

**Walking Mode Classification through Myoelectric and Inertial Sensors for Transtibial
Amputees**

Jason D. Miller

A thesis
submitted in partial fulfillment of the
requirements for the degree of

Master of Science in Mechanical Engineering

University of Washington
2012

Committee:

Dr. Michael E. Hahn

Dr. Per G. Reinhall

Dr. Randal P. Ching

Program Authorized to Offer Degree:
Mechanical Engineering

University of Washington

Abstract

Walking Mode Classification through Myoelectric and Inertial Sensors for Transtibial Amputees

Jason D. Miller

Chair of the Supervisory Committee:

Dr. Michael E. Hahn

Department of Mechanical Engineering

Myoelectric algorithms have the potential to provide motion intent information to a prosthetic system to allow the prosthetic to adapt biomimetically to changes in walking modality. While myoelectric algorithms have been explored extensively for upper limb amputees, little has been done to achieve similar advances for the lower limb. For upper limb amputees, it has been shown that fusion of myoelectric and inertial sensors benefits classification. Myoelectric signals from four muscle groups (tibialis anterior, medial gastrocnemius, vastus lateralis, and biceps femoris) and inertial signals from the lower limb segments were recorded for five non-amputee subjects and five transtibial amputees over a variety of walking modes: level ground walking at various speeds, ramp ascent/descent, and stair ascent/descent. These signals were decomposed into relevant features (mean absolute value, variance, wavelength, number of slope sign changes, and number of zero crossings, maximum, minimum) and used to test the ability of myoelectric classification algorithms for transtibial amputees using either Linear Discriminant Analysis (LDA) or Support Vector Machine (SVM) classifiers.

The fusion of myoelectric and inertial signals showed no benefit for amputee subjects and as a result inertial signals were removed from consideration. Detection of all seven walking modes

were observed to have an accuracy of 97.9% (± 0.22) and 97.9% (± 1.39) for amputee subjects when using LDA and SVM, respectively. The predominant misclassifications occurred between different walking speeds due to the similar nature of the gait pattern. Stair ascent/descent modalities had the best classification accuracy with 100% (± 0.00) and 99.8% (± 0.29) for amputee subjects when using LDA and SVM, respectively. Transitions into and out of stair modalities could be predicted one gait cycle ahead of the change for 95.0% and 90.0% of all transitions observed in this study when using LDA and SVM, respectively.

The robustness of the developed classifier was explored through tests of generalizability and stability under electrode shifting disturbance. While separations between certain modes were not possible through a generalized model or under disturbance, stair ascent/descent classification against all other modalities was consistent. This result highlights the possibility of a stair mode myoelectric control algorithm for lower limb amputees. Future efforts will further explore the robusticity of myoelectric classification under real world conditions such as stability of classification over long periods of time, classifier training methods, and real time capabilities of the classifier.

TABLE OF CONTENTS

List of Figures	iv
List of Tables	vi
Chapter 1. Introduction	1
1.1 Development of Problem	1
1.2 Background	1
1.3 Statement of Purpose	3
1.4 Specific Aims of Study	4
1.4.1 Measure EMG and IMU from transtibial amputees in several modes.....	4
1.4.2 Transtibial myoelectric mode classifications (steady state and transitional).....	4
1.4.3 Effects of disturbances on mode classification	4
1.5 Limitations	4
Chapter 2. Literature review	6
2.1 Myoelectric Signals and Inertial Measurements.....	6
2.1.1 EMG Signal Content.....	7
2.1.2 Amputee EMG Signals	9
2.1.3 Consistency of EMG Signal.....	10
2.1.4 Inertial Measurements.....	10
2.2 Healthy and Amputee gait	11
2.2.1 Healthy lower limb function	11
2.2.2 Functional adaptations-transtibial amputees.....	13
2.3 Machine Learning	14
2.3.1 Linear Discriminant Analysis	14
2.3.2 Support Vector Machine	15
2.3.3 K-fold Cross Validation	18
2.4 Myoelectric Control	19
2.4.1 Signal Segmentation and Window Definition	20

2.4.2	Feature Extraction	21
2.4.3	Signal Classification	23
2.4.4	Previous Lower Limb Myoelectric Controllers	24
2.4.5	Practical Considerations.....	27
Chapter 3.	Methodology	29
3.1	Subject Recruitment.....	29
3.2	Measurement System	29
3.3	Experimental Protocol	31
3.3.1	EMG and General Sensor Placement.....	32
3.3.2	Experimental Course and Data Collections	35
3.4	Signal Processing.....	38
3.5	Summary	38
Chapter 4.	Myoelectric Classification and Prediction	40
4.1	Research Subjects	40
4.2	Feature Extraction.....	41
4.3	Walking Mode Classifications.....	42
4.3.1	Mode Detection.....	44
4.3.2	Mode Prediction.....	47
4.4	EMG and IMU Sensor Fusion	53
4.5	Generalizability of Classification	54
4.6	Classifier Sensitivity to Disturbance.....	56
4.7	Summary	59
Chapter 5.	Discussion	61
5.1	Experimental System and Procedure Limitations.....	61
5.2	Classifier Limitations.....	61
5.3	Walking Mode Classification	62
5.3.1	Mode Detection.....	62
5.3.2	Mode Prediction.....	64
5.4	EMG and IMU Sensor Fusion	65

5.5	Generalizability of Classification	66
5.6	Classifier Sensitivity to Disturbance.....	66
5.7	Summary	67
Chapter 6. Conclusions and Future Work.....		68
6.1	LDA and SVM Comparison	68
6.2	Myoelectric Classification for Stair Detection and Prediction	69
6.3	Future Work	70
References.....		71
Appendix A: Subject Consent Form.....		75

