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Finite State Control of a Variable Impedance Hybrid Neuroprosthesis for Locomotion after Paralysis

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Abstract

We have previously reported on a novel variable impedance knee mechanism (VIKM). The VIKM was designed as a component of a hybrid neuroprosthesis to regulate knee flexion. The hybrid neuroprosthesis is a device that uses a controllable brace to support the body against collapse while stimulation provides power for movement. The hybrid neuroprosthesis requires a control system to coordinate the actions of the VIKM with the stimulation system; the development and evaluation of such a controller is presented. Brace mounted sensors and a baseline open loop stimulation pattern are utilized as control signals to activate the VIKM during stance phase while simultaneously modulating muscle stimulation in an on-off fashion. The objective is twofold: reduce the amount of stimulation necessary for walking while simultaneously restoring more biologically correct knee motion during stance using the VIKM. Custom designed hardware and software components were developed for controller implementation. The VIKM hybrid neuroprosthesis (VIKM-HNP) was evaluated during walking in one participant with thoracic level spinal cord injury. In comparison to walking with functional neuromuscular stimulation (FNS) alone, the VIKM-HNP restored near normal stance phase knee flexion during loading response and pre-swing phases while decreasing knee extensor stimulation by up to 40%.

Index Terms

Functional neuromuscular stimulation (FNS); Hybrid neuroprosthesis (HNP); Controllable Orthosis; Spinal Cord Injury; Gait

I. INTRODUCTION

Functional neuromuscular stimulation (FNS) is a technique for restoring function to individuals with paralysis after a spinal cord injury (SCI) [1]. Significant research has been conducted on the use of FNS to restore walking to individuals with paraplegia from SCI [2], [3]. Most of these systems utilize an open-loop control system with a smaller number of stimulation channels than lower extremity degrees of freedom resulting in gait composed of unnatural trajectories during swing and a stiff leg during stance. The lack of a closed loop feedback system prevents online adjustment of stimulation during walking, which can result in higher levels of stimulation than are necessary and suboptimal timing of stimulation, both of which can contribute to fatigue of the lower extremity muscles.

The hybrid neuroprosthesis (HNP) was first proposed in the early 1970s [4] with the concept being to control anatomical joints internally by means of FNS or externally using a 3-state joint actuator incorporated onto an exoskeletal brace. The objective was to minimize the need for external power and reduce muscle fatigue. The HNP field has since been further developed and is reviewed in numerous publications [2], [5]-[7]. HNPs merge FNS with controllable lower extremity bracing to leverage advantages and minimize shortcomings of each independent approach. Specifically, bracing provides support against collapse and restricts motion to the plane of progression, while FNS activates muscles to swing the limbs and propel the body forward. The first HNP systems combined FNS with knee-ankle-foot orthoses to provide body weight support during stance while using stimulation for swing [8], [9]. Another common approach used FNS to drive a reciprocating gait orthosis to provide gait to individuals with paraplegia, enabling users to walk further than with either FNS-only or brace-only systems [10]. Locking lower extremity joints provides the opportunity to support the body against collapse while reducing stimulation duty cycle; indeed this has remained central objective of most HNPs [2], [5]-[7]. Significant effort has been dedicated toward the development of a controllable knee mechanism which can support the knee during stance and allow unencumbered movement during swing [11], [12]. Other devices have focused on improving the swing phase motion of the limbs through trajectory shaping, joint coupling, energy storage and transfer, and/or powered assistance [5], [13]-[18]. Despite these advances, hybrid systems still lock the knee joint during stance phase to support body weight. However, considerable evidence suggests that it may be advantageous to allow some degree of knee motion during stance. Intelligent prosthetics which incorporate this capability are shown to offer some benefit over prosthetic knees which simply lock the knee during stance [19], [20].

We hypothesize that integration of a mechanism to regulate stance phase knee flexion in a HNP can improve the functionality of gait in individuals with SCI. Potential benefits of a more biologically correct stance knee flexion include reduced force and prevention of knee hyperextension at impact, maintenance of forward progression throughout stance, and reduction of hip power required during pre-swing for toe clearance during swing. In normal walking, stance knee flexion is regulated by eccentric contractions of knee extensor muscles. However, lengthening contractions which allow knee flexion during walking are difficult to control with FNS and increase the potential risk of falls or other injuries to system users. Incorporation of a mechanism which can permit and regulate knee flexion during stance phase without FNS should enable more natural and efficient gait while reducing stimulation duty cycle and delaying muscle fatigue.

We have previously reported the design and testing of a variable impedance knee mechanism (VIKM) composed of a four bar linkage with a magnetorheological damper [21]. The VIKM provides up to 65 Nm of torque to resist knee motion, with passive resistance less than 4 Nm and a response time of 35 ms. The VIKM can lock the knee joint to prevent

motion and can regulate knee flexion while supporting the body against collapse during stance. The control system presented here incorporates the VIKM into a new type of hybrid neuroprosthesis that supports the knee against collapse during stance while also restoring a more normal knee motion during this phase. The resulting system will reduce stimulation duty cycle of knee extensors compared to FNS-only by eliminating the need for muscles to support the knee against collapse under body weight, and restore stance phase knee flexion during loading response and pre-swing phases.

