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Development of hybrid orthosis for standing, walking, and stair climbing after spinal cord injury

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Abstract—This study explores the feasibility of a hybrid system of exoskeletal bracing and multichannel functional electrical stimulation (FES) to facilitate standing, walking, and stair climbing after spinal cord injury (SCI). The orthotic components consist of electromechanical joints that lock and unlock automatically to provide upright stability and free movement powered by FES. Preliminary results from a prototype device on nondisabled and SCI volunteers are presented. A novel variable coupling hip-reciprocating mechanism either acts as a standard reciprocating gait orthosis or allows each hip to independently lock or rotate freely. Rotary actuators at each hip are configured in a closed hydraulic circuit and regulated by a finite state postural controller based on real-time sensor information. The knee mechanism locks during stance to prevent collapse and unlocks during swing, while the ankle is constrained to move in the sagittal plane under FES-only control. The trunk is fixed in a rigid corset, and new ankle and trunk mechanisms are under development. Because the exoskeletal control mechanisms were built from off-the-shelf components, weight and cosmesis specifications for clinical use have not been met, although the power requirements are low enough to provide more than 4 hours of continuous operation with standard camcorder batteries.

Key words: assistive technology, bracing, functional electrical stimulation, gait, hybrid systems, mobility, neuroprostheses, orthotics, paralysis, rehabilitation engineering, spinal cord injury, stair climbing, standing, stepping.

INTRODUCTION

Inability to walk is often viewed as the major and most traumatic outcome of thoracic spinal cord injury (SCI), motivating significant effort in the field of orthotics to restore locomotion to persons with paraplegia. The three major approaches to restoring upright mobility receiving the most attention are mechanical bracing, functional electrical stimulation (FES), and hybrid systems that combine elements of both orthotic and neuroprosthetic interventions.

Abbreviations: ECU = external control unit, FES = functional electrical stimulation, FSPC = finite-state postural controller, FSR = force-sensing resistor, GED = gait event detector, GUI = graphical user interface, HNP = hybrid neuroprosthesis, HRA = hydraulic rotary actuator, NC = normally closed, RGO = reciprocal gait orthosis, SCI = spinal cord injury, SD = standard deviation, T= thoracic, THKAFO = trunk-hip-knee-ankle-foot orthosis, VCHM = variable constraint hip mechanism.

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A variety of mechanical orthoses have been designed and tested for lower-limb function after SCI. In general, reciprocal gait orthosis (RGOs) stabilize ankles, knees, hips, and trunk to provide upright posture and couple hip flexion with contralateral hip extension to facilitate walking, while long leg braces only fix the ankle and knee joints to provide stability and prevent collapse. In some configurations, the addition of a pelvic band provides extra stability. Most orthoses provide good postural stability, especially when the hip joints are reciprocally coupled to prevent bilateral hip flexion. The coupling also reduces metabolic energy consumption in a more natural-appearing reciprocal gait than the swing-through gait typical with long leg braces where both legs are brought forward together [1]. No significant difference in energy consumption was found between different reciprocal gait orthosis designs [2]. With all mechanical braces, upper-body strength is required for standing up and for forward progression during walking. Clinical reviews also indicate that brace users are consistently unable to achieve significant functional ambulation without some sort of pelvic control, that adequate hip flexion is an essential component of walking with braces, and that few individuals with paraplegia choose to use their orthosis for activities other than therapeutic exercise [3–4].

FES has been introduced in an effort to circumvent some of the shortcomings of mechanical orthoses [5]. Activation of one's own paralyzed muscles can stabilize the body against collapse and provide the power for forward progression. Many configurations of FES systems have been used to enable walking in persons with paraplegia [6]. Those configurations using electrodes applied to the surface of the skin are usually limited to six channels or less, with emphasis on locking the knees and hips in extension and eliciting a withdrawal reflex to move the legs for stepping [7]. FES systems using implanted intramuscular electrodes with percutaneous leads [8–11] have provided up to 48 channels of stimulation for improved stability and forward progression and finer control of movement during walking [12–13]. Multichannel implanted FES systems for walking after motor complete paraplegia have provided a swing-through [14–15] and reciprocal gait [16–18]. They reduced donning time and improved day-to-day repeatability compared with surface FES systems and eliminated site care of percutaneous systems. Most FES systems for walking employ open-loop or feed-forward control, in which preprogrammed stimulation patterns are activated for each step by switches or the electromyographic activity of nonparalyzed muscles [19]. However, rapid onset of muscle fatigue remains a major problem that more effective control of stimulation still needs to resolve. Consequently, FES walking in paraplegia requires high levels of metabolic energy [20] and remains primarily experimental and for therapeutic exercise [21–22].

In 1973, a hybrid actuator was described for orthotic systems in which the anatomical joint could be controlled internally by means of FES or externally by means of a hypothetical three-state joint actuator incorporated onto an exoskeletal brace [23]. This work initiated the field of hybrid orthotics and, specifically, defined the concept of a hybrid neuroprosthesis (HNP), in which FES is combined with external mechanical components. This article reviews the design specifications for HNP systems and presents preliminary data on the performance of a new prototype device incorporating a novel hip reciprocating mechanism with variable coupling that allows stair ascent/descent and stride length variation with walking speed.

BACKGROUND

HNPs potentially can combine the best features of mechanical bracing and FES into new systems for walking after SCI that offer more advantages than the individual components acting alone. The exoskeletal mechanical components of hybrid systems have been generally passive devices to minimize size, weight, and energy consumption, while the FES component serves as an active mechanism for limb propulsion. Kinematic constraints imposed on the user by the exoskeleton reduce the number of degrees of freedom driven by FES. Therefore, the secondary and tertiary actions of the stimulated muscles are constrained by the exoskeleton without the need to compensate by activating antagonist muscles.

Various prototype lower-limb exoskeletons use auxiliary passive mechanisms to reduce the number of muscles to be electrically stimulated. The controlled-brake orthosis incorporated magnetic particle brakes at the hip and knee joints to refine the sagittal limb dynamics driven by FES [24–25]. Another approach used a cam-slider mechanism to synchronize knee flexion with ankle dorsiflexion to assure proper foot-ground clearance during swing [26]. The spring-brake orthosis used excess spring energy stored from FES driven knee extension to facilitate knee flexion and assist hip flexion in the succeeding ipsilateral swing period [27]. Similarly, a design of an energy-storing orthosis that employed a pneumatic system that harnesses and transfers excess energy from knee extension to facilitate ipsilateral hip extension during stance showed promising results in bench testing [28].