LIST OF FIGURES

Figure 2-1. Comparison of OAO and OAA SVM multiclass algorithms.....	17
Figure 2-2. K-fold Cross Validation	19
Figure 3-1. Experiment measurement system schematic.....	30
Figure 3-2. EMG electrode placements for the (a) Tibialis Anterior (amputee), (b) Tibialis Anterior (control), (c) Medial Gastrocnemius (amputee), (d) Medial Gastrocnemius (control), (e) Vastus Lateralis, and (f) Biceps Femoris.....	33
Figure 3-3. Placement of Telemyo local transmitters of EMG sensors from the (a) non-amputee anterior and (b) non-amputee posterior.....	34
Figure 3-4. Final placement of all sensors on control subject from the (a) anterior and (b) posterior and amputee subject from the (c) anterior and (d) posterior.	35
Figure 3-5. Modal course schematic.....	37
Figure 4-1. EMG and IMU sub-window definitions (HS – Heel Strike, TO- Toe Off) ...	41
Figure 4-2. Gait cycle subset from data collection to be included in classification	42
Figure 4-3. Average walking speed at each instructed speed for (a) amputee subjects and (b) non-amputee subjects	43
Figure 4-4. Combined confusion matrix for all amputee (LDA – (a), SVM – (c)) and non-amputee (LDA – (b), SVM – (d)) subjects for modal detection.	46
Figure 4-5. Redefinition of modes into other (OTR), stair ascent (SUP), stair descent (SDW) and transition modes (Trans1-4) from the previous data to specifically predict stair modality	48
Figure 4-6. Finite state machine for switching between modalities when predicting transitions between level ground and stair surfaces	49
Figure 4-7. Definition of lead and follow transitions for all mode transitions considered	50
Figure 4-8. Comparison of myoelectric and myoelectric – inertial fusion for both classifiers and subject populations.....	53
Figure 4-9. Generalized classifier accuracy for all amputee subjects when using (a) LDA and (b) SVM.....	55

Figure 4-10. Combined confusion matrix for all amputee (LDA – (a), SVM – (c)) and non-amputee (LDA – (b), SVM – (d)) subjects for modal detection when medial gastrocnemius electrode location is shifted..... 58

LIST OF TABLES

Table 2-1. Time-domain EMG features from previous research	22
Table 3-1. Selected muscles for EMG collection and electrode placement, as described in Delagi et al. (1975).	32
Table 4-1. Test subject demographics and statistics	40
Table 4-2. Comparison of classifier accuracy for both LDA and SVM using features sets that either include or exclude auto regressive coefficients	45
Table 4-3. Error of classification (%; mean \pm SD (count)) for predictive detection of follow transitions between (a) level ground to stair ascent/descent, (b) stair ascent to level ground, and (c) stair descent to level ground.	51
Table 4-4. Accuracy of classification for predictive detection of lead and follow transitions between (a) level ground to stair ascent/descent, (b) stair ascent to level ground, and (c) stair descent to level ground.	52
Table 4-5. The difference in classification accuracy for a shifted electrode compared to the original placement for all amputee (LDA – (a), SVM – (b)) and non-amputee (LDA – (c), SVM – (d)) subjects for all four muscles used by the myoelectric algorithm: Tibialis Anterior (TA), Medial Gastrocnemius (MG), Vastus Lateralis (VL), and Biceps Femoris (BF).....	57

ACKNOWLEDGEMENTS

A special thank you is due to several people within the VA Center of Excellence for Limb Loss Prevention and Prosthetic Engineering without whom, this project would not have been possible. Jan Pecoraro was responsible for both scheduling and addressing the needs of all research subjects. Mahyo Seyedali laid the foundation for this project through her investigation of transtibial amputee myoelectric patterns. In addition, her experience with myoelectric signals was essential towards data collections. Dr. Michael Hahn spent many hours advising, brainstorming, and forming the concepts and objectives of the current study. He has been and continues to be an invaluable resource whom I have enjoyed working with.

This study was supported by the VA RR&D Service and a Department of Defense grant (W81XWH-09-2-0142).

Chapter 1. INTRODUCTION

1.1 DEVELOPMENT OF PROBLEM

While many advances have been made in lower limb prosthetics over the past decades, the majority of current commercial lower limb prosthetic systems are passive and thus provide limited mobility to amputee populations. These devices are unable to respond similarly to the healthy ankle foot system which provides a significant impairment. The non-responsive nature of current commercial systems is largely due to the amputee's inability to control the function of the prosthetic device as they would an intact limb. A potential solution to this problem is incorporation of electromyography (EMG) signals and/or inertial measurement unit (IMU) sensors from the residual limb and its musculature into a prosthetic system that includes myoelectric control laws. EMG and IMU measurements were chosen as it is believed that muscle activations and lower limb kinematics will change when completing different walking modes. Despite the significant advances in upper limb myoelectric control strategies, limited advances have been documented for the lower limb. Such control strategies provide the potential to restore partial control of the prosthetic system back to the user and insure increased stability during complex movements. Before myoelectric control laws or IMU sensing systems can be incorporated into lower limb prosthetic systems, an increased understanding of the abilities and limitations of lower limb control laws based on EMG and IMU signals must be gathered.

1.2 BACKGROUND

The human ankle is responsible for various functions during normal gait including control of tibial progression, adjusting joint impedance, and controlling power absorption/return. How the ankle responds is dependent on the terrain over which it is traveling. Transtibial amputees lose normal ankle function which reduces their functional capabilities during everyday activities including level ground walking, ascending/descending ramps, and ascending/descending stairs, as well as more complicated maneuvers. This loss of functionality significantly reduces the transtibial amputee's quality of life making standard levels of mobility more difficult.