II. CONTROL SYSTEM DESIGN

Commercially available FNS systems restore walking function using an open-loop control system that appropriately coordinates muscle actions via a preprogrammed stimulation pattern (the baseline pattern) [22]. Muscle response to stimulation is influenced by many factors including muscle spasticity, reflexes, fatigue, residual strength and conditioning, and thus, response to stimulation is non-linear, time-variant, and unpredictable [3, 23]. Consequently, many groups have investigated a wide range of closed loop control strategies to improve FNS [22, 24, 25]. While many of these strategies have shown promise in control of single joint actions, rule-based hierarchical controllers – or finite state machines – remain the dominant control system for restoring walking with FNS and hybrid systems due to their accuracy and safety [26].

Previous studies have shown the viability of utilizing finite state machines to restore walking using both FNS and hybrid systems [13, 24, 26–30]. These systems utilize an external sensor set to monitor lower extremity joint angles and foot contact for reliable and repeatable identification of gait phase. Finite state machines have also been employed to control lower extremity prostheses [31].

The finite state approach is advantageous for the control of FNS and passive hybrid orthoses because limb trajectory and timing of gait events can vary based on muscle response to stimulation. Classifying FNS driven walking into states based on the gait events adds robustness and consistency to an inherently variable process, and facilitates implementation of phase appropriate controllers. The hierarchical nature of these controllers allow for implementation of lower level controllers within each state for control of exoskeleton and stimulation.

Here, we present the design of a finite state machine that divides FNS-driven gait into discrete phases for feedback control to modulate stimulation and activate the VIKM to control knee motion during gait. There are three objectives. The first is to synchronize VIKM operation with FNS activity dictated by the baseline pattern. The second is to modulate the baseline FNS pattern in real-time to turn stimulation of target muscles off when the VIKM is active. The third is to adjust the VIKM resistance to shape the knee motion based on the gait phase. More specifically, the goal is to activate the VIKM to control knee flexion during loading response and pre-swing phases, and to lock the knee during terminal stance (Fig. 1). The VIKM is inactive during mid-stance and swing, when FNS controls knee motion. The control system of the VIKM-HNP has three modules which run in parallel to achieve these objectives: the FNS controller, the VIKM-HNP finite state machine, the VIKM torque controller.

A. FNS Controller

The FNS controller drives limb motion to facilitate standing and walking by coordinating application of stimulus pulses to multiple muscles according to a pre-programmed, task specific stimulation pattern [3], [23]. Force of electrically elicited muscle contraction is modulated by stimulation pulse width (μ s) and frequency (Hz). The response to stimulation

depends on muscle fiber population, fatigue and relaxation properties. Joint torques produced by stimulation vary widely between and within subjects and depend on numerous factors such as electrode placement relative to the target nerve, subject muscle strength and conditioning, and passive limb properties. As such, the stimulation pattern was customized for each individual using a rule-based tuning algorithm [3].

The user interface for the FNS controller consisted of a two button finger switch worn on the thumb and an LCD display on the stimulation control unit worn around the waist. From the seated position, the user stood by pressing the GO button to activate a pre-programmed standing pattern that extended the knees and hips. Once upright the user initiated walking by pressing the GO button again; electrical stimulation was then delivered according to the baseline pattern (Fig. 2a) to facilitate walking. The speed of gait was adjusted by scaling the pattern relative to the gait cycle. Walking was automated: each successive step was initiated automatically at the conclusion of the previous step. When the user pressed the STOP button, the current step was completed and stimulation of hip and knee extensors was held constant to resume standing. At this point, the user could press GO to continue walking, or STOP to initiate a sitting pattern.

Four supervisory control signals (2 per limb) derived from the stimulation pattern were used by the finite state machine (Fig. 2b): one signal corresponded to swing phase, and one indicated the pre-swing phase. The use of these signals is discussed in more detail below.

B. VIKM-HNP Finite State Machine

In normal walking a gait cycle is divided into eight distinct phases, five comprising stance and three for swing [32]. Because the VIKM only exerted control over the knee, the gait cycle was split into five phases based on knee behavior (Fig. 1). The first phase was loading response which began at foot contact and involved rapid knee flexion for shock absorption and preservation of forward progression. The second phase was mid-stance, a period of knee extension for forward progression. The third was terminal stance, during which knee extension was maintained for stable weight bearing. The fourth phase was pre-swing, which involved knee flexion as the limb was unloading in preparation for toe-off. The fifth and final phase was swing during which the foot remained off the ground as the knee flexed and extended to advance the limb.

