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Development of an Implanted Intramuscular EMG-triggered FES System for Ambulation after Incomplete Spinal Cord Injury

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Abstract— **Ambulation after spinal cord injury is possible with the aid of neuroprosthesis employing functional electrical stimulation (FES). Individuals with incomplete spinal cord injury (iSCI) retain partial volitional control of muscles below the level of injury, necessitating careful integration of FES with intact voluntary motor function for efficient walking. In this study, the intramuscular electromyogram (iEMG) was used to detect the intent to step and trigger FES-assisted walking in a volunteer with iSCI via an implanted neuroprosthesis consisting of two channels of bipolar iEMG signal acquisition and 12 independent channels of stimulation. The detection was performed with two types of classifiers– a threshold-based classifier that compared the running mean of the iEMG with a discrimination threshold to generate the trigger and a pattern recognition classifier that compared the time-history of the iEMG with a specified template of activity to generate the trigger whenever the cross-correlation coefficient exceeded a discrimination threshold. The pattern recognition classifier generally outperformed the threshold-based classifier, particularly with respect to minimizing False Positive triggers. The overall True Positive rates for the threshold-based classifier were 61.6% and 87.2% for the right and left steps with overall False Positive rates of 38.4% and 33.3%. The overall True Positive rates for the left and right step with the pattern recognition classifier were 57.2% and 93.3% and the overall False Positive rates were 11.9% and 24.4%. The subject showed no preference for either the threshold or pattern recognition-based classifier as determined by the Usability Rating Scale (URS) score collected after each trial and both the classifiers were perceived as moderately easy to use.**

I. Introduction

MOTOR system neuroprostheses utilizing functional electrical stimulation (FES) can improve or restore walking function in individuals paralyzed by spinal cord injuries by electrically activating a customized set of muscles selected to address individual gait deficits with pre-programmed patterns of stimulation to augment or produce cyclic movements of the lower extremities [1]. Users can trigger each step with a manual switch and progress through the customized pattern of stimulation to achieve walking function. The potential for triggering FES from the electromyographic (EMG) activity of muscles which remain under volitional control after partial paralysis to coordinate the actions of the stimulated muscles with voluntary movement has previously been evaluated with signals acquired from the surface of the skin [2]. The main objective of this study was to develop a method to identify optimal command sources and evaluate the feasibility of detecting the intent to take a step using the intramuscular electromyogram (iEMG) acquired from recording electrodes implanted permanently in the partially paralyzed muscles in two implant recipients with incomplete spinal cord injury (iSCI). The overall aim was to specify the development of a new command and control interface to trigger FES-assisted stepping that can be implemented with two channels of intramuscular EMG electrodes with a multichannel implantable stimulator-telemeter (IST) [3], [4].

The preliminary results from initial attempts to implement iEMG-based control systems in real-time with available implanted neuroprostheses are discussed in this paper.

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II. Methods

A. Subjects

Two male subjects with incomplete spinal cord injury volunteered for this study. Subject iSCI-1 was a male volunteer with C6 incomplete spinal cord injury (ASIA C). Subject iSCI-2 was a male volunteer with T1 motor and C6 sensory incomplete spinal cord injury (ASIA D) who could walk only short distances with great difficulty without the assistance from FES. They each received a 12 channel stimulator-telemeter (IST-12), 12 surgically implanted intramuscular stimulating electrodes [4] and two implanted intramuscular recording electrodes as part of a neuroprosthesis designed to facilitate household and limited community ambulation. Temporal patterns of stimulation to activate the muscles were customized for each subject's individual gait deficits according to established tuning procedures [5], [6] in order to achieve forward stepping in a rolling walker.

Informed consent was obtained from both the subjects before their participation and the Institutional Review Board of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center approved the study related procedures.

B. Command source selection

Subjects were asked to walk with surface FES for the presurgery data collection. The experimental setup for collecting surface EMG (sEMG) data during walking is shown in Figure 1. Surface EMG signals were collected from gluteus medius (GM), biceps femoris (BF), medial gastrocnemius (MG), rectus femoris (RF), tibialis anterior (TA), and erector spinae (ES) bilaterally.

