator when used for subjects with chronic spinal cord injury who can sometimes exhibit abnormal cardiac response to exertion.

Metabolic measurements were conducted for two subjects (BB and CC) using a MedGraphics CPX/D system. Oxygen uptake (VO₂), and carbon dioxide exhalation (VCO₂) were measured every 30 s during selected gait sessions for BB and breath by breath for subject CC. Average volume per meter of oxygen uptake were calculated over all data points as well as percentage increases for VO₂ and VCO₂ before and after each walk.

C. Protocol

All gait experiments took place within parallel bars, with the exception of those for subject BB who was able to use a walker. Because of the varying abilities and varying levels of training experienced by the subjects, protocol details varied from subject to subject. For all subjects, tests consisted of FES gait trials where the brace was worn but passive with the brakes off, and CBO gait trials with the brace and brakes active. Subjects kept the orthosis on for all trials so that the brace could be used as a data collection device to record joint angles during gait and to measure the IRC at specified intervals.

Trials for subject AA consisted of a series of 10-m walks down and back within 5-m parallel bars, with 3 min of rest between successive walks during which heart rate, blood pressure, and the IRC for the quadriceps were measured. Since there was no steering control in the system, turning around in the parallel bars was implemented through use of the upper limbs and twisting the torso. FES trials were 30 m long (three walks) while CBO trials were 50 m (five walks). Average gait velocity was recorded as the time to traverse 5 m. Experiment sessions occurred twice each week with one trial per session. Data was collected for four FES trials (120 m total) and seven CBO trials (350 m), but data from some trials were not usable.

Subject BB was able to use a walker for all trials. Each trial had a target distance of 9.1 m, although not all trials reached that distance. Heart rate, blood pressure, and quadriceps IRC were recorded before and after each trial. Data was collected for eight FES and 11 CBO trials over the course of several days. The protocol for subject CC was the same as that for BB except that the

target distance was a 3-m walk between parallel bars. Data was collected for 14 FES and nine CBO trials. Metabolic data was collected for subjects BB and CC, as described previously. Subject DD walked back and forth between short parallel bars. A walking trial continued until the quadriceps had reached a level of fatigue where they could no longer support the subject, thus, each walking trial was a different length. Data was collected from nine FES and eight CBO trials. For days where multiple trials were conducted in a single session, the sequencing of FES and CBO trials was randomized to prevent order effects due to fatigue.

III. RESULTS

A. Distance and Speed

For subject AA, the average velocity (\pm st.dev.) for FES walks was 0.092 ± 0.015 m/s ($N = 17$) and for CBO walks 0.107 ± 0.014 m/s ($N = 47$). The difference in average velocity was significant (two-tailed, unequal variance t-test, $p = .002$). For subject BB, the average FES velocity was 0.044 ± 0.014 m/s ($N = 8$) and average CBO velocity was 0.035 ± 0.014 m/s ($N = 11$), not significantly different ($p = 0.22$). For subject CC, the average FES velocity was 0.028 ± 0.007 m/s ($N = 14$) and average CBO velocity was 0.034 ± 0.009 m/s ($N = 9$), not significantly different ($p = 0.08$). For subject DD, the average FES velocity was 0.053 ± 0.014 m/s ($N = 9$) and average CBO velocity was 0.062 ± 0.018 m/s ($N = 8$), not significantly different ($p = 0.27$).

Subject AA completed all walks at the prescribed distances, so distance comparisons are not valid, although distances were set at 30 m for FES and 50 m for CBO because AA was able to walk longer distances using the CBO. Subjects BB and CC also had target distances, but the target was not always attained. For BB, the target 9.1 m distance was reached for 4 of 11 CBO walks (average distance = 6.2 m), but he was not able to complete the full 9.1 m for any of the FES walks (average distance = 4.2 m, significantly different, $p = 0.03$). CC reached the target 3 m for seven of nine CBO walks (average distance = 2.9 m) and nine of 14 FES walks (average distance = 2.7 m, no significant difference, $p = 0.21$). Subject DD walked until unable to continue for each trial. For eight CBO walks the distance averaged 13.5 ± 3.3 m while for nine FES walks the average distance was 5.6 ± 2.2 m, a significant difference ($p = 0.00$).

