A novel motion sensor-driven control system for FES-assisted walking after spinal cord injury: A pilot study

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\textbf{A B S T R A C T}

This pilot study reports the development of a novel closed-loop (CL) FES-gait control system, which employed a finite-state controller that processed kinematic feedback from four miniaturized motion sensors. This strategy automated the control of knee extension via quadriceps and gluteus stimulation during the stance phase of gait on the supporting leg, and managed the stimulation delivered to the common peroneal nerve (CPN) during swing-phase on the contra-lateral limb. The control system was assessed against a traditional open-loop (OL) system on two sensorimotor ‘complete’ paraplegic subjects. A biomechanical analysis revealed that the closed-loop control of leg swing was efficient, but without major advantages compared to OL. CL automated the control of knee extension during the stance phase of gait and for this reason was the method of preference by the subjects. For the first time, a feedback control system with a simplified configuration of four miniaturized sensors allowed the addition of instruments to collect the data of multiple physiological and biomechanical variables during FES-evoked gait. In this pilot study of two sensorimotor complete paraplegic individuals, CL ameliorated certain drawbacks of current OL systems – it required less user intervention and accounted for the inter-subject differences in their stimulation requirements.

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1. Introduction

After a spinal cord injury (SCI) leading to paraplegia, prosthetic gait can be achieved by means of functional electrical stimulation (FES). For this population, although ambulation is possible with mechanical orthotics, the leg muscle metabolism with this technique remains fairly low when compared to gait evoked by electrically-stimulated muscles [1–3]. As a result, the use of FES over the lower extremities has been reported to develop quadriceps hypertrophy and prevent orthostatic hypotension and circulatory hypokinesis [4–7].

The first successful attempt of FES-gait with paraplegic individuals was reported by Kralj and Grobelnik in 1973 [8]. However, only in the 1990s the first portable open-loop FES-gait system became commercially available (Parastep system, Sigmedics Inc., USA). This system, developed by Graupe and Kohn (1994), applies surface stimulation over the quadriceps and gluteal muscles and common peroneal nerve (CPN) [9]. The same authors reported that after adequate training approximately 400 paraplegic subjects could ambulate 6 to 9 m with the Parastep system, with some stepping up to 800 m [10]. With the same system, Brissot and co-workers (2000) found that 13 paraplegics could ambulate 2–350 m after an average of 20 training sessions [11]. With the Vienna FES System (Ottobock Healthcare GmbH, Austria), which allows the customisation of stimulation sequences, Bijak and colleagues (2005) reported overground walking distances from 4 to 60 m for 12 paraplegic individuals [12,13].

Although the results reviewed in this manuscript demonstrate promise towards the popularization of FES walking systems, complications have also been reported in relation to open-loop control of knee extension. Even though early quadriceps fatigue can be predicted via electromyography (EMG) feedback [14], after a fatigue-driven knee buckle event during gait, the stimulation increase over the quadriceps via button presses to restore knee extension requires significant user awareness at all times as operational errors may result in a fall [15,16].

In regards to the CPN stimulus required to initiate a leg lift in the swinging phase of gait, CPN reflexes latency has been shown to vary considerably across different SCI subjects. Granat
and colleagues (1993) have reported CPN latency variations of approximately half a second across their 8 SCI subjects [17]. Alternatively for incomplete SCI and hemiplegic patients, EMG feedback has shown promise in the detection of the voluntary intent to step prior to the initiation of swinging leg stimulation sequences [18,19].

The use of artificial neural network (ANN) controllers to create stimulation patterns required for FES-gait have been previously reported [22]. Although some of these studies have included human experiments, none of the proposed controllers could be reliably applied in a clinical environment. The causes of generally low reliability for ‘real world’ applications include: poor learning activation mechanisms and large computational time burden [25]; realistic perturbations were not included in the model [26]; inaccuracy or minimal output errors falling within an acceptable range of 5 to 10% [20,23,24,27,28]; no efficient process to reduce network complexity [29] or modeling errors [30].

Other feedback (closed-loop) control systems using multiple external sensors have been investigated. Tong and Granat (1999) reported an FES control system comprising 32 sensors – gonioimeters on the hip and knee joints, accelerometers, gyroscopes and inclinometers on the thigh, shank and crutch segments [28]. Williamson and Andrews (2000) derived an FES control system whereby each sensor consisted of clusters of accelerometers, magnetic sensors, a rate gyroscope, and a strain gauge [16]. Such a complex configuration of sensors seems likely to negatively impact clinical usability in a “real-world” environment [31,32]. There has been only sparse literature investigating biomechanical data or physiological outcomes with closed-loop FES-gait systems [20,21,33].