Surface [29–38] and intramuscular [39–41] FES systems have been combined with a conventional trunk-hip-knee-ankle-foot orthosis (THKAFO) for reciprocal gait in individuals with complete thoracic level SCI. Combining an RGO with a four-channel surface FES system provided a 16 percent reduction in energy expenditure for subjects with SCI level between thoracic (T), levels T1 and T10 relative to walking with the RGO only at a speed of 0.2 m/s [42]. The addition of FES to the glutei during stance when individuals used lower-limb bracing reduced crutch forces [43–44] and provided forward propulsion by driving the stance leg into extension. Users with paraplegia (complete T4–T12 SCI) required 70 percent of their maximum upper-limb aerobic capacity when walking with an RGO alone, while walking with an RGO combined with FES required 32 percent of the upper-limb and 25 percent of the lower-limb aerobic capacity, effectively shifting the metabolic burden from the muscles of the arms, shoulders and trunk to the large, otherwise paralyzed, muscles of the legs [45]. Further, individuals with paraplegia have been shown to walk significantly longer with a hybrid system than with either brace-only or FES-only systems, with hybrid users achieving an average maximum walking distance of 800 m [36].

FES-only systems require the user to maintain trunk stability via significant upper-body forces on a walker or other assistive device. This increases energy consumption and thus reduces walking times and distances. Instability of the trunk is often exacerbated by stimulation of the hip flexors during the initiation of the swing phase. Anterior trunk tilt of up to 40° has been associated with FES-only gait systems. The RGO combined with FES has been shown to reduce anterior trunk tilt to less than 18° [41]. However, the RGO has a fixed 1:1 hip flexion:extension coupling ratio (hip flexion is limited by the degree of contralateral hip extension). Individuals with paraplegia walking with the RGO only (no FES) at a 2:1 hip flexion:extension coupling ratio exhibited a 15 percent reduction in physiological cost index and 4 percent increase in stride length relative to an RGO with a 1:1 coupling ratio [46]. Adding FES-assisted hip flexion to an RGO with a 2:1 hip coupling ratio reduced the physiological cost index further and increased stride length and walking speed. A reciprocating mechanism with a fixed 1:1 coupling ratio can actually compromise peak walking performance. When a multichannel FES system was combined with a 1:1 coupled RGO fitted with a controllable locking mechanism at the knee joint to allow for knee flexion during swing, the average stride length and gait speed were significantly lower (0.64 m and 0.32 m/s, respectively) than when the reciprocator was disengaged (0.94 m and 0.49 m/s.) However, disengaging the reciprocator significantly compromised the postural stability, requiring increased upper-limb exertion [40].

With the incorporation of joint locks or brakes, standing and stance-limb stability against collapse can be accomplished with minimal muscle stimulation. These locks must be properly controlled and synchronized with both the gait cycle and FES to provide stability when needed, without restricting joint motion necessary for ambulation. A knee joint, which unlocks and locks by the weight of the locking bar, obviated the need for stimulation of quadriceps during standing and the stance phase of gait [47]. With applied flexion moment, unlocking has been a problem in designs based on cam and follower [48], roller clutches, lever locks, and wedge knees as employed in orthotic stance-phase control knee joints [49]. A commercial pendulum-locking knee joint that locks when the limb is extended in front of the user and unlocks shortly after midstance can allow swing-phase flexion [50]. Another mechanism uses a push rod displaced by body weight to engage the knee lock [51–52]. A wrap-spring clutch-controlled knee joint that would lock during stance and be free for swing [53] showed significant reduction in oxygen consumption during walking when compared with a locked knee brace [54].

In summary, an HNP combining bracing and FES has been shown to significantly improve walking distance and reduce energy consumption. A reciprocal coupling of the hips provides good trunk stability, and flexion-to-extension coupling ratios favoring flexion improve step length and energy cost. Unlocking the orthotic knee joints during the swing phase of gait improves foot-to-floor clearance and reduces energy cost, while locking them during stance postpones muscle fatigue from stimulation.

In this article, we discuss the development of an HNP that incorporates and expands the advantages of various hybrid configurations that were found to improve walking in people with paraplegia. These include a novel variable-constraint hip mechanism that either reciprocally couples the hips or individually locks them or allows them to move freely. This mechanism stabilizes the hips and trunk when coupled, while allowing increased hip flexion when uncoupled during swing to improve step length and maintain stance hip stability. The knee joints during swing are unlocked to provide foot-to-floor clearance and locked during stance to allow muscles to relax. This system includes control over all major muscles of the trunk, hips, knees, and ankles with an implanted FES system. It provides the power to bring the legs forward for stepping by direct muscle activation rather than the withdrawal reflex and moves the body forward by activation of hip extensors and plantar flexors. The coordination of joint coupling and locking with muscle activation is based on sensor information fed to a gait event detector (GED). The GED is in turn used by a postural controller, which assures proper coordination of stimulation and joint locking mechanisms and provides safety against collapse.

METHODS

HNP Design Specifications

A set of general design specifications for HNP systems was established and applied to the development and testing of a new prototype system. To achieve a practical system for upright mobility in paraplegia, we found it critical to combine FES and bracing in a coordinated fashion that takes advantage of the best features of each component. Bracing must be designed to provide postural stability without excessively hindering movements during forward progression. On the other hand, the FES system should provide major power for forward progression in an effective way that reduces muscle fatigue through control of the muscle stimulation patterns that adapt to the changing muscle properties and environment during gait. A practical HNP should possess the following characteristics:

1. Be cosmetic.
2. Be easy to don and doff in less than 5 minutes without assistance while sitting in a chair.
3. Be easy and intuitive to operate.
4. Provide the capability to stand up and sit down with minimal effort.
5. Provide postural support without power or stimulation for standing.
6. Provide the capability to go up and down stairs.
7. Carry its own weight.
8. Provide up to an hour of continuous walking.
9. Provide safety features in case of power failure.
10. Require less than 50 percent of individual's maximal aerobic capacity to walk.

Other HNP specifications that would improve the use and practicality include—

1. Mechanical components of the HNP complement the functional movements generated by FES.
2. The HNP minimizes and automatically adjusts muscle stimulation.
3. The HNP seamlessly combines bracing and FES system components.

The HNP system under development consists of an implanted FES system, a new THKAFO with electromechanically controllable joints, and a controller coordinating the two components based on real-time sensor information as shown in **Figure 1**.