The distinct knee behavior during these phases suggested that a finite state machine could be implemented to control the VIKM during walking. The VIKM-HNP finite state machine utilized sensors mounted on the brace (knee angle) and under the feet (heel and toe ground contact) to classify the gait cycle into 5 discrete states (Fig. 1). The VIKM controlled knee flexion during stance only; therefore, swing is designated as one state during which the VIKM damper remains off and the baseline FNS stimulation remains on. Stance was divided into four states – corresponding to the four phases described above – for control purposes: loading response, mid-stance, terminal stance, and pre-swing.

The VIKM-HNP finite state machine transitioned between states using feedback from the sensors and from the FNS controller. State transitions were based on knee angle and angular velocity thresholds (Table 1). Nominal thresholds for knee angle were based on previously published values for normal walking [32, 33]. The nominal thresholds were tuned for the subject during one session of walking with the VIKM-HNP (Table 1). The conditions for state transitions based on knee angle thresholds were robust and did not vary with fatigue (i.e. FNS driven knee extension during terminal swing was very repeatable, as was FNS driven extension during mid-stance). Furthermore, thresholds 4 and 5 were used in supervisory rules to assure safety by activating the damper if they were exceeded. Thus, tuned threshold values remained constant for all data collection sessions.

The conceptual operation proceeded as follows. State 1 (loading response) began when either the ipsilateral knee extended beyond Threshold 1 (Table 1) or the ipsilateral foot contacted the ground. During State 1, the VIKM damper was activated to absorb the shock of impact and accept body weight onto the stance limb. Simultaneously, the VIKM-HNP controller modified the baseline FNS pattern in real time by turning off knee extensor stimulation. The controller transitioned to State 2 (mid-stance) if knee flexion passed Threshold 2 (Table 1) or the contralateral foot came off the ground. During mid-stance, knee extensor stimulation was restored while the VIKM damper was deactivated. The damper remained off unless knee extension velocity fell below Threshold 3 (Table 1), in which case the VIKM was activated to prevent knee collapse. When the knee reached near full extension by crossing Threshold 1 (Table 1) the damper was reactivated while FNS of the knee extensors was simultaneously deactivated as the controller moved to State 3 (terminal stance). The transition to State 4 (pre-swing) was subject to supervisory control derived from the stimulation pattern. A pre-swing feedback signal (LPsw or RPsw, Fig. 2b) was high (1) for pre-defined period (approximately 10% of the gait cycle) before the onset of knee flexor stimulation and was then returned to low (0) after flexor onset. The transition to pre-swing required both contralateral foot contact and the pre-swing feedback signal to be high. During pre-swing, knee extensor stimulation remained off. The damper was initially turned off to allow passive knee flexion. If knee flexion exceeded Threshold 4 or Threshold 5 (Table 1), the damper was activated and knee extensor stimulation was resumed. Once the ipsilateral foot left the ground, the damper was turned off and stimulation returned to the baseline pattern to allow unencumbered knee motion during swing, after which the cycle repeats. The damper actively regulated stance flexion during States 1, 3, and 4 using the VIKM torque controller which is described in the next section.

Several supervisory rules governed behavior of the VIKM-HNP finite state machine and provided robustness in assuring timely transition of states. The first rule required the VIKM damper be active prior to turning off knee extensor stimulation. The second rule required knee angle to remain sufficiently extended during all periods of stance when knee extensor stimulation was off. If the knee flexed beyond the appropriate threshold (Table 1) the VIKM was activated at maximum level to ensure safety against collapse.

The third, fourth, and fifth rules utilized feedback from the FNS controller to assure correct transition between states (Fig. 2b & 2c). A feedback signal corresponding to swing phase of each limb (LSw & RSw) turns high (from 0 to 1) when hip and knee flexors of that limb become fully active. Rule 3 mandated transition of the corresponding limb to swing phase – if not previously achieved – based on this signal. Similarly, Rule 4 mandated transition of the contralateral limb to mid-stance phase based on this signal. Rule 5 required the swing feedback signal (LSw or RSw) to transition back to low (1 to 0) before loading response can occur; this prevented the VIKM damper from activating during early swing should the foot not clear the floor. Together, Rules 3–5 guaranteed progressive transition through the controller states based on the FNS pattern.

C. Torque Controller

During states when the VIKM damper regulated knee flexion, a proportional controller was employed to adjust the VIKM resistance based on angular velocity. The VIKM contains a magnetorheological (MR) fluid damper to provide variable resistance that is proportional to supplied current. A pulse width modulation scheme was utilized to control the activation level of the damper. The damper was connected to a boosted 12 V power supply through a MOSFET with its gate driven by an 800 Hz signal. An onboard microcontroller sets the duty cycle of the driving signal based on the output from the proportional controller through three digital signals for each damper providing seven discrete levels of resistance (Table 2). We refer to the duty cycle of the gate driving signal as the damper activation level. Digital

signals were used to control the damper because they were less sensitive to noise and easier to isolate than analog control signals. The digital signals resulted in discrete levels of torque (Table 2). The chosen duty cycle values achieved sufficient torque bandwidth and resolution to control knee motion during stance while balancing power consumption limitations. The torque controller operated in three different modes for loading response, terminal stance, and pre-swing. During loading response, controlled flexion is maintained up to Threshold 2 (Table 1). During the first step the damper was activated at the lowest damping level (8% activation) in loading response. However, the damping level was increased if the knee flexion velocity exceeded Threshold 5 (Table 1). If at any point during loading response the knee flexed beyond Threshold 2, the damping level was increased to maximum activation (51%) to prevent further knee flexion. In terminal stance phase the knee was locked in full extension to provide support against collapse. During this state, the damper was activated at maximal resistance (51%) to provide stability.