Recent advances in lower limb prosthetic technology have led to the development of intelligent prosthetic systems that are capable of changing function based on the needs of the terrain the amputee subject is navigating (Au, Berniker, & Herr, 2008). These advances, though encouraging, provide limited benefit without intuitive means of relating motion intent information from the amputee to the prosthetic system. These valuable connections are lost with amputation and result in increased instability. A potential method of replacing these connections is the use of EMG signals and other sensing systems from the amputee's residual limb. Electromyographic signals measure muscle activations which change with different functional modes and can still be under volitional control of the amputee subject.

Previous efforts have shown encouraging results outlining computationally efficient machine learning algorithms that are capable of determining walking modes of transfemoral amputees with accuracies above 90% for most steady state modes (Huang, Kuiken, & Lipschutz, 2009). Transitions and non-steady state modes have only been capable of accurate classification through a continuous algorithm that incorporated EMG and intrinsic force/moment measurements (Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011). However, this algorithm is computationally expensive and as a result is unlikely to be used in real world applications.

Myoelectric control has seen limited advances for transtibial amputees. The only inclusion of EMG measurements for mode selection required conscious muscle contraction and allowed for only limited mode selection (Au, Berniker, & Herr, 2008). Control laws for transtibial amputees have instead focused on muscle force reflex emulating controllers with the recent development of power generating ankle-foot prosthetic systems (Au, Berniker, & Herr, 2008; Eilenberg, Geyer, & Herr, 2010). These systems are novel in their ability to provide powered plantar flexion in a similar magnitude as the intact ankle foot system and to adjust propulsive power output with changing speeds and when ascending/descending ramps. This adaptive ability is dependent on the prosthetic system's ability to generate powered plantar flexion in response to intrinsic sensors, which is currently only available in a single prosthetic system. Despite this system's adaptive nature to limited modes, motion intent detection may yet allow for extended capabilities and more natural function.

1.3 STATEMENT OF PURPOSE

The cost and response of power generating ankle foot prosthetic systems may make them unrealistic or undesirable for the entire transtibial amputee population. A power generating prosthetic system is defined as a prosthetic that generates net work as part of its function in order to mimic powered plantar flexion or other features of the healthy ankle function. Alternatively, passive prosthetic systems generate no work, but store and release energy through a flexible spring or other low power mechanism. New advances in prosthetic technology have placed focus on developing a foot ankle system that generates positive power (Au, Berniker, & Herr, 2008). It is believed that transtibial amputees could still benefit from an intelligent prosthetic system that responds to different terrains, but is instead passive. Such an ankle foot system is currently under development by our collaborators at the University of Michigan. It is the goal of the current study to explore the use of myoelectric mode switching control specifically for use with a passive prosthetic system. Such a myoelectric mode control law will provide the amputee subject with more prosthetic options while still allowing for fluid control of the prosthetic during complex ambulation.

Previously published work towards mode switching myoelectric control has focused on transfemoral amputees (Huang, Kuiken, & Lipschutz, 2009; Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011). The preliminary work focused on differentiating between several steady state walking modes without including mode transitions. Ensuring that myoelectric classification of similar accuracies is possible during transition periods will allow for more real world uses of myoelectric classification and help insure that the prosthetic system has a stable response which the patient can anticipate. The only lower limb myoelectric controller that is capable of predicting transitions as well as steady state modes is a continuous controller that fuses EMG and load cell measurements. Such a controller is computationally expensive to operate and train appropriately. The overall goal of this project is to develop a computationally efficient myoelectric controller that is similarly capable of predicting mode transitions in the real world environment for transtibial amputees.

Lower limb myoelectric control studies have overlooked the issue of how the stability of classification is affected by disturbances and inconsistency of the EMG signal. These disturbances will likely have a negative effect on the accuracy of mode classification. How

disturbances affect classification and how to mitigate potential risks must be addressed before the realistic implementation of myoelectric mode control.

1.4 SPECIFIC AIMS OF STUDY

1.4.1 Measure EMG and IMU from transtibial amputees in several modes

The first step towards myoelectric control for transtibial amputees will be recording EMG and IMU measurements from transtibial amputees and non-amputee subjects during normal movement over several walking modalities. The primary modalities will include level ground walking, ramp ascent/descent, and stair ascent/descent based on previous successful classification through myoelectric signals (Huang, Kuiken, & Lipschutz, 2009). In addition, signals will be recorded over varying speeds (self selected, fast, and slow) in order to simulate the varying nature of level ground walking. Unlike previously reported research, this data collection will be collected outside the lab in a more realistic environment.

1.4.2 Transtibial myoelectric mode classifications (steady state and transitional)

Similar to the techniques used in previous transfemoral amputee mode classification algorithms, EMG and IMU measurements will be used to determine the mode classification ability and accuracy when using these signals with machine learning algorithms. The ability of traditional classification algorithms will be compared with newer methods. Developed classifiers will seek to combine computational simplicity with accuracy of predictions during both steady state and transition modes.

1.4.3 Effects of disturbances on mode classification

Disturbances of EMG signals have been explored for upper limb myoelectric mode control algorithms and shown a slight reduction in error to disturbance. The most problematic disturbances will be simulated for the lower limb and the effects on the myoelectric controller will be detailed.