FES System

The FES system for the prototype HNP consists of 16 channels of stimulation delivered via chronically indwelling intramuscular electrodes to activate (1) quadriceps muscles for knee extension, (2) hamstring muscles for hip extension, (3) gluteus maximus muscles for hip extension, (4) gluteus medius muscles for hip abduction, (5) iliopsoas muscles for hip flexion, (6) erector spinae muscles for trunk extension, (7) pretibial muscles for ankle dorsiflexion, and (8) calf muscles for bilateral ankle

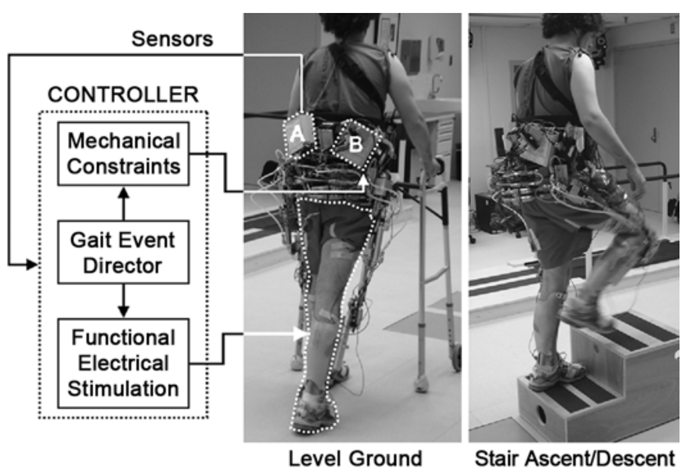

Figure 1.
Hybrid neuroprosthesis consists of functional electrical stimulation system, bracing with controllable joints, and control software. Gait event detector synchronizes stimulation of muscles with brace operation. A = sensor processing circuitry, B = mechanical constraint control circuitry.

plantar flexion. Electrodes can be connected temporarily to an external control unit (ECU) percutaneously or permanently to an implanted pulse generator powered and controlled via radio frequency by an ECU [16].

The ECU is powered by an internal Sony 15.8 Wh NP-F570 7.2–8.4 V lithium ion rechargeable battery pack (Sony Corporation of America; New York, New York). The ECU draws approximately 2 W of power for FES, allowing for approximately 8 hours of muscle activation.

Bracing System

Because conventional RGOs have a fixed 1:1 hip flexion:extension coupling ratio, which has been shown to limit stride length and gait speed [35,40], a variable constraint hip mechanism (VCHM) was designed to maintain posture while allowing for uninhibited sagittal hip movement [55]. The objective of the VCHM was to provide good hip and trunk stability and erect posture without interfering with functional lower-limb dynamic movements during walking and stair-climbing. The reciprocating bar of a standard isocentric RGO was replaced with the new VCHM and the medial uprights were removed. The resulting THKAFO is coupled to the body by means of chest, pelvic, and below-the-knee straps.

The VCHM consists of a hydraulic system with double-acting cylinders linked to each hip joint of the orthosis (**Figure 2**). The corresponding ports of the opposing cylinders are connected to produce a closed hydraulic circuit. Normally open two-way, two-position solenoid valves are attached to each port of the cylinders. Two additional normally closed (NC) two-way, two-position solenoid valves modulate the flow of fluid between the cap and rod ends of the hydraulic circuit and into an accumulator. Each hydraulic cylinder is mechanically linked to each hip via a custom rack-and-pinion transmission. When all the valves are de-energized, the mechanism provides the 1:1 hip coupling of a standard RGO. When one piston of a cylinder is forced to extend, the rod end of the piston of the contralateral cylinder is pressurized and thus forced to retract. By energizing specific solenoid valves, the hips can be reciprocally coupled, unlocked to move freely, and independently locked against flexion or extension or both.

Each hydraulic rotary actuator (HRA) of the VCHM was configured as follows. The cylinder was mounted to the thigh upright of the knee-ankle-foot orthosis via a clevis (**Figure 2**), and the pinion was fixed rigidly to the corset. The rack was connected to the rod via a clevis and

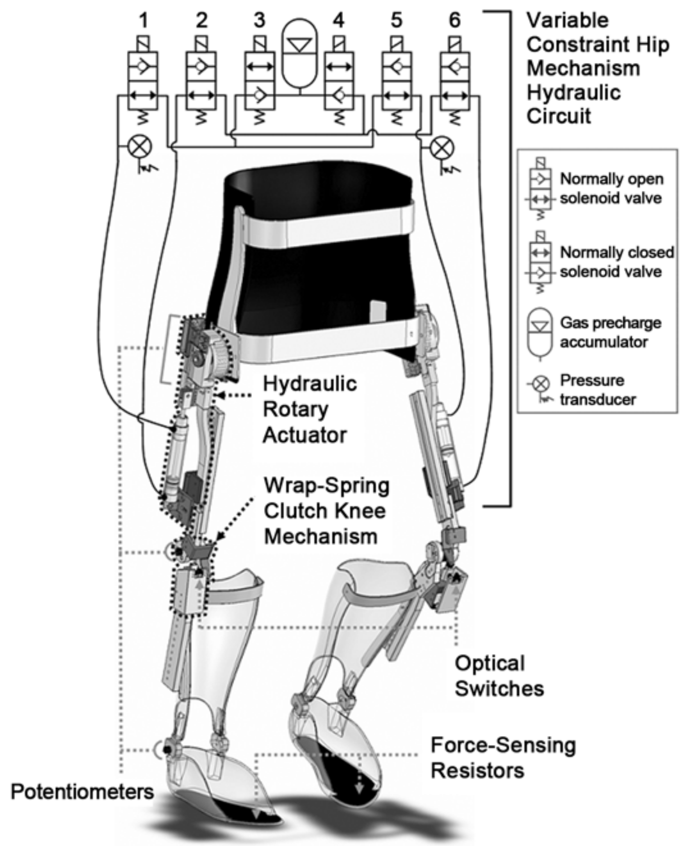

Figure 2.
Exoskeletal components of hybrid neuroprosthesis. Knee joints are instrumented with solenoid controlled wrap-spring clutches that provide support during stance and unlock for swing. Hip mechanism, depicted schematically with accumulator and valves, includes hydraulic rotary actuators attached to hips and controlled by variable constraint hip mechanism. Postural controller uses information from force-sensitive resistors, potentiometers, optical switches, and pressure sensors to regulate hip and knee mechanisms to maintain exoskeletal stability against collapse and to provide freedom to move legs with functional electrical stimulation.

meshed to the pinion, posterior relative to the hip joint. A polypropylene shield was placed around the pinion to protect the user from the gear teeth. The clevis connections made between the cylinder and thigh upright and between the cylinder rod and the rack allow the rotary actuator to move into abduction during donning and doffing (**Figure 3**). For real-time control, a slide potentiometer (Alps Electric Co; Tokyo, Japan) was instrumented to the rack to measure cylinder piston movement and digital pressure sensors (Gems Sensors Inc; Plainville, Connecticut) were attached at each port of the cylinder to monitor pressure. In addition, potentiometers were placed at the knee and ankle to measure angles and force-sensing resistors (FSRs) (B & L Engineering; Tustin, California) were placed in the insoles to measure foot-to-floor contact.