Control of the VIKM during pre-swing was similar to loading response. Knee flexion during this phase is predominantly passive because weight bearing has been reduced substantially and transferred to the contralateral limb [3]. Thus, the MR damper was initially inactive during pre-swing phase to allow knee flexion regulated by its passive viscoelastic properties. However, if knee flexion velocity exceeded Threshold 5, the damper was activated and stimulation was returned to baseline levels. If the knee angle exceeded Threshold 4 prior to swing – indicating collapse – the damper was activated at maximum level.

III. CONTROL SYSTEM VALIDATION

A. Implementation

The VIKM-HNP control system was implemented and evaluated on a prototype VIKM hybrid neuroprosthesis (Fig. 3). The lower extremity brace was a modified reciprocating gait orthosis (RGO) with the hip reciprocator disengaged, knee drop locks replaced by the four-bar linkage and damper mounted across the knee (the VIKM [21]), and ankles locked in neutral position by ankle-foot orthosis (AFOs). A sensor set and associated electronics for powering the sensors and the VIKM dampers were mounted on the brace. A percutaneous stimulation system was used for application of FNS, and an xPC Target based computer interface (The Mathworks, Inc., Natick, MA) was used for real-time control and data collection.

The finite state machine uses signals collected from sensors mounted on the orthosis to determine gait phase. Because of the four bar linkage at the knee joint, the linear displacement of the damper piston within the VIKM was used to monitor knee angle. Piston displacement was measured by linear potentiometers (ALPS Electric, Campbell, California USA). The piston displacement was mapped to knee angle using the linkage rotary-to-linear transmission ratio (0.47 mm/deg). The linear potentiometers were found to provide a more reliable measure of knee angle than accelerometers [34]. Angular velocity was obtained by numeric differentiation of knee angle. Force sensitive resistors (FSRs) (B&L Engineering, Tustin, CA USA) were used to measure foot-ground contact by placing them under the big toe, the distal end of the first and fifth metatarsals, and the heel. FSRs were mounted within the shoe insole under the foot plate of the AFO. The signals from the three forefoot FSRs were summed to a single signal representing the forefoot. The outputs of the forefoot and heel FSRs were normalized by their value during standing. Foot contact was then sensed when the output of either forefoot or heel was above 90% of this value.

The VIKM-HNP controller was implemented in the xPC Target environment on two personal computers (PCs). The target PC ran an xPC target kernel to collect sensor signals and to issue commands to control the VIKM orthosis and stimulation subsystems. The host

PC was a Windows® machine running a Matlab® based Simulink® graphical user interface (GUI) to monitor the target application via TCP/IP protocol. The custom designed GUI was an integral part of the VIKM-HNP control system architecture which allowed an operator to adjust thresholds, calibrate sensors, and control the VIKM and stimulation unit in real time. Use of the VIKM-HNP was initiated by pressing the 'Start' button on the GUI which activated the user's finger switch and LCD interface described above.

The hybrid system circuitry consisted of a custom designed circuit board which provided power and signal conditioning for the sensors used in the VIKM-HNP. The sensors were powered by a rechargeable Sony NP-F970 lithium ion battery. A custom DC/DC converter boosted the battery voltage to 12 V. The sensor signals passed through analog isolation prior to sampling by the target PC at a frequency of 200 Hz. The signals were low-pass filtered using 5th-order Butterworth filters with cutoff frequencies of 10 Hz for the potentiometers and 20 Hz for the FSRs.

Custom designed drive circuitry powered the dampers of the VIKM at the levels shown in Table 2. One rechargeable Sony NP-F570 lithium ion battery powered each VIKM. The drive circuit utilized a MSP430 series microcontroller (Texas Instruments, Dallas, TX) to generate an 800 Hz pulse width modulated drive signal for each damper within the VIKM. The duty cycles (pulse widths) of these drive signals are adjusted based on the states of six digital inputs (three for each damper) received from the xPC target computer (Table 2). The battery charge levels were monitored to assure proper VIKM function. All digital signals were isolated with optocouplers to ensure electrical safety.