The aim of this study was to quantify, both physiologically and biomechanically, the feasibility of a novel closed-loop motion sensors-driven control system with a simplified setup of four miniaturized sensors controlling both swing and stance phases of gait. The performance of this control system was compared against a traditional open-loop system providing customised stimulation sequences controlling knee extension via button presses. This study highlighted the integrated functional performance, physiological, kinetic and kinematic aspects of gait when evoked by FES-induced muscle contractions.

2. Methods

2.1. Neuromuscular stimulator

The Exostim™ system (Neopraxis, Sydney, Australia) comprised of 8 surface stimulation channels designed to deliver biphasic pulses within a range of 20–100 Hz, pulse width of 150–400 μs and amplitude of 0–180 mA (± pulse peak, constant current) [34].

2.2. Motion sensors

Kinematic sensors were used to provide feedback to the developed control system [35]. They consisted of two 2D accelerometers (ADLX202, Analog Devices, USA) and a single-axis gyroscope (ENC-03JA, Murata, Japan) that provided analogue signals to a 4 MHz micro-controller (AT-Mega103L, ATMEL, USA). These components were mounted in a circuit board and positioned inside a sensor pack (7.5 × 5.0 × 2.5 cm) with an orientation to most accurately measure angular displacements in the sagittal plane. The sensors were strapped onto the subject’s thighs and shanks and sampled at 10 Hz (Fig. 1). Knee angles were defined as the difference between the angles of the Shank and thigh segments.

Fig. 1. Configuration of the sensor packs in the lower extremities. The four sensors strapped to the subject’s thighs and shanks provided kinematic data from the sagittal plane (represented in the zx plane of the diagram).

2.3. Control unit

A C/C++ based software deployed in a hand-held PC (Casio EG-800, Casio Inc., Japan) controlled the Exostim™ and collected data from the motion sensors. The proposed control strategies were modeled in MATLAB Simulink (Mathworks Inc., USA). Using the MATLAB’s toolbox Real-Time Workshop, the Simulink models were built into algorithms transferred to the hand-held PC. During clinical deployment, the sensors and stimulation parameters data were logged as spreadsheet files.

2.4. Study participants

Subjects were two male AIS-A paraplegics (S1: T4, 50 kg, 14 yr post injury; S2: T8–9, 69 kg, 13 yr post injury). Both had at least two years of FES-gait training, usually performed 3 times a week. The subjects consented to the experimental protocol, approved by the Human Research Ethics Committee (Reference: 08-2005/3/8342) of the University of Sydney.

2.5. Stimulation parameters

Both quadriceps and gluteus muscles were stimulated at 33 Hz–150 μs. The CPN stimulation parameters were 50 Hz–400 μs for S1 and 100 Hz–400 μs for S2. These stimulation parameters, considered to provide a desirable swing leg motion during FES-gait training, were defined in a previous study [36].

2.6. Placement of the CPN electrodes

CPN stimulation was applied in the knee region of the popliteal fossa for S1. S2’s reflex responses when stimulated near the popliteal fossa was insufficient for stepping, but could be improved by stimulating CPN afferent nerve fibres in the foot region of the extensor digitorum brevis muscle and medial plantar arch (Fig. 2).

2.7. Control strategies

2.7.1. Open-loop (OL) strategy

The stimulation sequences for gait were customised for each subject in 5 assessment sessions (Fig. 3). This was aimed at optimising the performance of the OL control system [13]. Due to the weight transfer prior to the steps, the stimulation on the stance leg was increased by 20 mA to provide a greater 1-leg support during

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the swing phase. In the case of knee buckle, the stimulation amplitude in both quadriceps channels was increased simultaneously by 10 mA via a single button press.