1.5 LIMITATIONS

When working with human subject data, there is always the potential that the research sample does not accurately reflect the characteristics of the larger population. Based on the

diverse population of lower limb amputees, this is certainly a possible risk. Additionally, for all experimentation amputee subjects used their prescribed prosthetic foot, which was passive and non responsive to terrain changes. Using an intelligent prosthetic system is likely to change the way that amputee subjects ambulate especially if the prosthetic changes function based on walking mode. These changes will likely affect the EMG signals which may affect the stability of the myoelectric control law. The magnitude of this effect remains unknown. This project is part of a preliminary effort to evaluate the potential for myoelectric control in such a prosthetic device. Based on the results, future work could include exploring how to train such a controller as well as how stable the myoelectric control law is when applied in a more adaptive human-prosthetic system.

Chapter 2. LITERATURE REVIEW

Of the estimated 1.6 million patients that have experienced limb loss within the United States, 45% include major lower limb amputees. By comparison, major amputations of the upper limb include 8% of these patients. Major amputations in this estimate included amputations of the foot/hand or more proximal amputations and excluded the amputation of individual digits. In addition, the total number of general amputees is expected to double by the year 2050 (Ziegler-Graham, Mackenzie, Ephraim, Trivison, & Brookmeyer, 2007).

Despite this statistic, the majority of intelligent prosthetic systems utilizing myoelectric control or a similar form of user control are focused on upper limb amputees (Oskoei & Hu, 2007). Until recently, myoelectric control algorithms did not exist for lower limb amputees (Huang, Kuiken, & Lipschutz, 2009). The continued advancement and implementation of these algorithms is expected to have a significant benefit on the quality of life of lower limb amputees.

The focus of this study was to develop myoelectric mode classifications for transtibial amputees. Myoelectric control algorithms require a multidisciplinary approach with an understanding of physiological signals and their origins, general gait biomechanics, and machine learning algorithms. Each of these topics will be reviewed in this chapter as they apply to transtibial amputees. Lower limb and general myoelectric control laws that have been presented in previous literature will also be discussed as well as their potential limitations.

2.1 MYOELECTRIC SIGNALS AND INERTIAL MEASUREMENTS

The fundamental commonality in all myoelectric control algorithms is the use of EMG signals to relate motion intent information from the amputee subject to the controlled device. An understanding of what EMG sensors are recording and how the signal changes with muscle activation is required. Physiologic signals (more so than mechanical measurements), and specifically EMG signals are known to demonstrate intra and inter subject variability even under similar measurement conditions (Vigreux, Cnockaert, & Pertuzon, 1979; Clancy, Morin, & Merletti, 2002). Since all myoelectric control schemes rely heavily on measurements from the EMG signal, minimizing and adjusting to signal variability will be important to preserve the accuracy of the myoelectric control law. Changes to the EMG signal which are not the result of changes in the underlying muscle activation will be termed signal disturbances. These disturbances will be discussed.

Inertial measurement systems, specifically those used in lower limb applications, will also be discussed. These systems have previously been shown to provide reasonable estimations of joint kinematics (Mayagoitia, Nene, & Eltink, 2002; Williamson & Andrews, 2001). It may also be possible to use them in conjunction with EMG signals to improve the accuracy of myoelectric classification.

2.1.1 EMG Signal Content

Skeletal muscles are constructed of groups of motor units that are capable of generating contraction and as a result, tension. Each of these motor units is further separated into individual muscle fibers. In order to generate a contraction, neural stimulation of the muscle fibers is required. Similar to the nervous system, stimulation of a muscle fiber results in a change in the electrical potential of the fiber. This change in electrical potential is the source of EMG signals. Inferences of muscle contraction level can be extracted from EMG recordings based on changes to the signal during neural activations. When the nervous system is attempting to induce higher muscle contraction levels, the nervous system either stimulates more motor units or stimulates the existing motor units at an increased frequency. Since the EMG signal reflects the activations of the muscle fiber potentials within each motor unit, the recorded EMG signal similarly increases in magnitude and/or frequency based on the changes to the stimulated muscle fibers. The amplitude of EMG recordings can range between a fraction of a μV to several hundred μV with frequency content up to 2 kHz, which fluctuates based on the level of muscle activation (Fridlund & Cacioppo, 1986). Within this range, muscle signals generally occur between 10 and 200 Hz (Hayes 1960; Fridlund & Cacioppo, 1986).

The majority of EMG recording techniques use a bipolar electrode configuration, which consists of two sensing electrodes and a common ground electrode. The electrical potential is measured between the two sensing electrodes relative to the ground electrode. The two signals are then differentiated and reported as the EMG signal. Historically, monopolar electrodes have been used for EMG recording, measuring the electrical potential between a sensing electrode and a ground electrode. However, monopolar electrodes detect any electrical signal within the area of placement as opposed to sensing directly the underlying skeletal muscle activations. Differentiating two monopolar signals removes the electrical signal not associated with the

whole body resulting in an EMG signal which is more comprised of the skeletal muscle electrical stimulation (Nigg & Herzog, 1999).

Electromyography sensors can either be indwelling or surface type sensors. Indwelling sensors are placed subcutaneously and used to measure intrinsic electrical signals or electrical signals from deep muscle groups. Surface sensors can be used to measure EMG signals from superficial muscles, but unlike indwelling sensors, the electrical signal is insulated by the skin and subcutaneous tissue. Surface sensors, however, avoid the need for invasive implantation.

Several noise and signal attenuation sources are prevalent in EMG signals. The most easily accounted for includes the electrical impedance of the skin and subcutaneous tissue between the EMG sensor and the muscle body. This impedance reduces the muscle based electrical signal present at the surface of the skin where EMG is recorded, effectively increasing the signal to noise ratio. As may be expected, the magnitude of electrical impedance increases with thickness of the superficial tissue. The loss of physiological muscle signal can be mitigated by cleaning the surface of the skin prior to electrode placement, removing hair, and coating the skin in conductive gels, all of which reduce the magnitude of tissue impedance and allow for richer signal content (Clancy, Morin, & Merletti, 2002).