The VIKM-HNP utilized a Universal External Control Unit (UECU) for stimulation and user interface [35]. The UECU contained 2 stimulation boards, each with 12 cathodic channels and 1 anode (ground) enabling up to 24 channels of stimulation. The stimulus waveforms were constant current, biphasic charge balanced pulse trains characterized by three parameters: pulse width (PW), frequency or inter-pulse interval (IPI – the inverse of frequency), and current amplitude. In this application, stimulus amplitude was set at constant 20 mA for each channel and PW was limited to 250 μ s for safety with stainless steel intramuscular stimulating electrodes [36]. The baseline pattern for walking was tuned by adjusting PW and IPI values. Due to software limitations only two stimulation frequencies were used in the baseline pattern. IPI of 60 ms (16.7 Hz) was used for most of the pattern to minimize fatigue and IPI of 30 ms (33.3 Hz) was used when additional force was needed (Fig. 2) [3].

The UECU was worn on a belt around the waist. A finger switch connected to the UECU enabled the user to navigate through menus of options visible on an LCD display. The UECU communicated with the xPC target computer serially at 33.3 Hz through an isolation unit. Stimulation parameters were delivered and inputs from the finger switch were collected with a custom designed Simulink® toolkit [35].

B. Validation in an Able Bodied Individual

The finite state machine and VIKM function were evaluated during walking with one able bodied individual over two sessions [37]. The purpose of the able bodied testing was to verify that the controller could accurately determine gait phases and synchronize VIKM function during normal walking. There was no statistical difference in average cadence, gait speed, or step length during walking with the VIKM-HNP finite state machine active and walking with the VIKM off during the entire stride [37]. Thus, the VIKM-HNP control system was able to synchronize the activity of the VIKM without impeding walking motion.

IV. EVALUATION IN PARTICIPANTS WITH SCI

A. Study Participant

One individual with paraplegia was recruited to evaluate the prototype VIKM-HNP and was consented for participation in this research study. The participant was a male with a thoracic (T7) level SCI with complete loss of motor and sensory function below the level of injury. He was 50 years old (27 years post-injury), weighed 62.2 kg, and measured 1.74 m in height.

B. Stimulation System

The participant was previously implanted with a complete set of 16 chronically indwelling intramuscular electrodes with percutaneous leads in muscles controlling hip flexion (sartorius, tensor fasciae latae, gracilis) and extension (gluteus maximus, posterior portion of adductor magnus), knee flexion (sartorius, gracilis) and extension (vastus medialis, vastus intermedius, vastus lateralis, and quadriceps), and ankle dorsiflexion (tibialis anterior and peroneus longus) (Table 3). Single electrodes for knee extensors and ankle dorsiflexors recruited multiple muscles. The percutaneous leads were connected to the UECU to deliver stimulation as described above. The participant had extensive experience (more than 20 years) with exercise FNS walking with standby assist prior to enrolling in the study.

C. Experimental Setup

To compare walking with FNS-only (control case) to walking with the VIKM-HNP system (experimental case) the same baseline stimulation pattern was used. For the control case experiments, the participant walked using the preprogrammed baseline stimulation pattern (Fig. 2a) under open loop control. The user wore AFOs prescribed with his system to lock the ankle in a neutral position. Gait speed was adjusted by linear scaling of the pattern to the participant's preferred pace. Reflective markers were placed on bony landmarks of the lower extremity, trunk, and upper body [38] to monitor segment trajectories with the Vicon MX40 motion capture system during gait. All data were collected at a sampling frequency of 200 Hz.

During experimental case trials, the participant donned the prototype VIKM-HNP prior to walking by transferring from a wheelchair into a chair containing the brace. Leg uprights of the VIKM brace are adjustable [21] and were previously fit to the subject. Two straps across the chest and one strap below each knee secured the exoskeleton to the user. The total time to don the VIKM-HNP exoskeleton with assistance was approximately one minute. Although the HNP contained a trunk corset, the hips remained free to move under FNS control. Similar to the control case, the ankles were locked using AFOs. Walking speed was adjusted to comfortable levels by scaling the baseline pattern. Steps were initiated automatically with baseline stimulation pattern while the controller modulated stimulation to knee extensors and damping of VIKM to approximate normal knee trajectory during stance. To accommodate the brace, a modified set of 21 reflective markers was used to measure lower extremity kinematics [39]. Like the control case, motion capture and walker load cell data were collected at 200 Hz.

During each trial, the user walked approximately 8 meters at his preferred speed. A spotter remained close to the participant throughout walking to assure safety. All data were averaged ± 1 standard deviation with respect to percentage gait cycle, defined as heel strike to heel strike. The heel strikes were identified by local minimum of the heel markers in the vertical axis of the Vicon capture volume [40].

Data for FNS-only (control case) and for VIKM-HNP walking were collected over two sessions each for a total of 38 and 30 strides of data, respectively. The first two and last two steps of each trial were discarded to ensure only steady state walking was analyzed. A preliminary session of walking with the VIKM-HNP was used to tune the control system thresholds based on examination of kinematic data (Table 2) and to train the participant in walking with the system.