A solenoid-actuated wrap-spring clutch mechanism based on a design by Irby et al. was employed for supporting the knee (**Figure 2**) [53]. The wrap-spring clutch knee mechanism was installed at the knee joints of the exoskeleton with a posterior offset to reduce knee flexion moment induced by gravity. A 5.9 W, 12 Vdc latching solenoid (Guardian Electric; Woodstock, Illinois) was used to engage/disengage the wrap-spring clutch (Warner Electric; South Beloit, Illinois). Unlatching (extension of the plunger out of the solenoid) disengages the clutch, which locks the knee against flexion but still allows extension. Latching (retraction of the plunger into the solenoid) engages the clutch, allowing for both knee flexion and extension. A pulse of 100 ms is used to latch/unlatch the latching solenoid. An optical switch (TT Electronics; Weybridge, United Kingdom) monitors the movement of the plunger of each latching solenoid to assure that the state transition (lock/unlock) of the knee has been completed.

The mechanical orthosis was designed to fit in a standard wheelchair so donning and doffing can take place in a seated position (**Figure 3**). In this seated configuration, each hip is freed in the sagittal plane by opening both NC valves of the VCHM to allow for full hip flexion. Abduction of the hips is achieved by releasing a manual slide lock. The clutch of each knee mechanism is engaged to allow for flexion. As seen in **Figure 3**, the user can easily transfer from his wheelchair into the exoskeleton; slip his feet into the ankle foot orthosis placed in his shoes; tie chest, pelvic, and knee belts; and lock the abduction joints before he is ready to stand up.

Controller Design

The software for controlling the mechanical orthosis was developed in the xPC Target/Simulink (The MathWorks, Inc; Natick, Massachusetts) real-time environment. A graphical user interface (GUI) was developed to simplify calibration, implementation, testing, and data acquisition. The GUI runs on a host computer and sends commands to and acquires signals from the target PC during real-time implementation via Ethernet communication. All sensor signals are sampled at 200 Hz. Joint angle signals are low-pass filtered at 10 Hz, while pressure sensor and FSRs signals are low-pass filtered at 20 Hz.

For simpler operation of the mechanical orthosis, the only input required from the user is pressing a button to select a preprogrammed stimulation pattern for the desired task: stand, walk, climb up and down stairs, or sit. Walking and stair climbing can only be selected once the user is standing. The user is provided a visual confirmation of his action through a liquid crystal display on the ECU. When the user is ready to stand from a seated position, the hips are free to move in the sagittal plane, while the knee clutches are disengaged, allowing only for extension. During the sit-to-stand motion, the knee acts as a ratchet

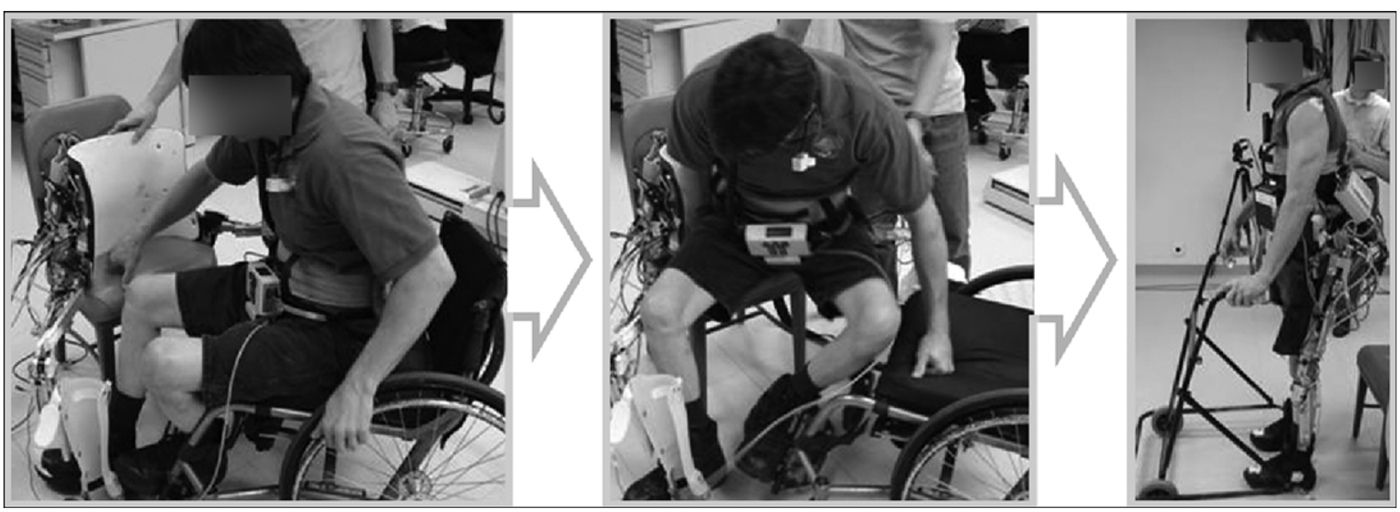

Figure 3.
Subject donning hybrid neuroprosthesis.

mechanism to provide resistance against knee flexion. The user is driven to a standing position through a combination of FES of trunk, hip, and knee extensors and upper-limb effort against a walking aid. Calibration of all sensors occurs automatically as soon as the user has achieved quiet standing. Sitting is accomplished by freeing both the hips and knees, allowing users to lower themselves down by gradually ramping down the stimulation.

To appropriately modulate the constraints of the VCHM for postural control during walking, we developed a finite-state postural controller (FSPC) [56]. The FSPC modulates the state of the hip constraints based on sensor information (**Figure 4**). FSRs, placed under each foot to record foot-ground contact, are employed to discriminate among double-stance, single-stance, and swing phases of the gait cycle. During the double-stance phases of gait, the hips are coupled to prevent bilateral hip flexion. During single stance, the stance hip is free to extend.