The sEMG was collected using Ag/AgCl electrodes with 2 cm. inter-electrode distance following the SENIAM

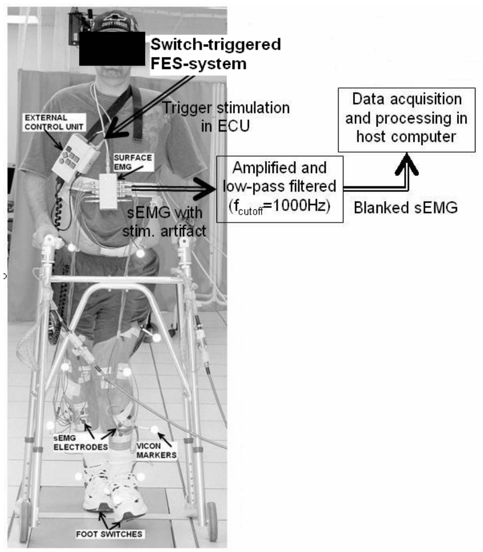

Figure 1: Experimental setup for data collection during FES-assisted walking with the block-diagram for the FES system.

guidelines [7]. The sEMG signals were amplified and low-pass (f_{cutoff}=1000 Hz) filtered by CED 1902 amplifiers (Cambridge Electronic Design, England) before being sampled at 2400 Hz (AT-MIO-64F-5, National Instruments, USA) in the host personal computer. Baseline sEMG data were collected during 3 seconds of initial standing before the start of each trial. During each trial, the subjects were asked to reach a self selected speed within ~5m of the start position and then decelerate to come to rest at the end of the walkway. They had to wait in the terminal stance for 3 seconds at the end of every trial. The subjects made multiple passes across the straight level walkway. Gait events (foot-strike and foot-off) were derived from foot-floor contact patterns obtained from insole-mounted foot switches placed bilaterally at medial and lateral heel, first and fifth metatarsal, and big toe, and confirmed with the kinematic data that were acquired simultaneously.

The sEMG linear envelopes (LEs) during a gait cycle were then divided into double-support (DS) phase – when both the feet were in contact with the ground, and swing (SW) phase – when the foot was not in contact with the ground. The sEMG LE during each trial was normalized by its maximum magnitude during that trial.

The normalized LEs of each muscle were divided into two classes: the class 'True' was comprised of LEs during double-support phase prior to foot-off and the class 'False' consisted of the LEs during terminal stance and initial standing. Half of the data were randomly allocated to training and used to find a characteristic pattern of activation by ensemble averaging the LEs. The characteristic pattern found for the class 'True' was cross-correlated with the LEs from the other half of the data (test data) for the classes 'True' and 'False'. A Receiver Operating Characteristics (ROC) curve showed the tradeoff between sensitivity (i.e. True Positive rate) and 1 – specificity (i.e. False Positive rate) of the binary classifier. A Discriminability Index (DI) was defined as the area under the ROC curve (AUC) which gave a measure of performance for the binary classifier [8]. This identified the muscles yielding the best separation of classes, and hence the primary targets for the implanted recording electrodes.

The best location for implantation of the intramuscular recording electrode was estimated based on a similar analysis of the DI from the sEMG acquired from different locations on the bellies of the target muscles. A matrix of

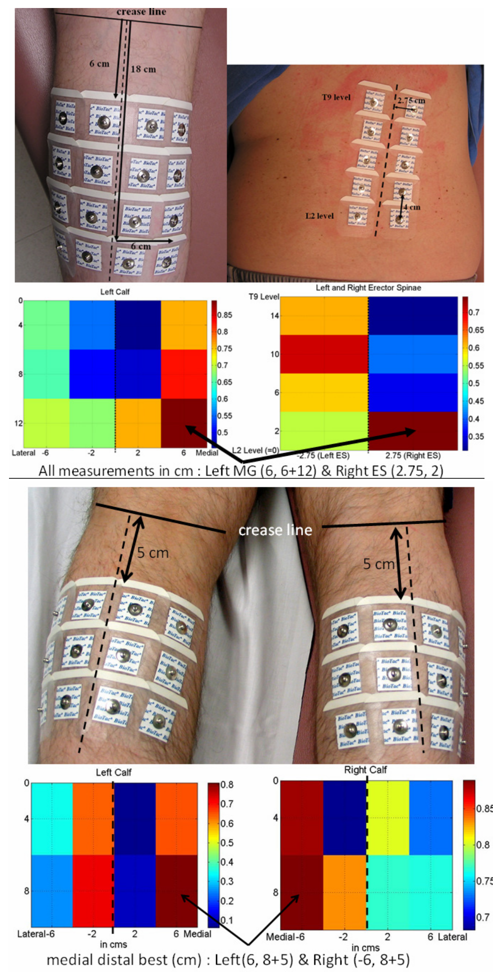

Figure 2: Best location found from the surface EMG for implanting intramuscular EMG electrodes Top panel: left gastrocnemius and right erector spinae. Bottom panel: left and right gastrocnemius.

sEMG electrodes was placed to cover the whole muscle belly, as shown in Figure 2. Multiple bipolar sEMG recordings were made along the length of the muscle. The sEMG data were collected with the same experimental protocol and analyzed similarly to find the best location on the muscle belly that had the highest DI. The best location was noted with respect to the anatomical landmarks for identification during surgery when the subject was under general anesthesia.