Data from walking with the VIKM-HNP were analyzed to validate the control system. Average VIKM damper activation level and knee extensor stimulation pulse width were computed over normalized the gait cycle. The effect of the VIKM-HNP on knee extensor activation was further quantified by computing the average muscle duty cycle with respect to stride. Muscle duty cycle is the duration of time muscle stimulation is active relative to the total duration of the stride. The percentage reduction was computed by dividing the value observed during VIKM-HNP gait with the value observed during FNS-only gait. For comparison across experimental and control conditions, a one way analysis of variance (ANOVA) with a 95% confidence interval ($p < 0.05$) was used to determine statistical significance.

D. Results

A noticeable increase in knee flexion was observed during loading response phase with the VIKM-HNP as compared to FNS-only walking (Fig. 4). This change in knee angle was accompanied by a reduction in knee extensor stimulation during stance. Fig. 5 shows the percent VIKM activation, knee extensor stimulation pulse width, and knee angle averaged over the normalized gait cycle for the left and right legs. For the left leg, the damper was active at low levels during the first 10% of the gait cycle while average knee extensor pulse width was much lower than baseline, resulting in knee flexion for loading response. As knee flexion exceeded Threshold 2 on the left limb (16°) the VIKM activation increased rapidly while knee extensor stimulation was activated. With the transition to mid-stance, the damper activation level decreased, on average, until threshold 1 was reached. At this point (40% GC, on average) transition to terminal stance occurred with high levels of damper activation without knee extensor stimulation. The damper remained active at a high level until pre-swing phase (55–70% GC) during which activation level decreased. The decreased damper activity coincided with reduced knee extensor stimulation, providing consistent knee flexion during pre-swing. After toe-off (70% GC), the left damper remained inactive during swing phase as knee extensor stimulation returned to baseline levels.

For the right leg, loading response was similar to the left. However, Threshold 2 (18°) was not reached and thus, the damper was active at low levels prior to mid-stance. During mid-stance (15–30% GC), knee extensors were stimulated while the damper remained active at moderate levels, on average. The moderate activation level of the damper during mid-stance for both limbs is an artifact from the averaging process because of the stride to stride variability of the percentage gait cycle at which Threshold 1 was reached. When Threshold 1 was reached the damper activation increased as knee extensor stimulation was turned off. Unlike the left leg, right knee extensors were activated during the later stages of pre-swing phase as the knee flexion exceeded Threshold 4 on many strides. Like the left leg, the damper remained off during swing.

The effect of the supervisory rules is evident during the gait cycle. A relatively high degree of variability, observed as relatively large values of standard deviation, was present in stimulus pulse width during loading response and pre-swing while the VIKM activation level had relatively low variability during these periods (Fig. 5). Conversely, the VIKM damper activation level was more variable during the mid-stance and terminal stance phases,

yet the stimulus pulse width was more consistent. The supervisory rules of the VIKM-HNP finite state machine were responsible for this behavior. The requirement for stimulation modulation was more conservative than those for VIKM activation (e.g., during loading response, the VIKM was activated when the FSR senses ground contact, regardless of knee angle; but the knee must be sufficiently extended for stimulation modulation to occur). Likewise, the supervisory rule requiring knee extensor stimulation to be active during mid-stance phase led to more consistency than the damper activation level during this phase, which was only decreased until the knee reached near full extension. The net result of these supervisory rules led to consistent knee function during stance phase.

The effect of the VIKM-HNP on knee extensor muscle stimulation is shown in Table 4. The muscle duty cycle of knee extensors was significantly decreased for both legs during walking with the VIKM-HNP compared to FNS-only. Knee extensor muscle stimulation duty cycle was reduced by approximately 40% for the left limb and 34% for the right limb. The right limb was prone to excessive knee flexion in pre-swing, which resulted in less deviation from baseline stimulation than on the left side.

V. DISCUSSION

The VIKM-HNP control system was designed to synchronize the VIKM orthosis with FNS driven limb motion during walking to restore stance phase flexion and reduce stimulation of knee extensors compared to FNS-only systems. The VIKM-HNP control system reduced duty cycle of knee extensors by turning off stimulation when the VIKM was active during loading response, terminal stance, and pre-swing phases. The VIKM resistance was reduced while knee extensor stimulation was on during mid-stance phase for knee extension. When the knee reached full extension after loading response (typically occurring between 30–45% of the gait cycle) the VIKM resistance increased to support the knee joint. This support is critical for stimulation to be turned off without knee collapse. Stimulation of knee extensors and activation of VIKM occurred during pre-swing only if knee flexion became excessive prior to toe-off. The net result of the VIKM activation - and coincident knee extensor stimulation deactivation - was a significant reduction in knee extensor stimulation duty cycle during VIKM-HNP walking compared to FNS-only.

The VIKM-HNP significantly altered the knee angle during gait compared to walking with FNS-only. The distinct presence of knee flexion during loading response was observed during the first 15% of the gait cycle while knee extensor stimulation was significantly reduced. This contrasts with the control case where the knee was slightly hyper-extended during early stance. No increase in knee extensor stimulation frequency was necessary during mid-stance phase, indicating the baseline stimulation was sufficient to extend the knee. Thus, the knee flexion during loading response did not require a compensatory stimulation increase in the following phase.