Any single-stance hip flexion (forward trunk tilt) is prevented by the postural controller using velocity and pressure feedback to unidirectionally lock the hip only against flexion while allowing hip extension. Unidirectional locking of the VCHM is controlled by the hip angular velocity calculated from cylinder position and the instantaneous rod-side cylinder pressure. Once the hip flexion angular velocity exceeds a threshold value, ω_{lock}, it causes the ipsilateral rod side valve to close. Thus, the hip is prevented from flexing, causing the hip angular velocity to drop below ω_{lock}. However, the initially imposed hip flexion torque on the VCHM will cause the rod-side cylinder pressure to increase above a pressure threshold, p_1, keeping the valve closed and maintaining the hip locked against flexion. When the rod cylinder pressure decreases below a second pressure threshold value, p_2, because of the reduction of user hip flexion torque, the rod-side valve will open, allowing for free hip extension. The postural controller uses two pressure thresholds because the pressure threshold to close the valve (p_1) must be relatively small to facilitate a quick response while the pressure threshold to open the valve (p_2) must be relatively large with respect to p_1 to prevent the hip from extending against an impedance due to a pressure differential between the rod and cap side of the cylinder.

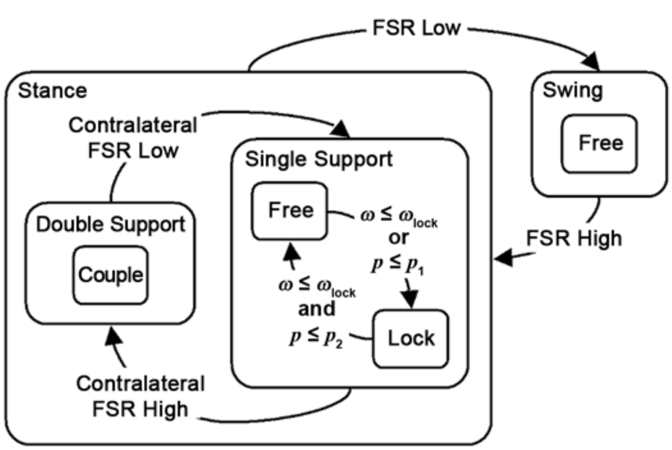

Figure 4.
Finite-state postural controller. Insole-mounted force-sensing resistors (FSRs) determine current gait period. During swing, hip is free. Hip locked from flexing but still free to extend by hip angular velocity and pressure feedback during single support. Hips are reciprocally coupled at double support. ω_{lock} = angular velocity threshold, p_1 and p_2 = cylinder pressure thresholds for respectively locking and unlocking variable constraint hip mechanism.

The FSPC allows the user to ambulate up and down stairs with the same postural control algorithm as level-ground walking. Thus, the user only has to select the preprogrammed stimulation pattern for functions such as walking or going up or down stairs, and the postural controller maintains his or her posture while allowing for movements generated by FES to achieve the necessary range of hip and knee motion to accomplish the task.

The knee mechanism is locked against flexion during the stance phases and freed during the swing phases of gait. The control algorithm was designed to stabilize the stance knee, minimizing the amount of stimulation to the knee extensors. This stabilization allows the mechanical orthosis to be self-supporting during the entire gait cycle, preventing the user from bearing the additional weight of the device.

A finite state machine was developed to determine the occurrence of stance and swing during the gait cycle to control the knee constraint. Feedback signals from the latching solenoid optical switches and FSRs are used to verify that the stance knee is locked against flexion and the swing leg is freed. Three conditions need to be met for the knee in flexion to be freed: (1) the contralateral optical switch is high, indicating that the solenoid plunger is completely unlatched and the contralateral knee is locked against flexion; (2) any of the contralateral FSRs are high, indicating weight bearing; and (3) the ipsilateral heel FSR is low, indicating that heel-off has occurred and the ipsilateral limb is about to move into the swing phase. The first two conditions indicate that the contralateral limb is in stance phase and supporting the user, while the third indicates the transition from double- to single-limb support.

The HNP was designed to require no power during quiet standing because (1) no FES-induced muscular contractions are required as a result of the constraints provided by the mechanical orthosis and (2) the VCHM and the knee mechanisms require no power when the hips are reciprocally coupled and the clutches are disengaged, thus stabilizing the hips and knees, respectively. This conserves electrical and biological energy while both extending battery life and avoiding muscular fatigue.

Custom-designed circuitry was made for powering, controlling, and driving the mechanical orthosis and for providing signal conditioning for the sensors. A Sony 47.5 Wh (6,600 mAh) NP-F970 7.2–8.4-V lithium ion battery powers the VCHM solenoid valves as well as the knee mechanism latching solenoids through a 12-Vdc/dc converter. The sensors and associated processing circuitry consume a total current of approximately 110 mA and are currently powered in the laboratory by a 14 V rack-mounted isolated power supply.

The battery voltages of the ECUs for the FES system and for the bracing system are monitored by comparator circuits, which generate an audio signal when the voltage drops below 6.9 V. Testing has shown that the batteries continue to function down to approximately 5.6 V. An audio signal notifies the user when the battery voltage drops to 6.9 V, providing the user sufficient time to reach a safe location where the battery can be replaced or recharged. Furthermore, power loss causes the operation of the VCHM to default to reciprocally couple the hips with a standard 1:1 coupling as in a conventional RGO. The knee joints remain locked against flexion with wrap-spring clutches to prevent collapse. Therefore, users can safely ambulate as they would with an RGO and stand without upper-body exertion on a walking aid in the event of catastrophic power failure.

Bench Testing

We performed bench tests to measure passive resistance of the VCHM and to determine thresholds for the FSPC [55–56]. The passive resistance was a measure of torque necessary to drive the hip at various angular velocities representative of paraplegic gait with the hips coupled or free to move independently. The movement was controlled with a dynamometer (Biodex Medical Systems; Shirley, New York).

Similarly, we determined postural controller threshold values of the angular velocity (ω_{lock}) and cylinder pressures (p_1 and p_2) during bench testing of the VCHM using the dynamometer to simulate hip dynamics during gait. Three trials were conducted for each threshold value. We chose values for ω_{lock} and p_2 to minimize hip flexion angle and the dynamometer-applied extension moment, respectively. Even if the VCHM is uncoupled (both hips are independently free), movement of one HRA can influence the pressure measured on the contralateral HRA, because the VCHM is a closed hydraulic system. As a result, flexion of the contralateral swing hip can cause accidental locking of the stance hip. We determined the value of p_1 to prevent this effect. With the VCHM uncoupled, the hip joint was actuated at various flexion angular velocities by the dynamometer while we measured the pressure of the contralateral cylinder.