B. Stimulated Muscle Fatigue

Fig. 2 illustrates how the quadriceps torque degraded during a walk as a result of stimulated muscle fatigue. Muscle fatigue was quantified via the IRC records as the relative decrease in peak knee torque at the end of a trial compared to what was measured before the walk began. For subject AA, torque decrease averaged $4 \pm 17\%$ over three CBO trials while for three FES trials the decrease was $67 \pm 1\%$, a significant difference ($p = 0.02$). IRC data was not collected for subject BB. For subject CC, the torque decrease was $1 \pm 7\%$ ($n = 9$) for CBO walks and $17 \pm 10\%$ ($n = 11$) for FES walks ($p = 0.00$). For subject DD, the torque decrease was $4 \pm 5\%$ ($n = 3$) for CBO walks and $35 \pm 17\%$ ($n = 5$) for FES walks, again a significant difference ($p = 0.00$).

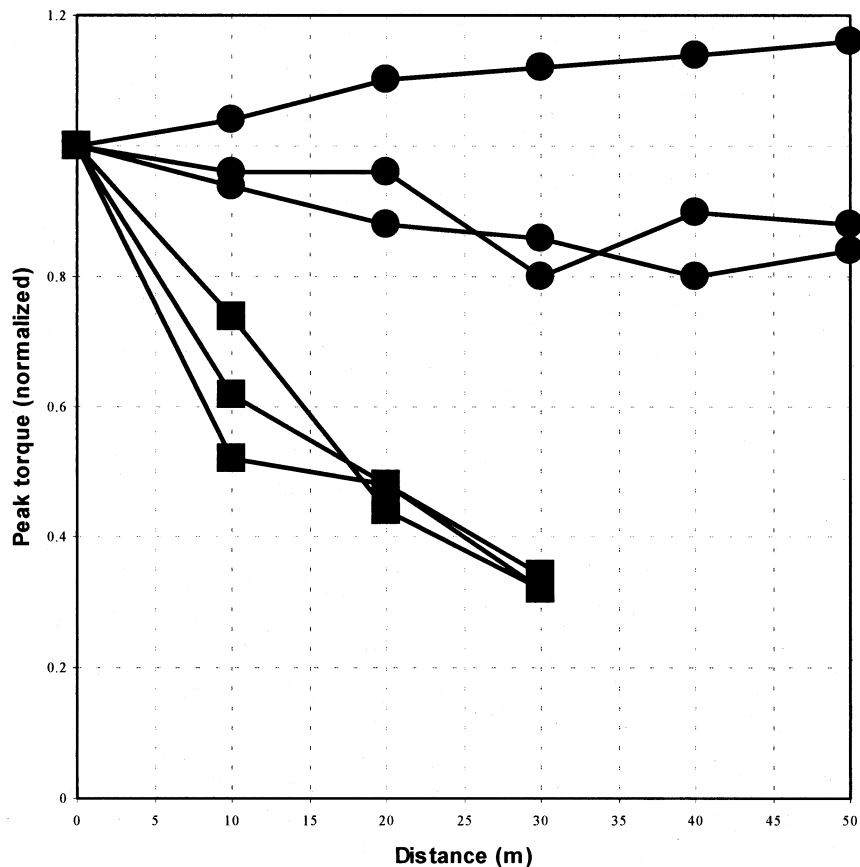


Fig. 2. Normalized peak knee torque as a function of distance for three CBO (circles) and three FES (squares) walks for subject AA. Right quadriceps IRC data is recorded every 10 m. Data is normalized to IRC recorded before the start of the walk.

C. Trajectory Control

Fig. 3 presents data from subject AA that demonstrates the ability of the controlled-brake system to control trajectory over 50 steps. The tighter the spread, the better the control. Data from the other three subjects were similar. In the CBO knee-joint plot, the traces that fall below 60° of knee flexion are indicative of steps that the CBO could not control because the stimulated withdrawal reflex was too weak to achieve full knee flexion.

D. Exertion

Exertion was estimated by measuring heart rate (HR) and systolic and diastolic blood pressures (SBP, DBP) at periodic intervals during gait and reporting the percentage change after a walk. Table II shows this data for all subjects. None of the measures showed a significant difference between CBO and FES walks at the $p = 0.05$ level, however, when the data was normalized to the distance walked (right two columns of Table II), all subjects except BB had significantly lower heart rate per meter walked for CBO trials than for FES trials ($p < 0.05$). This can be explained by recognizing that for all subjects, CBO walks were longer. No significant differences were found in blood pressure increases even when distance was taken into account.