2.7.2. Closed-loop (CL) motion sensor-driven strategy

The motion sensor-driven control system was structured as a finite-state controller. After subjects stood via quadriceps and gluteal stimulation, the initial knee lock position (0° of flexion) was determined by the sensors position after 6 s of stable stance. When the command to initiate a step was triggered via a button press, the stimulation on the quadriceps muscles and gluteal muscles was switched off and the CPN stimulation was activated (toe-off). From the previous stance position, when knee angle flexed more than 15° and thigh segment lifted more than 10°, CPN stimulation was switched off and quadriceps stimulation amplitude was ramped back up (swing through) to the previous levels in 300 ms followed by gluteus stimulus (heel-strike) (Fig. 4). If this thigh segment and knee angle criteria was not met after 1 s of CPN stimulation, this channel was switched off and the rest of the quadriceps and gluteal stimulation sequence was activated. Similar to the open-loop approach, the stance leg’s quadriceps muscle had a stimulation amplitude increment of 20 mA during swing phase. The angular criteria of the leg swing were tested over 240 stepping trials in 3 complete paraplegics [36].

![Fig. 2. CPN electrode placement. Electrodes were placed in the foot region of the extensor digitorum brevis muscle (a) and medial plantar arch (b) for S2 and in the region of the knee popliteal fossa (c) for S1.](image)

![Fig. 3. Customised open-loop stimulation sequences during stepping. From the double support phase, the subject’s weight was transferred to the stance leg prior to the initiation of a step. After the stepping command was triggered, toe-off commenced with CPN activation and quadriceps/gluteus deactivation. Near the middle of the swing phase, quadriceps stimulation was switched on bringing the foot forward prior to heel-strike. The termination of this sequence included the activation of gluteus to augment hip stabilization.](image)
scale from 0 to 10. II) Overground walking (OVER-G): These tests were performed with the same protocol as TREAD, but on a 10-m marked pathway. The walking was carried at a patient-selected cadence and the measurements included were: Heart rate (HR), step length, and walking time. To assess quality of gait the same visual analogue scale deployed during TREAD was used. III) Biomechanical walk (BIOMECH): 1 day of testing was performed at a biomechanics laboratory with both strategies. Data from multiple kinematic and kinetic variables were collected from three 2-m walks per strategy. The order of the strategies was alternated between walks.

As a safety measure, subjects wore a harness system at all times to prevent falls in case of a severe knee buckle. Subjects also walked with the aid of a walking frame with unassisted foot placements.

2.9. Data collection

2.9.1. Physiological measurements

Physiological responses were monitored during TREAD. HR was measured at all times (Portascope CR55, Cardiac Recorders Ltd., UK). Expired/Exhaled gases were collected breath-by-breath via open-circuit spirometry (CPX-D system, Medical Graphics Corp., USA). The main exercise response variable collected was oxygen uptake (VO2; ml kg⁻¹ min⁻¹). Using the same metabolic cart, non-invasive cardiac output (Qc; l min⁻¹) was assessed via Defares CO₂-rebreathing technique at rest and at the end of the third walking trial. In addition, left ventricular stroke volumes (SV; ml·beat⁻¹) and arteriovenous oxygen extractions (C(a-v)O2; mlO₂·ml⁻¹) were calculated. For both HR and VO₂, the resultant values were obtained from the average of 30 s of measurements, at rest and at the end of the third walking trial. Net values, i.e. the differences between final exercise (at the end of 3rd gait trial) and rest were presented accounting for inter-subject differences in resting data.

Near infrared spectroscopy (NIRS) was used to estimate quadriceps oxyhaemoglobin levels (ISS 96.208 oximeter, ISS Inc., USA). The NIRS probe was placed over the middle section of the subject’s left quadriceps muscle. Oxygen saturation data (O2Sat) was normalised in the range from 0 to 100% at rest via arterial occlusion of the upper thigh. This procedure used an inflatable pressure cuff (E20 & AG101, D. E. Hokanson Inc., USA) set to 270 mmHg. This occlusion was held until the decrease in O2Sat had stabilised (0% O2Sat). The 100% O2Sat level was considered the mean O2Sat value prior to the occlusion [38].

2.9.2. Biomechanical measurements

BIOMECH testing was performed in a biomechanics laboratory using an 8-camera system (Eagle, Expert Vision Advanced™, Motion Analysis Corp., USA). Video data was captured at 100 Hz. Retro-reflective markers defined subjects’ trunk and lower body segments [35]. Subjects walked over two single force platforms (9281C, Kistler Instrument Corp., Winterthur, Switzerland) to record the ground reaction forces at 1 kHz.