Similar to many measurements, motion artifact is a large source of noise for EMG signals which is present in two forms: electrode motion artifact and cable motion artifact. Electrode motion artifact is characterized by electrical potential fluctuations that occur as a result of the electrode moving relative to the surface of the skin as well as relative to the muscle body as the skin deforms due to pressure or movement. Use of recessed electrodes which consist of a gap between the surface of the skin and the electrode which contains a conductive gel is an effective damper for this form of motion artifact. Additionally, since electrode motion artifact occurs at a low frequency (less than 20 Hz), the noise can be attenuated by using a high pass filter without significant loss of physiological muscle signal (Clancy, Morin, & Merletti, 2002).

Cable motion artifact occurs due to motion and bending of the wire connection between the EMG sensor and the recording source which affects the wire's internal resistance and skews the electrical potential recordings in an unpredictable manner. This motion artifact is known to occur at frequencies below 50 Hz. The optimal method to reduce this noise source is to securely fasten all cables to the subject in order to reduce motion at high frequencies. It is also possible to use an active electrode. This includes the use of an operational amplifier which magnifies the

EMG signal at the collection sight but does not amplify the cable motion artifact which is generated during transmission to the recording source. As a result, the final recorded signal has a greater magnitude and is more comprised of physiological signal (Clancy, Morin, & Merletti, 2002). Use of an active electrode will likely not be optimal for myoelectric control based on the power requirements and the increased profile required to house the amplifier. The increased electrode profile reduces the feasibility of recording signals within the prosthetic socket. High pass filtering of EMG signals can be used to mitigate the motion artifact. However, since the range of possible frequencies overlaps the range of physiological signals, this is not an optimal approach.

The final noise source is power-line interference resulting from the alternating current (AC) voltage source of the electrical sensors. Use of the alternating current through the wires generates a magnetic field surrounding the wires which in the vicinity of the EMG sensor generates a false signal that can be much greater than the EMG signal itself. Due to the consistency of the voltage source, the power line interference is presented at 60 Hz and its harmonics for 120 V sources. Shielding the EMG sensor from the magnetic field can reduce the presence of the power line interference by blocking the magnetic signal from the EMG sensor. Notch filtering of the signal can also be used to attenuate the power line interference, but has the potential to similarly attenuate physiological signal as the frequency of the interference overlaps the range of physiological signal frequencies (Clancy, Morin, & Merletti, 2002).

2.1.2 Amputee EMG Signals

During a transtibial amputation, the muscles of the shank are transected along with the bone and soft tissue of the limb while the more proximal thigh musculature remains unaffected. Despite the intact nature of the proximal musculature, muscle activation signals have been observed to be significantly different in the amputated limb of transtibial amputees compared to the unaffected limb and control sampling. This is suggested to be a result of compensatory mechanisms to overcome musculoskeletal limitations in gait due to the missing limb (see Section 2.2.2).

Based on the transected nature of shank muscles for the transtibial amputee as well as the relocation of attachment points, it is expected that EMG and general muscle activation patterns for these muscles will vary significantly between control subjects and transtibial amputees.

However, there is limited work focusing on the analysis of these signals which makes predictions of the signal content difficult. Despite the lack of information regarding signal content, it has been shown in previous myoelectric control efforts that transected muscles for both transfemoral (Huang, Kuiken, & Lipschutz, 2009; Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011) and transtibial amputee (Au, Bonato, & Herr, 2005) generate enough unique content to be useful.

2.1.3 Consistency of EMG Signal

The consistency of EMG signals has been questioned with regard to myoelectric control as EMG signal has been observed to be affected by sensor location (Vigreux, Cnockaert, & Pertuzon, 1979)(Nigg & Herzog, 1999), magnitude of contraction (Broman, Bilotto, & De Luca, 1985), and muscle fatigue (West, Hicks, Clements, & Dowling, 1995), among other factors. Any myoelectric control scheme is dependent on the consistency of signals in order to provide motion intent from the amputee subject to the prosthetic system in a repeatable fashion. Of the noted disturbances, location shifting has been observed to have the most significant effect on myoelectric classification and muscle fatigue has been observed to have the least effect (Tkach, Huang, & Kuiken, 2010).

The above referenced disturbances were simulated on an upper limb amputee while the myoelectric classifier attempted to separate between different hand motions. In the experimentation, electrode shifting was simulated by recording EMG signals from adjacent locations along the muscle body simultaneously. A sudden shifting of electrode was reproduced by switching the EMG channel used during classification. Such a sudden shift is likely to occur during real world use of myoelectric classifiers and will be experienced on a daily basis as the placement of a prosthetic on the residual limb varies throughout the day and when the prosthetic is donned and doffed. It was observed that upper limb myoelectric classifier accuracy is reduced due to disturbances in EMG signals (Tkach, Huang, & Kuiken, 2010). The effects of these disturbances have not been evaluated on lower limb myoelectric classification.

2.1.4 Inertial Measurements

Inertial measurement units (IMUs) consist of accelerometers, rate gyroscopes, and/or other mechanical sensors that are used to measure the kinematics of a rigid body. These systems have been used in the estimation of lower limb kinematics (Mayagoitia, Nene, & Veltink, 2002) and the control of orthotic and prosthetic systems. Examples of IMUs as control signals for

prosthetics and orthotics include detection of gait events (Moreno, Rocon de Lima, Ruiz, Brunetti, & Pons, 2006), instability/fall detection (Lawson, Varol, Sup, & Goldfarb, 2010), and finite state control (Zlatnik, Steiner, & Schweitzer, 2002) among others. As the lower limb is generally assumed to be a set of rigid bodies connected through articulating joints (ankle, knee, and hip), placement of IMUs on the major segments of the leg is sufficient to characterize the kinematics of the lower limb. These segments can include the foot, shank, thigh, and upper body.