Nondisabled Subject Testing

Two nondisabled subjects were recruited and signed an informed consent form approved by the Louis Stokes Department of Veterans Affairs Medical Center Institutional Review Board (committee on human subjects' protection in research) prior to participation. Both subjects weighed approximately 70 kg.

The ability of the VCHM to safely support the user during unstable trunk movement was tested for the two modes of the postural controller: (1) single stance and (2) double stance. In both tests, the subjects were standing wearing THKAFO with the VCHM. In the first case, single stance was simulated with the subject in quiet stance and the FSRs in one foot insole disabled. The subjects were then instructed to forcibly tilt their trunk forward. In the second case, the subjects stood initially in quiet stance. The subjects were then instructed to step forward and forcibly tilt their trunk forward upon heel strike. We calculated the torque applied by the subject on the VCHM from the measured cylinder pressures.

To evaluate whether the postural and knee controllers can reliably modulate the constraints of the hip and knee over level ground walking as intended, we instructed the nondisabled subjects to walk with the exoskeleton at three different speeds: slow, preferred, and fast. For each speed, each subject walked 10 times across an 8 m walkway. We collected approximately three to four complete strides of data for each walk by using a 16-camera Vicon MX (Vicon; Oxford, United Kingdom) motion analysis system. Sagittal joint angles, cylinder pressures, foot-ground contact information, and valve and solenoid activity were measured. Since nondisabled gait is approximately periodic, we assumed the measured signals were invariant with respect to the same gait event among subsequent gait cycles. The gait cycle was divided into six gait events: loading response, mid-stance, terminal stance, preswing, initial swing, and late swing [57]. We automated gait event determination by using forefoot and heel contacts with the ground.

The hip and knee controllers were also evaluated for stair ascent. The controllers were designed such that no changes are required between level-ground walking and stair ascent. A trial consisted of a nondisabled subject walking up two steps with the FSPC and the knee controller and then descending two steps without the controllers with the constraints freed (controller development for stair descent has yet to be completed). Both subjects chose to ascend a stair step by first stepping up with the right limb, then raising the left limb to the same stair step as the right limb. The trial was repeated five times for each subject. The same signals were collected as in the level-ground walking trials.

Additional tests involved a nondisabled subject walking on a treadmill with the FSPC and knee controller active while power consumption of the system was measured.

SCI Subject Testing

Initial testing was conducted with one subject weighing 68 kg, who had paraplegia resulting from complete SCI (T7, American Spinal Injury Association A). The subject signed an informed consent form approved by the Louis Stokes Department of Veterans Affairs Medical Center Institutional Review Board prior to participation. The subject was implanted with a multichannel percutaneous intramuscular FNS system and had more than 17 years experience with the system for exercise and walking [22]. A user-specific set of muscle stimulation patterns, based on established rules for generating FES walking [12], was preprogrammed into the ECU. The stimulation pattern was tuned to a comfortable walking speed. Because the VCHM was designed to stabilize against extrinsic/intrinsic perturbation throughout the entire gait cycle, the FSPC did not need to be synchronized with FES. The knee constraint unlocking/locking was synchronized with the onset/offset of electrical stimulation. The knee controller used feedback signal from the muscle stimulator, which indicated the exact timing of the onset/offset of electrical stimulation to knee flexors/extensors. The torque applied on the VCHM was determined from cylinder pressure data and the knee constraint state was recorded.

RESULTS

The passive resistance of the VCHM was found to have a negligible effect on the movement of the hip joints. When the hips were uncoupled and independently free to move, the median resistive torques measured were less than 2 N·m at angular velocities below 45°/s and less than 5 N·m at angular velocities below 90°/s. When the hips were reciprocally coupled, the median resistive torque was less than 4 N·m and 6 N·m, respectively, for the low and high hip angular velocities. This amount of torque required to actuate the VCHM translates to less than 10 percent of the achievable hip torque generated by FES [12].

Bench testing for threshold values for the postural controller of the VCHM showed that the maximum noise inherent in the hip angular velocity control signal used for feedback in the FSPC was ±3°/s. To prevent the hip from accidentally locking at 0°/s, we had to determine a threshold that exceeded the maximum noise amplitude. The resulting hip-flexion angles at hip locking for ω_{lock} values between 4°/s and 10°/s were not statistically different (p = 0.08). Thus, a ω_{lock} value between 4°/s and 10°/s was found acceptable for the FSPC. Because the hip flexion angular velocity in paraplegia generally does not exceed 60°/s [58] and the changes in cylinder pressure were less than 5 psi at angular velocities up to 75°/s, p_1 values between 5 and 10 psi were found suitable for the FSPC. A hip-extension torque was required to unlock the VCHM for cylinder pressure p_2 values of less than 30 psi. Therefore, a p_2 value greater than 30 psi was found acceptable for the postural controller. However, the p_2 was limited to 70 psi, because at greater values the cylinder pressure did not exceed this threshold when the hip was locked, and the hip unlocked when the cylinder pressure dropped below the p_1 threshold, which required significantly greater extension moment to unlock the hip.

The nondisabled safety trials verified that the VCHM provided adequate support to the user during instances of trunk instability and confirmed that the VCHM and the knee mechanism both changed states as intended during gait. The mean ± standard deviation (SD) maximum torque applied to the VCHM in the single and double stance were 28 ± 9 N·m and 26 ± 11 N·m for Subject 1, and 20 ± 10 N·m and 24 ± 9 N·m for Subject 2, respectively. The maximum applied torque to the VCHM was 42 N·m.

Figure 5 shows the mean ± SD hip and knee angles with respect to percentage gait cycle of the right limb of nondisabled Subject 1 walking with the exoskeleton of the HNP. The vertical lines partition the gait cycle into six gait events [57]. The horizontal bars under the plot of hip angle indicate the average periods of hip coupling primarily during the loading response and preswing, which are the double-stance phases of the gait cycle. The hip locking against flexion during single stance for either limb is not shown, because its occurrence was not significant when averaged over multiple strides. The horizontal bar under the plot of knee angle indicates the average period when the knee was locked. An optical switch measured when each solenoid was completely latched/unlatched. However, the engagement (unlocked) and disengagement (locked) of a clutch does not require that the solenoid be completely latched and unlatched, respectively. The dark horizontal bars designate the period when the solenoids were completely unlatched while the lighter bars designate the transition period of each solenoid from latched to unlatched and vice versa. Locking of the knee generally occurred at the beginning of loading response, while unlocking occurred at mid-preswing.