E. Metabolic

Table III contains metabolic data from two subjects. Data is based on eight FES and 11 CBO walks for subject BB and 14 FES and nine CBO walks for subject CC. The oxygen consump-

tion data is normalized to distance walked with units of ml/m. None of the data demonstrated significant differences between FES and CBO walks.

IV. DISCUSSION

The objective of the CBO is to reduce muscle fatigue and, thereby, improve walking distances for FES-aided gait. A second objective is to provide more control and more repeatability over limb trajectories during gait. The results demonstrated that the CBO can indeed reduce muscle fatigue as quantified by the isometric recruitment curves for the quadriceps recorded before and after walks. The fatigue reduction results from using the locked orthosis rather than stimulated muscle to stabilize the system during standing and the stance phase of gait. In FES trials, the quadriceps was stimulated for approximately 87% of the walk, while for CBO trials it was stimulated for only 12%. Fatigue when using the CBO improves as stance time is increased since during stance phase the muscles are not stimulated. The addition of the brace also opens FES-aided gait to a wider pool of subjects. For example, subject DD with an incomplete cord injury could achieve brief periods of passive standing solely due to extensor spasticity aided by proper positioning. DD could not stand for long periods, nor walk very far with FES assist. Adding the CBO allowed DD to stand much longer and to walk reasonable distances.

Although it appears that use of the CBO led to increased gait distances, the protocol used renders a direct comparison impractical. Subject AA was regularly able to conduct 50-m trials with

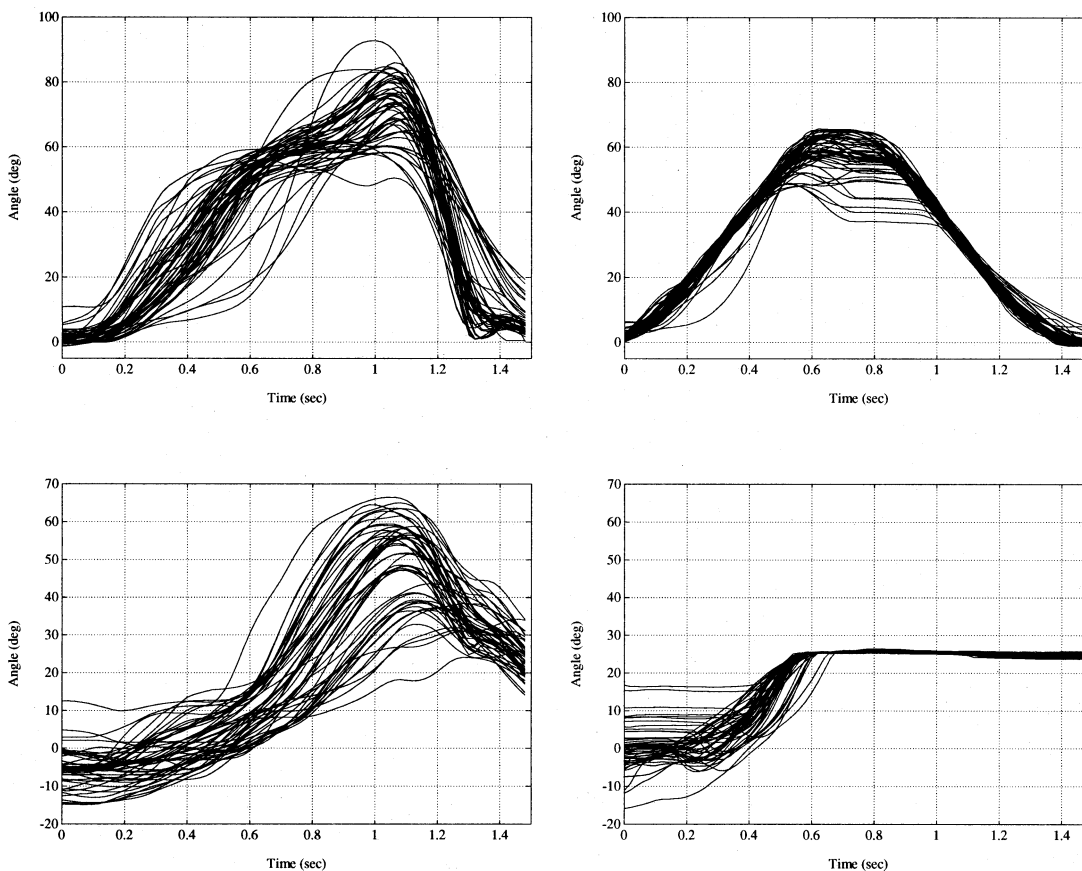


Fig. 3. Trajectory control of the knee and hip joints during the swing phase of gait. Each plot shows the joint angle for 50 steps, superimposed without normalization. FES steps are on the left, CBO steps on the right, knee on top, hip on the bottom. (Subject AA.)