Biomechanical data was analysed using KinTrak 6.2 (Human Performance Laboratory, University of Calgary, Alberta, Canada). Ground reaction forces recorded by the force platform in the up-right direction were considered to be inversely proportional to the weight taken by the subjects through the walking frame. To make
sure that the walking frame didn’t touch the force platforms, a fully rigged frame was used alongside the force platforms.

3. Results

3.1. Differences on overground walking performance

Table 2 presents the main outcomes during the OVER-G testing. Generally, both subjects demonstrated slower cadences for OL when compared to CL. S2’s ambulation distance was 19.2 m for OL and 27.9 m for CL. S1 achieved 30 m with both OL and CL. For both subjects the number of steps per meter did not vary considerably between CL and OL (S1: OL= 4.2, CL=5.1 | S2: OL= 3.2, CL=3.1 [step/m]). Both subjects consistently reported a higher gait quality scores for CL.

3.2. Differences in treadmill walking performance

For both subjects some consistent results were found during TREAD (Table 3). HR displayed a trend to be slightly lower during CL than for OL. Cardiac output was lowered, while stroke volumes and C(a-v)O2 were increased during CL as compared to OL. Quadriceps O2Sat was significantly higher for CL than for OL. The total ambulation distance over three walking trials was slightly shorter for CL (S1: OL=46.4, CL=43.2 | S2: OL=32.7, CL=29.1 [m]). In order to maintain knee extension during stance phase, CL applied stimulation amplitude increases whenever \( \theta_{Knee} \geq 10^\circ \). During OL, in contrast, stimulation amplitude increases occurred only when knee flexion angles were higher than 10° (Fig. 5). Similar to OVER-G, the quality of gait scores had lower values for OL when compared to CL (S1 = 5 (OL), 8 (CL) | S2 = 6 (OL), 9 (CL)).

3.3. Differences on biomechanical performance

There was no discernible difference between OL and CL for either toe excursion or knee angular displacement (Fig. 6).

Hip angular velocities during both CL and OL displayed very irregular patterns (Fig. 7). Considering leg power in the sagittal plane as the sum of ankle, knee and hip joint power, the patterns of S1 and S2’s leg power were unlikely to be replicable (Fig. 8).

During swing phase, the weight taken through the single stance leg was markedly lower than the subject’s body weight. We believe this to be linked to the upper-body effort and the weight transferred through the frame (Fig. 9). With S1 and S2’s weighting approximately 500 N and 700 N respectively, their stance leg ground reaction forces in the upright direction were still only in the range of 300–400 N. This corresponded with at least 40% of the subject’s weight being supported by their upper body at all times.

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Fig. 6. Kinematic data of a single trial during each strategy. For both S1 and S2, toe excursions and knee angular displacements indicated that the swinging leg trajectories were likely to be associated with the leg responses to the stimulation rather than to the strategy applied.

4. Discussion

Considering the limitations of past and current FES walking systems, the proposed motion sensor-driven control system resolved a number of issues: (i) the inter-subject differences in the stimulation requirements by controlling knee extension during stance phase and stepping motion during swing phase; (ii) the use of a simplified setup of sensors; and (iii) the use of a control algorithm that provided closed-loop stability.

The motion sensors sampling frequency of 10 Hz was relatively slow. The reasons for this could be attributed to: (i) the Exostim’s microcontroller speed of 4 MHz, and to, (ii) the currently outdated
Pocket PC. Even though the slow communication protocol was altered to enable higher sampling frequencies, only at 10 Hz was the accuracy of the control system preserved [35]. Notwithstanding this limitation, the numerous clinical trials performed during this study demonstrated good functionality with the reported sampling frequency.

During OVER-G, stepping cadences were slower during OL because subjects had to interrupt stepping to increase the quadriceps stimulation in the event of a fatigue-driven knee buckle. The slower cadences that were observed during OL probably occurred as subjects exerted a greater upper body effort on the frame after knee buckle. This was especially true for S2. During the 3 OL gait trials, these knee buckle events did not influence the completion of the 10-m pathway for S1, but certainly did for S2. The definition of quadriceps stimulation increases of 10 mA per button press were defined in a previous study [39]. While values greater than 10 mA were associated with earlier quadriceps fatigue, values lower than 10 mA were likely to incur in more stimulation increases and thus interruption of gait.