Successful performance of the controller required tuning of thresholds (Table 2) during one initial session of training with the VIKM-HNP. All pre-tuned thresholds remained constant during the experimental evaluation. Knee flexion during loading response and early mid-stance is controlled by the VIKM and Threshold 2, and thus is not susceptible to fatigue of stimulated muscle. Thresholds 1 and 3 govern transition to loading response and terminal stance phases (Fig. 1) and are dependent on stimulation of knee extensors. The thresholds were tuned to subject specific levels that were readily achieved during walking with the VIKM-HNP with emphasis on reaching a fully extended position for stance stability. The VIKM-HNP reduced stimulation demands on knee extensors by providing support against collapse during most of stance. As a result, we did not observe a decrease in the ability of stimulation to extend the knee to reach Thresholds 1 and 3 over the course of our

experiments. However, it is possible that fatigue of knee extensors would prevent Thresholds 1 and 3 from being reached after longer periods of walking. In this case, Threshold 2 could be lowered to ease stance knee extension requirements, or Threshold 1 and 3 could be increased to assure correct state transitions.

Thresholds 4 and 5 govern knee flexion during pre-swing phase. If these thresholds are exceeded, the VIKM and knee extensor stimulation are utilized to slow flexion and prevent collapse prior to toe-off. The thresholds were better tuned for the left leg, as controlled flexion during pre-swing with the VIKM-HNP stayed below thresholds 4 and 5, decreasing left knee extensor activity compared to FNS-only (Fig. 5b). The right limb thresholds were not as well tuned, resulting in higher average pulse width and VIKM activation during pre-swing compared to the left leg. In the future, Thresholds 4 and 5 should be decreased for this leg to allow better control of flexion by the VIKM, without the activation of knee extensors at the end of stance. Pre-swing knee flexion plays a crucial role in swing phase flexion and leg clearance [41], particularly in stiff knee gait similar to FNS driven walking [42]. Improved pre-swing control of knee trajectory by well-tuned VIKM-HNP has potential to enhance swing limb clearance and forward progression compared to stiff leg FNS-only walking.

Aside from a reduction in stimulation to knee extensors during stance phase, the baseline stimulation pattern (Fig. 2a) was used to drive walking with the VIKM-HNP. The ability to complete steps or maintain walking was not compromised with the VIKM orthosis. Thus, the additional weight of the orthosis did not inhibit FNS driven gait. The maximum damper activation level was 51.2% (47 Nm of torque) indicating a smaller, custom designed damper could be used in walking. The results from this study demonstrate a control framework capable of automatically regulating knee motion during stance phase of FNS-driven locomotion. This framework will be applied in the future to control knee flexion during stair descent, walking down ramps, and sitting down. Restoring these functions will expand the environment in which the HNP can be employed, which may increase user acceptance of such devices. Further study is required to characterize the supportive knee torque required in these activities before final torque bandwidth of the VIKM can be specified.

The participant's left leg knee flexors were much stronger than his right flexors, resulting in excessive left knee flexion (Fig. 5a). Left knee flexion was reduced during swing with the VIKM-HNP despite slightly increased knee flexion during pre-swing phase compared to FNS-only. This reduction did not affect foot-floor clearance during swing. The weight of the VIKM orthosis (3.5 kg per leg) likely decreased left leg swing phase knee flexion. Right knee flexors were weaker than left and peak swing knee angle and ground clearance were similar across conditions, despite the weight of the orthosis. This result suggests that VIKM-HNP controlled knee flexion during pre-swing phase aided swing limb clearance when flexor strength was compromised.

This study utilized an implanted stimulation system with percutaneous electrode leads for attachment to the stimulator [43]. This approach enabled control of hip and knee flexion and extension, and ankle dorsiflexion. While surface stimulation systems are effective for hip and knee extension, they are unable to activate muscle groups located deep below the skin surface, such as hip and/or knee flexors, which are critical to achieve walking. However, the VIKM augments knee motion during stance, and thus, the VIKM-HNP concept could be extended to use with a less invasive surface system whereby stepping is initiated using the withdrawal reflex [44].

The data presented here validate the VIKM control system design in a feasibility study with one subject. The VIKM-HNP restored a more normal knee flexion during early stance phase

and improved consistency of knee flexion during pre-swing phase through implementation of a finite state controller. In addition, the VIKM-HNP reduced stimulation duty cycle of knee extensors compared to walking with FNS-only, the limiting factor for walking time and distance with electric stimulation [45]. The VIKM-HNP can improve the functionality of FNS-only gait by regulating knee flexion during stance. Restoring this capability has potential to reduce loading on the limb during impact absorbance, place the limb in a biomechanically advantageous position at toe-off, and allow FNS walking over uneven terrains and down stairs. Future work will focus on quantifying the kinematic, kinetic, and energetic differences between walking with stimulation only systems and the VIKM-HNP. Furthermore, advanced control systems will be designed to evaluate the feasibility of utilizing the VIKM-HNP for knee control during stair descent and stand-to-sit maneuver, functions important in activities of daily living.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Fig. 1.