In general, IMUs are light weight and easily accessible which makes them promising for prosthetic control. It is expected that different walking modalities will experience varying kinematic patterns for both healthy and lower limb amputees based on the changing function of the limb. With the cyclic nature of gait, it is expected that these changes in kinematic features will be detectable and assist with the classification of locomotion task. It has been previously shown for upper limb myoelectric classification that inclusion of accelerometer signals significantly increases the classification accuracy (Fougner, Scheme, Chan, Englehart, & Stavdohl, 2011). Similar benefits are expected to be seen for lower limb classification.

2.2 HEALTHY AND AMPUTEE GAIT

The loss of normal lower limb function affects the amputee's ability to achieve normal gait patterns as well as more complicated tasks such as managing stairs or ramps and turning. In this section the normal function of the human lower limb as well as the adaptations the lower limb amputee uses to overcome the limitations of non-responsive prosthetics is briefly outlined. Focus is placed on potential improvements to amputee quality of life when using intelligent prosthetic systems.

2.2.1 Healthy lower limb function

Normal gait patterns over level ground follow a cycle which repeats with each heel strike of the same limb. The four primary phases of each cycle include controlled plantar flexion, stance, pre-toe off, and swing. The function of the lower limb changes for each phase, which is reflected in different muscle activations and as a result, significantly changes EMG signals over each phase (Huang, Kuiken, & Lipschutz, 2009). Controlled plantar flexion occurs between heel strike and foot flat. During this phase the foot contacting the ground is accepting the weight of the body. Slight plantar flexion of the ankle is observed which allows the full profile of the foot to contact the ground. With full foot to ground contact, the stance phase begins. The shank

rotates over the foot during this phase allowing for forward motion of the body and results in dorsiflexion of the foot. As the foot prepares to leave contact with the ground, weight is focused on the toe section of the foot. This initiates the pre-toe off phase. It is during this phase that the mechanical power of the foot is generated through full plantar flexion of the foot to propel the body superiorly and anteriorly. As the toe leaves the ground, the swing phase of gait is begun. During this phase, the foot is not in contact with the ground and returns to neutral position in anticipation of the next heel strike.

The functional response of the healthy ankle changes considerably with speed of level ground walking and with more complicated gait phases (i.e. stair ascent/descent, ramp ascent/descent, and turning). The healthy ankle switches from a net energy absorbing structure at slow walking speeds to net energy generation at faster walking speeds. During the first approximately 80% of the stance phase of gait, the ankle is absorbing energy. For slow walking speeds, the amount of energy produced by the ankle during pre toe off is less than the total energy already absorbed. As the speed of gait is increased, the amount of power generated pre toe off is increased and the onset of power release is observed sooner in the stance phase of gait, which results in a net energy increase for walking speeds above self selected (Hansen, Childress, Miff, Gard, & Mesplay, 2004).

For transitions between level ground walking and ramp ascend/descent, it has been observed that lower limb kinetics do not change until the late swing phase of gait directly before contact with the ramp. The stance phase kinetics of the transition cycle is similar in nature to normal self selected level ground walking speeds (Redfern & DiPasquale, 1997; Prentice, Hasler, Groves, & Frank, 2004). After the transition period, it was observed that ramp ascent gait cycles were associated with increased energy production by the ankle, knee, and hip joints (Prentice, Hasler, Groves, & Frank, 2004). Intuitively, ramp descent studies show decreases in energy generation of the lower limb specifically for the ankle joint where there is less power generation at toe off (Redfern & DiPasquale, 1997).

As expected, the ankle angle and moment profiles of stair ascent/descent do not resemble level ground walking profiles. Most notably, when descending stairs the ankle assumes a fully plantar flexed position prior to stair contact with ankles angles around 20° plantar flexed (Protopapadaki, Drechsler, Cramp, Coutts, & Scott, 2007). This allows the ankle to accept the weight of the subject on the toe of the foot, eccentrically controlling the resulting dorsiflexion.

During the swing phase, the ankle returns to a plantar flexed orientation. Alternatively during stair ascent, the ankle begins slightly dorsiflexed at heel strike and transitions into a plantar flexed orientation during toe off. During swing phase the ankle angle returns back to its original slightly dorsiflexed position. While stair ascent is more closely related to ankle angle profiles of level ground walking, distinct differences are observed; the most notable of which is the significant reduction in dorsiflexion during the stance phase of gait (Protopapadaki, Drechsler, Cramp, Coutts, & Scott, 2007).

The differences in gait during these different walking modes emphasize the need for a prosthetic system that responds to different walking terrains. Ideally, the prosthetic limb would respond similarly to the healthy ankle for transtibial amputees during all walking modes experienced by the typical subject. The current limitations of commercially available passive prosthetic systems do not allow for this change in functionality.

2.2.2 Functional adaptations-transtibial amputees

For transtibial amputees, the loss of plantar flexor muscle function is the most detrimental musculoskeletal result of amputation. In unimpaired gait it is estimated that this muscle group is responsible for generating 80% of the lower limb's power (Oliveria, Yamaguti, Mochizuki, Amadio, & Serrao, 2009). The loss of ankle power generation has been observed to increase metabolic energy costs in transtibial amputees by 20-30% when compared to control subjects (Waters & Mulroy, 1999; Calbourne, Naumann, Longmuir, & Berbrayer, 1992). These increased energy costs suggest that transtibial amputees are less likely to remain active for longer periods and less likely to complete more complicated gait patterns.