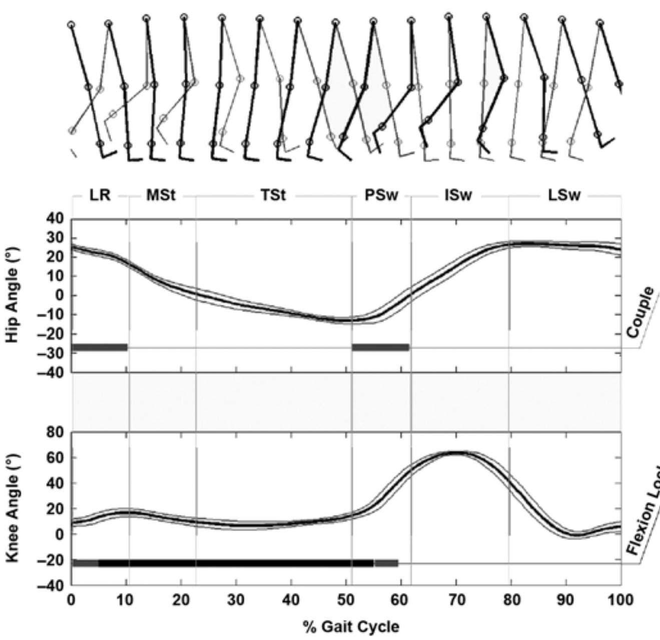

Figure 5.
Mean ± standard deviation hip and knee angles (°) with respect to percentage gait cycle during level ground walking. Horizontal bars below each curve indicate state of joint. ISw = initial swing, LR = loading response, LSw = late swing, MSt = midstance, PSw = preswing, TSt = terminal stance.

Typical mean ± SD gait parameters are shown in the **Table** for nondisabled Subject 1 walking at slow, preferred, and fast speeds with the prototype exoskeleton of the hybrid neuroprosthesis. An increase in speed is correlated with an increase in cadence, step length, and hip excursion (the angle between the hips at heel strike.)

Figure 6 shows the mean ± SD hip and knee angles of nondisabled Subject 2 ascending a stair step. The stair step cycle has been partitioned into three events: swing, double stance, and single stance, indicated by the vertical lines. Under the hip angle curves, the dark horizontal bars indicate the average instances when the left hip was locked against flexion. The lighter bar indicates when hips were coupled. Note that the instances of the right hip locking against flexion were not significant when averaged over multiple steps. The horizontal bars under the knee angle curves show the instances when each knee was locked against flexion (top row for left knee, bottom row for right knee).

In the SCI walking tests, similar to the nondisabled results, the subject applied an average torque of 23 ± 13 N·m on the VCHM, with the maximum torque of 41 N·m. **Figure 7** shows the mean ± SD knee angle and state of the knee constraint with respect to percentage gait cycle. The knee angle was relatively constant when the knee constraint was locked. Once the knee constraint was unlocked, the knee moved into flexion. The feedback sig-

Table.
Nondisabled subject gait parameters walking at slow, preferred, and fast speeds (data given as mean ± standard deviation).

Gait Speed (m/s)	Cadence (steps/min)	Step Length (m)	Hip Excursion (°)
0.50 ± 0.04	58 ± 6	0.51 ± 0.04	37 ± 2
0.90 ± 0.10	95 ± 7	0.55 ± 0.07	40 ± 4
1.10 ± 0.10	112 ± 6	0.60 ± 0.08	44 ± 5

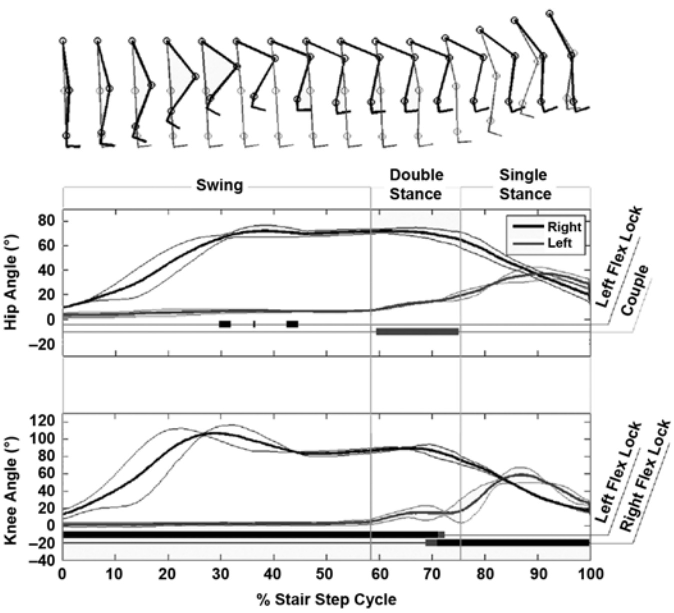

Figure 6.
Mean ± standard deviation hip and knee angles (°) during ascent of one stair step by nondisabled subject. Horizontal bars below each curve indicate state of joint. Flex = flexion.

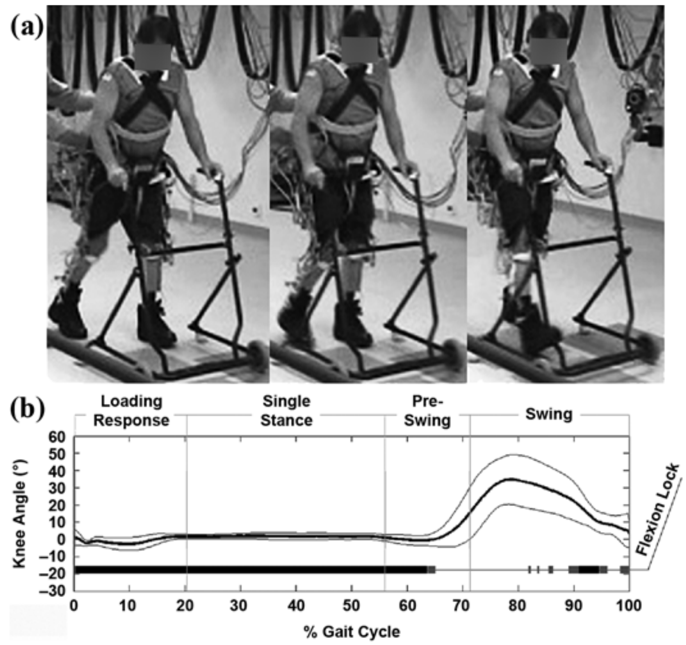

Figure 7.
(a) Subject with spinal cord injury walking with hybrid neuroprosthesis and **(b)** mean ± standard deviation knee angles (bottom) with respect to percentage gait cycle. Horizontal bars below each curve indicate state of joint.

nal from the muscle stimulator locked the knee mechanism against flexion prior to heel strike, preventing the knee from buckling at the heel strike.