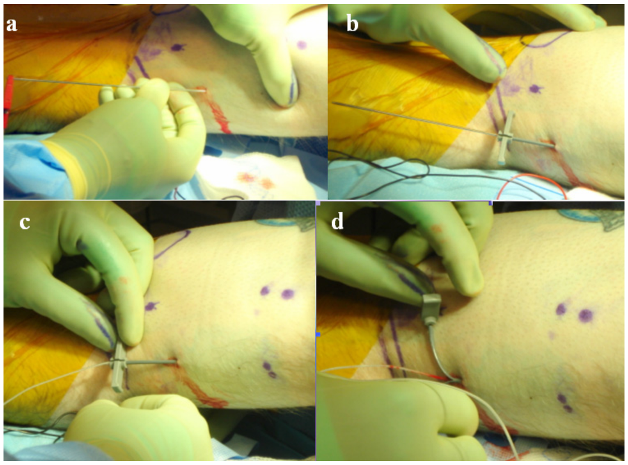

Figure 3: The steps during the implantation of intramuscular EMG electrode a) insertion of probe, b) deployment of peelable sheath over probe, c) insertion of the iEMG electrode through the peelable sheath, d) peeling off of the polymer sheath leaving the iEMG electrode in place.

A. Implantation of intramuscular EMG electrode

The implantation procedure for the iEMG electrode is shown in Figure 3. First a stimulation probe was inserted subcutaneously to the best location that was identified based on anatomical landmarks, as shown in Figure 3a. Stimulation was applied by clipping a cable to the probe to ensure that the tip of the probe is at the desired site with viable muscle fibers. A peelable polymer sheath was then inserted on the top of the probe with the help of the markings such that its tip approximately coincided with the probe tip, as shown in Figure 3b. The probe was then removed and the intramuscular EMG electrode was inserted in the place of the probe with the help of the lead carrier. The cannula-like lead carrier held the iEMG electrode lead in place during insertion through the sheath. The lead carrier was then removed which left the iEMG electrode lead in the peelable sheath, as shown in Figure 3c. The polymer sheath was then gently peeled off leaving the iEMG electrode at the selected location, as shown in Figure 3d.

B. Classifier for iEMG-triggered FES-assisted stepping

Two kinds of iEMG-based classifier – one based on thresholding and the other based on a pattern recognition algorithm [2] were developed. The left foot-off (i.e., the intent to initiate left swing) and right foot-off (i.e., the intent to initiate right swing) were detected sequentially and independently by the classifiers to trigger FES-assisted left and right steps respectively. The iEMG of the each channel was sampled and integrated for 10ms sequentially one after the other every 100 ms. The IST-12 telemetered back to the External Control Unit (ECU) the integrated iEMG of each channel at 10 Hz.

For the pattern recognition classifier, the iEMG patterns from the class ‘True’ were ensemble averaged and served as the feature for classification. The feature was cross-correlated with all the iEMG patterns in the class ‘True’ and the average cross-correlation coefficient served as the initial threshold. The initial threshold for the thresholding classifier was equal to the average running mean of the iEMG signal for all the iEMG patterns in the class ‘True’. Initial thresholds were slightly changed with binary search (mostly lowered) during online evaluation to lower False Negative rate while keeping False Positive rate constant or minimized.

The threshold-based binary classifier started computing the running mean of the relevant iEMG signal after the start of the stimulation pattern of a step. When the running mean exceeded a selected threshold, the stimulation pattern advanced and stepping of the contralateral limb was triggered. The pattern recognition classifier started processing the iEMG time history at the same time as the threshold-based classifier started processing the iEMG level. The pattern recognition classifier cross-correlated a windowed portion of the relevant iEMG signals to detect feature templates required for triggering the contralateral step. A trigger was then generated when the cross-correlation coefficient exceeded a discrimination threshold.

C. Online testing of the classifier in the laboratory

Subject iSCI-2 evaluated walking and stopping with both the classifiers separately while the true positive (1-false negative) and false positive rates were recorded as measures of performance. The subject walked with the iEMG triggered FES assisted stepping on a straight walkway across the gait laboratory. The iEMG classifier was started with a manual switch during standing to trigger the first step. After that the iEMG triggered the steps during ambulation across approximately 8m before stopping with the iEMG classifier. The pattern recognition and the threshold-based classifiers were presented in a random order during two days of evaluation. Total eight trials (39 left steps and 39 right steps) for the threshold-based classifier and nine trials for the pattern recognition classifier (45 left steps and 42 right steps) were captured.