In addition, the inability to voluntarily modulate the ankle function gives the amputee less control over stability. In order to compensate for the lack of functional ankle control, the transtibial amputee adjusts his or her normal gait cycle by modulating the residual limb and unaffected limb which are still functional for many amputee subjects. It has been observed that unilateral transtibial amputees have asymmetric gait patterns, with less time spent in stance phase of gait, decreased stride length (Powers, Rao, & Perry, 1998) and reduced ground reaction forces on the amputated side (Beyart, Grumillier, Martinet, Paysant, & Andre, 2008) when compared to the intact limb and non-amputee populations. These observations suggest that the amputee

subject lacks confidence in their replacement limb. These functional changes to amputee gait cycles result in reduced self selected walking speed (Powers, Rao, & Perry, 1998).

The kinetics of the residual limb knee and hip are also adjusted in transtibial amputees. To compensate for the loss of normal ankle function, the hip increases the power absorption during early stance and increases power generation during toe off (Winter & Sienko, 1988). Over long periods of time, this increased activity of the hip joint has been attributed to increased pain in the residual limb and correlates with the onset of joint arthritis (Postema, Hermans, Vries, Koopman, & Eisma, 1997). The knee of the residual limb alternatively shows less power absorption and generation for transtibial amputees. This is due to the increased co-contraction of the thigh extensor and flexor muscle groups of the knee (Powers, Rao, & Perry, 1998).

By developing a more intelligent prosthetic system that reacts and responds to the amputee's changes in gait, it is hoped that the amputee's sense of stability will increase and reduce the need for compensatory mechanisms.

2.3 MACHINE LEARNING

Machine learning techniques are a broad branch of algorithms used to predict results and outcomes based on potentially unobservable patterns in correlating inputs. These classifiers are typically trained based on a sample set of data and are expected to detect similar patterns in new data sets in order to provide continued classification for novel examples. A wide range of machine learning and pattern recognition strategies have been used to interpret motion intent from EMG signals. Machine learning allows for the detection of changes in the EMG signals that are relevant to a functional change in the use of the prosthetic which may not be otherwise detectable. The optimal machine learning algorithm for myoelectric control would be computationally inexpensive and highly accurate while still allowing for rapid training and even provide the potential for adaptive, online learning. Linear discriminant analysis has been used frequently in myoelectric classification work due to its high functionality and low computational cost. More recently, alternative machine learning algorithms have also been explored.

2.3.1 Linear Discriminant Analysis

Linear Discriminant Analysis (LDA) has been used extensively in myoelectric control algorithms because it is computationally simple to resolve, provides accurate, fast classifications, and allows for multiclass prediction with a single (Oskoei & Hu, 2007; Huang, Kuiken, &

Lipschutz, 2009). Generally, LDA operates by using a linear regression to create a defining boundary between classes based on relevant features. Features of the class are measurements that reflect information that could be used in separating between classes (see Section 2.4.2). A fully trained LDA classifier is defined by a weight vector, w , and bias constant, b . When classifying data, a features vector, x , is evaluated in eq. 2.1 which defines the linear boundary between different classes. The sign of the result defines which class the data set is classified as since $y=0$ defines the separating boundary.

$$y = w^T x + b \quad 2.1$$

2.3.2 Support Vector Machine

Support Vector Machine (SVM) classifiers are an extension of LDA with three distinct differences: 1) SVM optimize the boundary between defined classes, 2) SVM allows for nonlinear separation through use of kernels, and 3) SVM only use a subset of the training data to define the boundary. SVM is named for its use of “support vectors” in generating separation boundaries. Support vectors are training set data which are the closest to data sets of a different class within the feature space. Only these data points are used to define the separation between classes which allows the classifier to ignore data points that are well separated from other classes. In LDA, these well separated data points can result in skewing of the linear boundary which may result in decreased accuracy for new data sets.

$$\text{Min} \left[Q(w) = \frac{1}{2} \|w\|^2 \right] \quad 2.2$$

$$y = K(w, x_j) + b \begin{cases} \geq 1 \\ \leq -1 \end{cases} \quad 2.3$$

While LDA uses regression to define the boundary between different classes, SVM selects the optimal boundary which maximizes the separation between the boundary and the training data sets while still separating the classes of the training data set. The fundamental optimization problem is provided in eq.2.2. When evaluating the classifier to new data sets, eq. 2.3 is used to define the linear boundary between the classes. Similar to LDA, the sign of the result determines the predicted class (Abe, 2005).

The function K defines the kernel. Different kernels can be used to provide better classifications and allow for nonlinear separations. Kernels provide a mapping from the original

feature space into a new space which appears linear in its projection. The two most common kernels used are the linear eq. 2.4 and radial basis function eq. 2.5 (Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011)(Abe, 2005). Examples of other suggested kernels include neural network kernels and polynomial kernels of any degree (Abe, 2005). Any user defined function can be used as a kernel which makes the number of possible kernels infinite.

$$K(x_i, x_j) = w^T x_j \quad 2.4$$

$$K(x_i, x_j) = \exp(-\gamma \|w - x_j\|^2) \quad 2.5$$

The original optimization problem is a quadratic program formulation which is computationally expensive to solve. The dual form of the original optimization problem can be represented as eq. 2.6. This formulation produces a similar result as the original optimization problem, but it instead uses sequential minimum optimization (SMO) to iteratively solve for α_i which can then be related to w using eq. 2.7. The range of possible values of α_i is limited by the operator defined constant C , the slack variable. The original optimization problem determines a boundary between the classes for which the entire training data set is accurately classified. For many classification problems this is desired. However, if there is an outlier on the training data set, this rigid constraint can lead to training a classifier that is poorly formulated to make new predictions. The slack constant allows for an optimized solution which misclassifies distinctive training set data that does not follow typical trends to overcome this limitation. Choosing a large slack constant will enforce a firm boundary and reduce the number of training set misclassifications and vice versa. Defining the slack constant as infinity will define a rigid boundary similar to the original optimization problem (Abe, 2005).