Power consumption measured during walking was 11.2 W. Based on this measurement, the 47.5 Wh Sony NP-F970 battery can supply enough power to allow the subject to walk for more than 4 hours before replacing or recharging the battery.

DISCUSSION

An HNP, which combines an implanted FES system and an exoskeleton with a variable constraint coupling hip mechanism and controlled locking of the knees, has been evaluated and shown to be feasible for walking in paraplegia. The hydraulic mechanism of the VCHM provides minimal resistance to hip motion, measuring less than 10 percent of the moment produced by FES [12]. While this resistance may be more pronounced with continued use and muscle fatigue, efforts are under way to synchronize muscle stimulation with the operation of the exoskeleton so that the duty cycle of stimulation can be reduced to delay the onset of fatigue. Others have found substantial reduction in FES muscle effort through brace stabilization by locking the joints [25].

In a study by Dall et al., in which the hip torque applied to an RGO was determined during gait in individuals with paraplegia, a maximum torque of 35 N·m was obtained (subjects' body weight ranged between 54 and 84 kg) [59]. Cylinder pressure measurements in this study showed that the VCHM can constrain against hip flexion torques typical during walking between 20 and 30 N·m and against torques up to 42 N·m during perturbations without failure. Thus, the VCHM was demonstrated to safely provide the needed postural support to a user with paraplegia during gait.

The postural support against stance hip flexion was provided by the FSPC, which monitored angular velocity and cylinder pressure of the stance hip and locked the hip when it was flexing while allowing corrections into extension. This locking was quick and smooth, and no jerky motions were observed (**Figure 5**) or reported by the users. While immediate corrections in the current system are done by the user's upper limbs, a muscle controller is under development that will provide correctional forces through FES activation of hip and trunk extensors as soon as hip locking against flexion occurs. Decoupling of the hips during swing phase of gait allows uninhibited hip flexion during swing to modulate step length with the speed of walking as shown in the **Table**. Previous studies have shown that increasing the coupling ratio of the RGO to favor flexion significantly improved walking [46]. Similarly, studies in which SCI subjects used FES with an RGO, the step length was significantly increased with decoupled reciprocator but at the expense of significant forward trunk lean [41]. This study shows that the VCHM allows variable step lengths facilitated by changes in the range in hip motion while preventing stance hip flexion.

This FSPC has been tested during stair ascent in nondisabled individuals and found to provide resistance to postural instability, while the VCHM provides sufficient range of hip motion to negotiate stairs (**Figure 6**). The FSPC is the same for walking and for ascending stairs, so the SCI user only needs to select the appropriate stimulation pattern from the menu of choices.

Because this is a feasibility study, the requirements for system size, weight, and cosmesis for a practical system were compromised in favor of cost effectiveness by using off-the-shelf components and low-cost material in the construction of the mechanical components of the bracing. As a result, the ease of sit-to-stand motion and climbing stairs was compromised because of excess weight. The weight of the VCHM is partially borne by the subject when the stance knee is in flexion. When the knees are locked, the brace components of the HNP support their own weight. The influence of inertial forces on the user has been minimized by localizing components of the VCHM to as close to the axis of the sagittal hip rotation as possible. In the future, reducing the weight of the prototype through customization of components using materials with higher strength-to-weight ratios will alleviate upper-body effort during sit-to-stand and stair climbing.

Work is currently in progress to synchronize brace operation with the automatic modulation of muscle stimulation patterns. To achieve this, the controller for the HNP will ultimately consist of the three modules shown in **Figure 1**: (1) a module to control the constraints of the mechanical orthosis (as described here), (2) a module to adjust electrical simulation to target muscles, and (3) a module to synchronize mechanical orthosis operation with muscle stimulation.

For neuroprosthetic systems to be practical solutions for ambulation, the muscle stimulation patterns must adapt to the changing muscle properties during gait to increase walking duration and distance. The design of the FES controller must account for the muscle recruitment duration necessary to achieve the desired force output. Because of the relatively long response times of the paralyzed muscle, correcting for gait deviations as they occur is currently impractical with FES. However, performing corrections to the next gait cycle based on deviations detected in the current cycle is feasible [60–62]. By knowing the gait event times, one can assess the joint trajectories of the current gait cycle and, if necessary, modify them in the next gait cycle by altering the muscle stimulation patterns appropriately. Extensive work has gone into developing GEDs for controlling FES walking systems. Heuristic approaches [63–66], machining learning [67–71], and soft computing techniques [72–73] have been employed to define the rule base for such state machines.

A GED that is being developed for the HNP incorporates a dual-layer control algorithm consisting of (1) a fuzzy inference system to estimate the gait events and (2) a supervisory rule set to refine the gait event estimates [70,74]. Sensors measuring the sagittal hip, knee, and ankle angle and the foot-ground contact pressures of the forefoot and heel of each foot will provide the information for gait event detection. Both joint angle and foot-ground contact pressure have been shown to contain adequate information for gait event detection [73–74]. Along with modulating FES patterns, the gait event times will also be employed as feedback signals for the FSPC and knee controller, thus synchronizing the mechanical constraints with changing FES patterns.

CONCLUSIONS

HNPs that combine the advantages of advanced orthoses and electrical stimulation to allow individuals with paraplegia to stand, walk, and ascend/descend stairs are feasible and can be realized with off-the-shelf components to meet a majority of the preliminary design constraints. New orthotic components, including a variable constraint hip mechanism, were designed, prototyped, and successfully tested on nondisabled volunteers and an individual with SCI. The default, fail-safe mode of operation of the variable constraint hip mechanism is identical to that of a conventional RGO that couples hip flexion to contralateral hip extension in a 1:1 ratio. The hydraulic mechanism and control maintain erect posture while allowing free movement for walking and stair climbing. Because the hybrid was built from off-the-shelf components to minimize development costs, weight and cosmesis specifications for clinical use have not been met, although the power requirements are low enough to provide more than 4 hours of continuous operation with two standard camcorder batteries. Further refinement of the mechanism, as well as additional orthotic components for the trunk, knees, and ankles, remain to be completed before the hybrid approach of combining orthotic and electrical interventions can be practical clinical options for persons with SCI.

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