After each trial, the subjective assessments of perceived ease of use of each classifier during FES-assisted stepping in real-time were evaluated with Usability Rating Scale (URS) [9]. Each walking trial was evaluated independently so the subject only rated his most recent walking experience and was not required to compare his current perception to a prior walking trial.

III. RESULTS

A. Muscles and location selection for intramuscular EMG

The left medial gastrocnemius (MG) and the right erector spinae (ES) were selected as the command sources for iSCI-1. The best location for intramuscular EMG was estimated based on the DI from the surface EMG from the left MG and right ES of iSCI-1, which are shown with color scale in Figure 2: Top Panel. The best location on left MG was 6 cm medial and 18 cm distal from the popliteal crease line. The best location found on right ES was 2.75 cm lateral to the spinous process of L2 and 2 cm superior to the L2 level. The right MG and left MG were selected as the command sources for iSCI-2. The best location for intramuscular EMG that was estimated based on the DI from the surface EMG

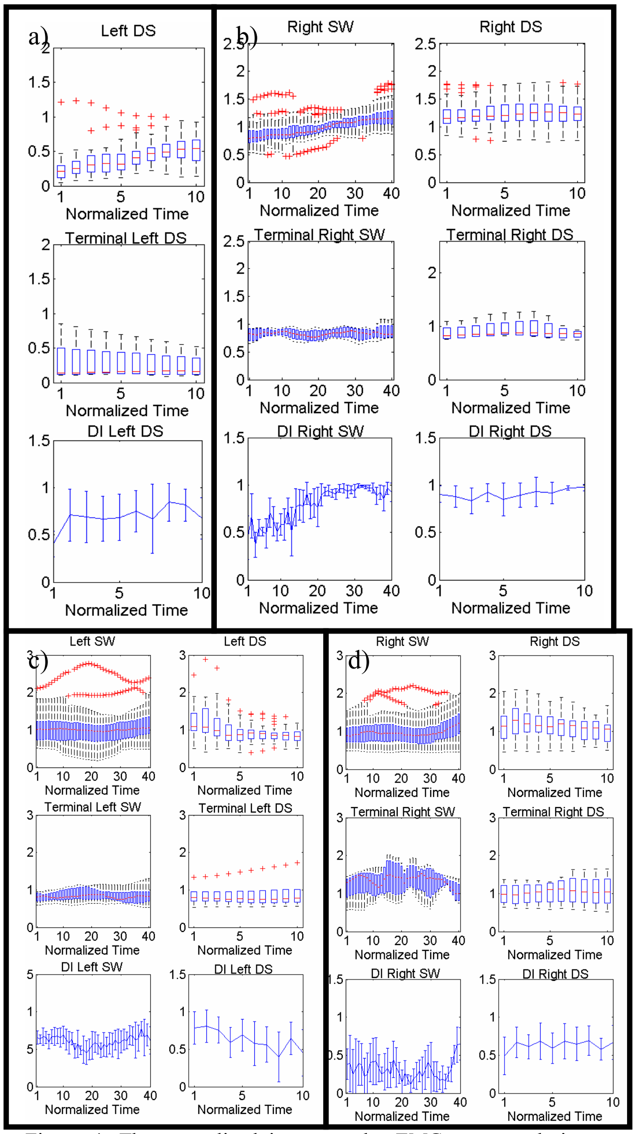

Figure 4: The normalized intramuscular EMG patterns during over-ground walking with their Discriminability Index (DI) a) left medial gastrocnemius (MG) during left double support (DS) phase (class 'True') and terminal left DS phase (class 'False') for iSCI-1, b) right erector spinae (ES) during right swing (SW) & DS phase (class 'True') and terminal right SW & DS phase (class 'False') for iSCI-1, c) left MG during left SW & DS phase (class 'True') and terminal left SW & DS phase (class 'False') for iSCI-2, d) right MG during right SW & DS phase (class 'True') and terminal right SW & DS phase (class 'False') for iSCI-2.

from the left MG and right MG of iSCI-2 are shown with color scale in Figure 2: Bottom Panel. The best location found on the left and right MG was 6 cm medial and 13 cm distal from the popliteal crease line.