The physiological outcomes during TREAD might indicate the reason of longer ambulation in both subjects during OL. During CL, the earlier stimulation increases to sustain knee extension compared to OL increased metabolic demand for oxygen, therefore resulting on higher values of quadriceps VO2Sat and whole body C(a-v)O2. Thus, the presented data could indicate that earlier quadriceps fatigue was not caused by lack of blood supply [40] but possibly because of accommodation of the action potentials in the electrically stimulated nerves [41].

This study reported some important biomechanical variables not previously reported during FES-gait. One interesting aspect observed for both S1 and S2 was that the peak power generated by their leg joints was within a ±20 W range during swing phase. When compared to FES cycling where a constant exercise power around 8 W can often be observed [42], the short duty cycle during FES-gait was particularly linked to the long time spent on stance phase. At this point, the generated joint powers could be associated with the hip joint flexion when subjects were pushing the frame forward. This corresponded to very high upper body forces applied over the frame.

Popovic and colleagues (2003) investigated the automatic triggering of stimulation sequences for stepping versus the hand-triggered operation [21]. Results revealed that five of their six subjects preferred the slower walking speeds and one preferred the hand-triggered operation. The slower synchronization between the

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Fig. 8. Sum of ankle, knee and hip joint power in the sagittal plane. The developed joint power during stance phase was probably associated with the frame being pushed forward.

Fig. 9. Upright ground reaction forces. Note that during the 1-leg supported stance phase even the peak forces were only a fraction of the subjects’ body weight.
upper and lower body was deemed to be the reason for their choice. For this study, the hand-triggered operation was considered safer since the failing of a step could potentially result in a fall.

During stepping, CL was able to account for differences in the CPN responses of S1 and S2 that had different placements of CPN electrodes. For stroke patients suffering from foot drop syndrome, Seel et al. (2015, 2016) have described the effectiveness of a similar strategy for the stimulation of the peroneal nerve during the swing phase of the paretic foot also using 2 skin electrodes in the region of the knee popliteal fossa [43,44]. Their control system captured the entire pitch angle trajectory of the paretic foot measured by means of a 6D Inertial Measurement Unit (IMU). Starting with a conservative CPN stimulation profile results revealed that the desired foot motion was achieved within one or two strides. Such functionality to modulate CPN stimulation could certainly be introduced as a stimulation mode to CL and in addition benefit patients with foot drop syndrome.

In relation to CL, Fuhr and colleagues (2001) were one of the first groups to describe a comparable gait strategy via closed-loop control [45]. Although successful steps were reported for two SCI subjects, their setup was fairly complex. Their subjects had electrogoniometers measuring joint angles of the hips, knees and ankles; gyroscopes on the pelvis, thighs, shanks and feet and insole pressure sensors. With a similar setup Neukokar and Erfanian (2012) used independent fuzzy logic closed-loop control modules for each muscle-joint dynamics modulating both pulse width and stimulation amplitude [46]. Their results demonstrated very similar gait patterns to our study where pulse amplitude was also automatically increased during the walking trials to compensate for muscle fatigue. The application of orthosis in combination of FES via simplified computational modeling was another proposed solution [47]. Mohammed et al. (2012) presented the modeling and the control of a knee joint actuated by the quadriceps muscles. Stimulation patterns were computed as a function of the desired lower limb knee joint movements and parameters of the biomechanical model were identified based on experimental kinematic data. Even though their controller has shown satisfactory results in terms of regulation, stability and robustness with respect to external disturbances their control system is yet to be tested in SCI patients [48]. In comparison, the complexity of our closed-loop controller was considerably reduced resulting in a solution less computationally intensive. In this aspect, the performance of our CL control system in conjunction with its simplified setup of motion sensors can result in a promising rehabilitation therapy outside the research environment.

5. Conclusion

The results of this study indicate the feasibility of the motion-sensor driven CL control system in a clinical setting. The closed-loop control of leg swing was efficient, but did not necessarily imply in major advantages compared to OL. Future studies investigating stand-to-walk transition is suggested, as CL may provide greater benefits compared to OL during this phase more relevant to the ambulation community in relation to steady gate [49]. Nonetheless, CL automated the control of knee extension providing a safer gait and the performance of this control system already envisages bringing contributions to the FES field and SCI community.

Ethical approval

Ethical approval was granted by the University of Sydney Human Research Ethics Committee for Reference: 08-2005/3/8342 ("Surface stimulation strategies for functional mobility in individuals with spinal cord injury").

Competing interests

The authors declare that they do not have any financial or personal relationships with other people or organizations that could have inappropriately influenced this manuscript.

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