The five discrete states of the VIKM-HNP finite state machine. (a) The schematic indicates the damper state and knee position for the leading limb during each controller state. An open circle indicates the VIKM is off, a half-filled circle indicates the damper is active but allows flexion, and a black circle indicates the VIKM is active at a high level to prevent flexion. (b) A schematic of the VIKM-HNP finite state machine including knee extensor stimulation (on-off), VIKM activation level, and transitions between states. Note that FNS Psw feedback refers to the control signal generated from the stimulation pattern (see Fig. 2).

Fig. 2.

The FNS pattern and stimulation based feedback control signals for a right heel strike (RHS) to RHS gait cycle. Vertical bar indicates approximate left heel strike. (a) 16 channel baseline stimulation pattern for walking. Dark areas represent high frequency (33.3 Hz), light areas low (16.7 Hz). See Table 3 for abbreviations. (b) Feedback signals derived from the stimulation pattern used to aid in transition to pre-swing phase and to provide supervisory control of the VIKM-HNP finite state machine. (c) States of the VIKM finite state machine. LR is loading response, Mst is mid-stance, Psw is pre-swing.

Fig. 3.
Participant with SCI donning the prototype VIKM-HNP.

(a)

(b)

Fig. 4.
A comparison of loading response (leading limb) and pre-swing (trailing limb) phases during walking with (a) FNS-only and (b) VIKM-HNP.

Fig. 5.

The average (± 1 SD) (a) VIKM damper activation, (b) knee extensor pulse width, and (c) knee angle with respect to gait cycle for left and right limbs in walking with VIKM-HNP (solid) and FNS-only (dashed). Data is averaged over 30 and 38 strides for the VIKM-HNP and FNS-only conditions, respectively.

TABLE I

Nominal and experimentally tuned values of the VIKM-HNP controller thresholds

Threshold	Nominal Value	Tuned Value		Unit
		Left	Right	
1	3	5	5	°
2	15	16	18	°
3	-5	-6	-6	°/sec
4	40	40	40	°
5	180	180	180	°/sec

TABLE II

Power consumption and torque output of the VIKM dampers at each activation level

Damper Activation (%)	Average Power (W)	Average VIKM Torque Output^a (Nm)
0.0	0	2.5
8.0	0.38	10.3
17.6	1.15	19.8
24.8	2.15	26.4
32.0	3.46	32.6
39.2	5.04	38.4
51.2	8.45	47.2

^aTorque output was averaged over four trials at angular velocity of 90 °/sec.

TABLE III

Implanted muscle set for FNS driven walking

Channel	Side	Abbrev.	Muscle(s)	Primary action
0	L	Med/Lat	Vastus medialis / lateralis	Knee extension
1	L	Grac	Gracilis	Knee flexion
2	L	Quad	Quadriceps	Knee extension
3	L	P Add	Adductor magnus (posterior)	Hip extension
4	L	Gl Max	Gluteus maximus	Hip extension
5	L	Tensor	Tensor fasciae latae	Hip flexion
6	L	Sart	Sartorius	Hip flexion / knee flexion
7	L	TA/Per	Tibialis anterior	Ankle dorsiflexion
8	R	Int/Lat	Vastus intermedius / lateralis	Knee extension
9	R	Tensor	Tensor fasciae latae	Hip flexion
10	R	Gl Max	Gluteus maximus	Hip extension
11	R	P Add	Adductor magnus (posterior)	Hip extension
12	R	Quad	Quadriceps	Knee extension
13	R	Sart	Sartorius	Hip flexion / knee flexion
14	R	Grac	Gracilis	Knee flexion
15	R	TA	Tibialis anterior	Ankle dorsiflexion

TABLE IV

Average knee extensor muscle duty cycle during FNS-only and VIKM-HNP GAIT

Muscle Condition	Left vastus medialis / lateralis	Left quadriceps^a	Right vastus intermedius / lateralis	Right quadriceps^a
FNS-only	81 (1)	79 (2)	75 (1)	75 (1)
VIKM-HNP	49 (6)	47 (7)	49 (8)	49 (8)
Reduction (%)	40 (8)	40 (8)	34 (10)	34 (10)
p-value	<0.001	<0.001	<0.001	<0.001

Duty cycle is calculated as percentage time electric stimulation is delivered through the electrode relative to total time of the gait cycle. Data in Table 4 was averaged over 38 and 30 strides for FNS-only and VIKM-HNP, respectively. The number in parenthesis is one standard deviation.

^a(Note: multiple muscles are recruited by a single electrode. Quadriceps refers to a single implanted electrode that activates the four heads of the quadriceps for knee extension).