TABLE II
PERCENT INCREASE IN HEART RATE AND BLOOD PRESSURES AFTER FES AND CBO WALKS. THE RIGHTMOST TWO COLUMNS SHOW DATA NORMALIZED TO DISTANCE WALKED. MEAN ± STD. DEV.

Parameter	Subject	FES	CBO	FES (per m)	CBO (per m)
% Increase HR	AA	112 ± 30	55 ± 19	3.1 ± 1.0	1.0 ± 0.6
	BB	38 ± 41	53 ± 35	8.6 ± 8.0	8.3 ± 6.0
	CC	50 ± 15	50 ± 12	18.9 ± 6.0	16.7 ± 4.0
	DD	24 ± 14	23 ± 19	2.1 ± 2.9	1.7 ± 1.7
% Increase sys. BP	AA	30 ± 17	10 ± 3	1.0 ± 0.6	0.2 ± 0.1
	BB	26 ± 19	24 ± 15	6.3 ± 4.9	4.2 ± 2.4
	CC	-1 ± 9	4 ± 8	-0.4 ± 4.0	1.2 ± 2.7
	DD	3 ± 14	11 ± 7	0.2 ± 3.1	0.8 ± 0.6
% Increase dias. BP	AA	9 ± 10	16 ± 33	0.3 ± 0.3	0.3 ± 0.7
	BB	-5 ± 2	-2 ± 6	-1.7 ± 0.7	-0.2 ± 0.7
	CC	-2 ± 7	1 ± 8	-0.5 ± 2.6	0.2 ± 2.7
	DD	7 ± 10	4 ± 5	0.8 ± 1.9	0.3 ± 0.6

TABLE III
METABOLIC DATA FOR FES AND CBO WALKS. OXYGEN CONSUMPTION IS ml/m. DATA IS REPORTED AS MEAN ± STD. DEV.

Parameter	Subject	FES	CBO
O ₂ per meter	BB	613 ± 264	462 ± 149
	CC	463 ± 178	378 ± 75
% Increase V _{O₂}	BB	297 ± 98	320 ± 126
	CC	228 ± 60	184 ± 71
% Increase V _{CO₂}	BB	366 ± 136	318 ± 73
	CC	305 ± 148	226 ± 53

the CBO but only 30-m-trials for FES. Subject BB reached the target 9.1-m distance more times with the CBO than with FES, while subject CC could only manage a short distance for either

CBO or FES. Subject DD, the only one allowed to walk as far as possible, went significantly further with the CBO than with FES. From observations and self-reports, gait distance was limited by knee collapse due to quadriceps fatigue or upper body fatigue. Accommodation of the withdrawal reflex, which would lead to diminishing knee flexion, was not a problem and no subjects reported hand pain. More training followed by trials where free-roaming is allowed would be necessary to make definitive conclusions about distance.

Using the flexion withdrawal reflex to initiate the step is common to many surface FES-aided gait systems, including the early systems by Kralj *et al.* [4] and the commercially available Parastep [31], but does represent a weak link because, for some

TABLE IV
SPEED AND DISTANCE FOR VARIOUS FES-AIDED GAIT SYSTEMS. THE ARGO STUDIES DID NOT USE FES

System	Avg vel (m/s)	Max vel (m/s)	Distance (m)	Citation
CBO	0.06	0.11	3-50	[this paper]
Ljubljana	0.15	0.40	20-200	[37], [38]
Parastep	0.20	0.60	2-350	[31]
Parastep	0.15	0.40	1-350	[39]
Parastep	0.20	0.40	11-62	[40]
RGO	0.20	0.45	30-1000	[41], [36], [42]
ARGO	0.20	0.58		[20]
CWRU	0.24	0.90	300+	[43], [44]

individuals, that reflex is erratic while for others it habituates during gait. In our study, poor reflex response was a subject exclusion criteria. Of the four subjects, one had an erratic reflex response that on occasion prevented data collection, but in general reflex habituation did not limit gait distances.