TABLE I

Trial #	# left steps	# right steps	False Negative (FN) right Side	False Negative (FN) left Side	False Positive (FP) right Side	False Positive (FP) left Side
1	5	5	1	0	2	0
2	6	5	0	0	3	3
3	5	4	2	2	2	2
4	5	5	0	0	3	3
5	4	5	3	0	1	0
6	5	5	5	0	3	3
7	5	5	1	0	0	1
8	4	5	3	3	1	1
Total	**39**	**39**	**15**	**5**	**15**	**13**
		Mean	**1.875**	**0.625**	**1.875**	**1.625**
		SD	**1.73**	**1.19**	**1.13**	**1.3**
		FP & FN rates	**0.384**	**0.128**	**0.384**	**0.333**

Performance of the threshold-based classifier for iSCI-2.

TABLE II

Trial #	# left steps	# right steps	False Negative (FN) right Side	False Negative (FN) left Side	False Positive (FP) right Side	False Positive (FP) left Side
1	5	4	1	0	0	1
2	6	5	3	0	0	1
3	5	5	1	0	0	1
4	5	5	0	3	0	1
5	5	4	3	0	0	0
6	5	6	6	0	0	1
7	5	4	1	0	3	3
8	4	4	1	0	2	2
9	5	5	2	0	0	1
Total	**45**	**42**	**18**	**3**	**5**	**11**
		Mean	**2**	**0.33**	**0.56**	**1.22**
		SD	**1.8**	**1**	**1.13**	**0.83**
		FP & FN rates	**0.428**	**0.067**	**0.119**	**0.244**

Performance of the pattern recognition classifier for iSCI-2.

B. *Classifier development and online performance*

The normalized iEMG patterns during over-ground walking allocated to training and used to find a characteristic pattern of activation are shown in Figure 4. The temporal length of the contiguous iEMG pattern, selected as the characteristic pattern of activation was based on the Discriminability Index (DI) such that the DI stayed on an average above 0.7. Figure 4a shows the left medial gastrocnemius (MG) during left double support (DS) phase (class 'True') and terminal left DS phase (class 'False') in iSCI-1. The ensemble average during normalized time from 2 to 10 in left DS was used to identify left foot-off in iSCI-1. Figure 4b shows the right erector spinae (ES) during right swing (SW) & DS phase (class 'True') and terminal right SW & DS phase (class 'False') for iSCI-1. The ensemble average during normalized time from 25 to 40 in right SW and 1 to 10 in right DS was used to identify right foot-off in iSCI-1. Figure 4c shows the left MG during left SW & DS phase (class 'True') and terminal left SW & DS phase (class 'False') for iSCI-2. The ensemble average during normalized time from 35 to 40 in left SW and 1 to 2 in left DS was used to identify left foot-off in iSCI-2. Figure 4d shows the right MG during right SW & DS phase (class 'True') and terminal right SW & DS phase (class 'False') for iSCI-2. The ensemble average during normalized time from 30 to 40 in right SW and 1 to 10 in right DS was used to identify right foot-off in iSCI-2.

Performance data was collected only for iSCI-2 who finished rehabilitation at the time of this study while iSCI-1 was still training with the iEMG-triggered FES-system. The elapsed time from the instant of the desired muscle activity to initiation of stimulation was 0.53 ± 0.12 seconds. Table I shows the performance of the threshold-based classifier for iSCI-2. The threshold-based classifier for triggering the right step had a false positive rate of 38.4% and a true positive rate of 61.6%. The threshold-based classifier for triggering the left step had a false positive rate of 33.3% and a true positive rate of 87.2%. Table II shows the performance of the pattern recognition classifier for iSCI-2. The pattern recognition classifier for triggering the right step had a false positive rate of 11.9% and a true positive rate of 57.2%. The pattern recognition classifier for triggering the left step had a false positive rate of 24.4% and a true positive rate of 93.3%.

The average Usability Rating Scale (URS) score was found to be 2 in a 7 point scale for both the classifiers, indicating that both the classifiers were moderately easy to use.

IV. Discussion and Conclusions

This study presented a selection criterion to identify the command sources for an iEMG-based classifier to trigger FES-assisted gait. The feasibility of a simplified threshold-based classifier and a pattern recognition classifier based on iEMG for triggering FES-assisted steps was demonstrated during real-time operation in one subject. The pattern recognition classifier generally outperformed the threshold-based classifier, particularly with respect to minimizing false triggers. Subject showed no preference for either the threshold- or pattern-recognition based classifier as determined by the Usability Rating Scale (URS) score collected after each trial.

More research needs to be done in evaluating the optimality of the implantation site for the intramuscular EMG electrode found from non-invasive surface EMG recordings from the muscle belly. Advanced source localization techniques can be applied to multi-electrode surface EMG recordings to determine optimal command sources.

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