There were no significant differences between FES and CBO in average walking velocity, with the exception of subject AA who was able to walk slightly faster with the CBO. The average speed for all subjects was 0.054 m/s using FES and 0.060 m/s using the CBO. These speeds are significantly lower than those of other FES-aided gait systems. Table IV shows average and maximum speeds and gait distances reported by the Ljubljana group, which used a four-channel surface stimulation system similar to our FES protocol; two studies, one with 12 subjects, one with 13, using the commercial Parastep system, also a four-channel surface system; 20 subjects using the RGO, a hybrid orthosis/surface-stimulation FES-aided gait system designed and tested at LSU; and the percutaneous electrode FES-gait system of Marsolais and colleagues at Case Western Reserve University, Cleveland, OH. For comparison purposes, the table also shows data from IJzerman and colleagues who used the ARGO without FES. The most likely reason for the slow speeds demonstrated in our study is that the subjects were not habitual users of an FES system, with the only use being the time they were in the laboratory participating in experiments. Subject BB was an experienced Parastep user, and one would expect his speeds using the Parastep and our FES system to be similar since the operational principles of the two are similar. His CBO and FES speeds were 0.035 and 0.044 m/s, but he was able to attain 0.070 m/s with his Parastep system (slower than the average speed reported in [31]), possibly due to the additional training. Three of four subjects were walking within parallel bars which may have been another reason for the slow gait speeds. One should also keep in mind that the speeds discussed here are considerably slower than able-bodied gait which averages 1.5 m/s [32], [33] and locomotion in a wheelchair which averages 0.55 m/s [34], [35]. The average CBO speed of 0.060 m/s is too slow for functional walking, but may have therapeutic benefits.

The metabolic data showed no significant differences between FES and CBO walks and neither were there significant differences in HR and BP before and after walks. However, when HR increases were normalized to distance walked there were significant differences, implying that HR increase per meter walked is lower with the CBO. It also implies that the length of a walk is dictated not only by muscle fatigue, but also by elevation in HR, an indirect measure of physical exertion.

As can be seen in Fig. 3, adding the CBO greatly improved trajectory control over the limbs. In addition, the hip-adduc-

tion stop eliminated the scissoring which occurred for subject AA during FES walks. One might speculate that with more gait training, the better trajectory control achieved with the CBO would result in faster walking speeds since the user would know that their foot placement would be consistent from step to step. Unlike orthoses whose joints are locked at all times during gait, the controllable joints of the CBO enabled more natural knee and hip trajectories.

The variation present in the CBO gait joint angle trajectories was caused by inadequate muscle stimulation joint power during some steps. When the joint power was insufficient, the dissipative controller upon which the CBO is based was ineffective. This lack of power was particularly apparent in steps for which the flexion withdrawal reflex was too weak to achieve full knee flexion. Lack of power and the day-to-day inconsistency of the flexion withdrawal reflex is the primary weakness of both FES and CBO gait. The CBO can address many of the problems associated with FES gait, but cannot compensate for insufficient joint power.

As indicated in Fig. 3, hip control with the CBO is a more challenging task than knee control. The knee controller regulates both knee flexion and extension, and, thus, can control knee position for the entire gait cycle. Since the CBO system incorporates four channels of stimulation with no activation of hip extensors, the hip controller can regulate hip flexion only. Active hip extension for enhanced propulsion could be achieved by adding two additional stimulation channels for the gluteal muscles, as is done sometimes with the Parastep system. This comes at the cost of system complexity and the difficulty users with paraplegia have in donning electrodes over the gluteal muscles. For our system, passive hip extension, which occurs during stance phase, is effected primarily by the individual's upper body. Since the hip controller regulates hip motion for only one half of the gait cycle, nearly every swing phase hip trajectory begins with an initial tracking error. Since the controller can only remove power from the joint, it is limited in its ability to drive the error to zero, and instead must wait for the system to arrive in a region of the trajectory where it can impose effective control.

In FES gait, the hip typically exhibited excessive flexion then fell back as the leg dropped due to gravity resulting in a form of gait that resembled marching (bottom-left of Fig. 3). The CBO was able to lock the hip joint at full flexion, yielding larger step lengths and a somewhat more able-bodied gait appearance (bottom-right of Fig. 3). The controller did not regulate hip extension during stance phase, thus, most swing phase hip trajectories began with a tracking error.

The brace was worn for all trials, including those for FES gait where the brakes were inactive. The comparisons between FES and CBO gait thus, focus on the effects of controlled braking. There are further differences between gait with the brace on and brakes off, and gait without the brace. For example, the CBO limits the leg to roughly planar motion and the ankle brace limits motion of the foot. The effect of the added inertia and friction of the brace was not quantified, but visual observation of many trials indicated that the rotational inertia, joint friction, and joint misalignment of the CBO did not have a significant effect on FES gait dynamics. Some subjects exhibited adduction of the leg during the swing phase, which meant gait would have

been impossible without the adduction limit stop provided by the brace.

In assessing the validity of the CBO concept, several engineering and human factors design issues must be considered. The CBO has a distinct disadvantage when compared to plain FES gait systems because the orthosis hardware is bulky, heavy and difficult to don and doff independently. For acceptance and use on a daily basis, users should be able to don and doff the orthosis in under 5 min with little or no assistance, an achievable goal as shown by a study using the RGO where 94% of the 70 subjects were able to don and doff the RGO without assistance [36]. To attain this goal, the CBO requires a significant engineering redesign effort.

Further design work is required to simplify the donning and doffing of surface stimulation electrodes and the routing of electrode leads. The CBO concept would work with implanted electrode systems as well, but surface stimulation is appropriate for a substantial portion of the potential user population if it can be made reliable and easy to use.

The fit of the brace must be improved. Although the research version of the CBO can be adjusted for limbs of different lengths, the quality of fit to limbs of different shapes varied. One reason subject AA was able to achieve reasonable walking distances with the CBO was that the brace fit this subject particularly well. For other subjects, the brace would occasionally twist around the limb, compromising its ability to hold the subject during stance and control the limb during swing.

A viable gait assist system must be self-contained and battery powered. Since the CBO demands less muscle stimulation, power drain on the battery is reduced. This reduction in load is offset in the current CBO design by the electrical power drawn by the magnetic particle brakes which required an average of 15 W over a typical gait cycle. For the next generation CBO, we are developing a novel controlled brake whose power requirements are far less than magnetic particle brakes and are in a locked state when no power is applied.

Another design consideration relates to the brace structure and the sharing of gravity loads between the skeletal system and the brace. When a normal knee joint is loaded, it is structurally supplemented by tension in the patellar ligament imposed by contraction of the quadriceps or by being in the "screwed home" position held in place by the joint ligaments. During CBO gait, the orthosis provides the isometric knee torque in the extension/flexion plane, but relies on the skeleton and the knee joint to bear all compressive loads due to gravity. During CBO gait stance phase, the knee is fully loaded without muscle contraction. If the joint ligaments are lax, this loading could cause buckling in the mediolateral plane and damage ligaments and connective tissue. This danger is present with all long-leg gait orthoses that rely on the brace to support body weight. Joint instability is not a problem with FES gait since active contraction of the quadriceps stabilizes the knee joint. The solution is careful fitting of the CBO and using an AFO to orient the foot in a toe-out position that tightens the knee ligaments and guides the knee joint into its screw home position. In our study, subjects AA and CC periodically exhibited knee laxity which when noticed required cancelling gait experiments for that day. In future studies, subjects with excess knee laxity will be excluded from CBO use.

V. CONCLUSION

The controlled-brake orthosis provided significantly better trajectory control and reduced muscle fatigue when compared to FES-only gait. For some subjects, this resulted in being able to walk further, but for most, gait speed was largely unaffected. A study with more subjects and a longer training period is required to thoroughly compare CBO to FES gait. The ability of the brace to effect trajectory control is limited by its dissipative nature. Insufficient joint power, especially in the flexion withdrawal reflex, sometimes rendered the brace controller ineffective. Since the burden of maintaining knee joint stability during stance has been assumed by the CBO, the most serious consequence of quadriceps fatigue, collapse of the individual without warning, was eliminated. The results of the study were sufficiently encouraging to justify further effort to reengineer the CBO. Significant design are required before a more rigorous evaluation study can be undertaken, and before the CBO concept can be considered as a viable form of assistive technology.

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