$$\text{Min } [Q(\alpha_i) = \sum_{i,j=1}^M \alpha_i \alpha_j y_i y_j K(w, x_j) - \sum_{i=1}^M \alpha_i] \quad 2.6$$

$$0 \leq \alpha_i \leq C$$

$$w = \alpha_i y_i \quad 2.7$$

Unlike LDA, SVM are inherently limited to binary classification (separations limited to two states) because of the form of the optimization problem used to train the classifier. In order to allow for classifications between several states, multiclass algorithms must be utilized. The two most common multiclass algorithms for SVM are one against one (OAO) and one against all

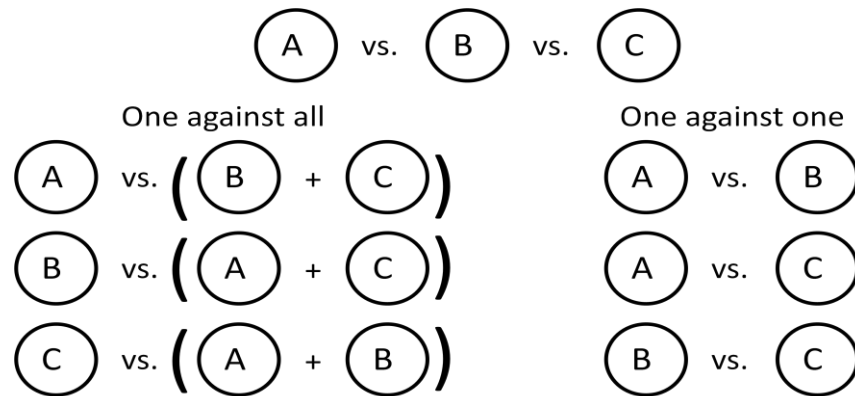


Figure 2-1. Comparison of OAO and OAA SVM multiclass algorithms

(OAA) (Hsu & Lin, 2002). In Figure 2-1, a visual comparison of both multiclass algorithms is provided which show sample (though not complete) separations between classes using these multiclass methods. Both algorithms involve training multiple SVM classifiers to recognize the difference between the distinctive classes.

For the OAO multiclass algorithm, a SVM is trained for comparisons between each individual class (i.e. Class A vs. Class B, Class A vs. Class C, Class B vs. Class C, etc.) utilizing only training data from the two classes the classifier is focusing on. Similar SVM separations for each combination are trained until a classifier exists to compare every possible state to every other non-identical state. This results in $n*(n-1)/2$ total classifiers where n is the number of possible classes. Alternatively, OAA algorithms train classifiers by making separations between a specific class and all other possible classifications (i.e. Class A vs. not Class A, Class B vs. not Class B, Class C vs. not Class C, etc.) utilizing all training data.

When the trained classifiers are used for predicting the class of a new set of data, each classifier is evaluated and a voting scheme is used to determine the overall correct classification. When using the OAO multiclass algorithm, each predicted class receives a “vote” for that class as each classifier is evaluated. For the OAA algorithm, if the separated class is selected (i.e. Class B predicted over not Class B) that class receives a single vote. If that class is not predicted, all other classes receive a vote. Regardless of the voting scheme, the class with the most votes when all classifiers have been evaluated is selected as the overall predicted class (Hsu & Lin, 2002).

Ties between classes are inevitable regardless of the voting scheme. As such, rules for breaking ties are well outlined. When using the OAO multiclass algorithm, ties are resolved by accessing the classifier trained to separate between the two tied classes. Whichever class is predicted by this classifier is selected as the final class. The OAA algorithm resolves ties by evaluating the classifier trained to separate the tied class against all other classes. The class that shows the furthest separation from the defined boundary is defined as the selected class (Abe, 2005).

Each multiclass algorithm has inherent benefits. Most notably, significantly fewer classifiers are needed to be trained when using the OAA multiclass algorithm. This results in a reduction in both the time needed to train the classifiers and also the time required for prediction when the classifier is being used. The difference in the number of classifiers when using OAA and OAO algorithms increases with the number of possible classes. This reduction in classifiers results in a loss of accuracy as use of the OAO algorithm has seen better classification accuracy for both general SVM use (Hsu & Lin, 2002) and in classification of myoelectric signals (Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011).

2.3.3 K-fold Cross Validation

When evaluating the accuracy of any machine learning algorithm it is necessary to ensure that the classifier is capable of accurately predicting the proper class for data sets that were not used to train the classifier. This shows the robustness and flexibility of the classifier. It is also more realistic as the functional use of the classifier will likely be making classifications of new data sets based on only a subset of previous examples. If the accuracy of the classifier were evaluated by training the classifier using all available data and evaluating the accuracy of classification with the same data set, the classifier would be receiving more information than it normally would prior to making each classification.

K-fold cross validation, Figure 2-2, is used to correctly determine the classifier's accuracy to new data sets. When using a finite data set, classifier accuracies are evaluated by separating the data into training and test data sets. The training data set is used to train the classifier while the test data set is used to evaluate the classifier's accuracy. Both the training and test data sets are subsets of the original data and share no similar data points. Separations

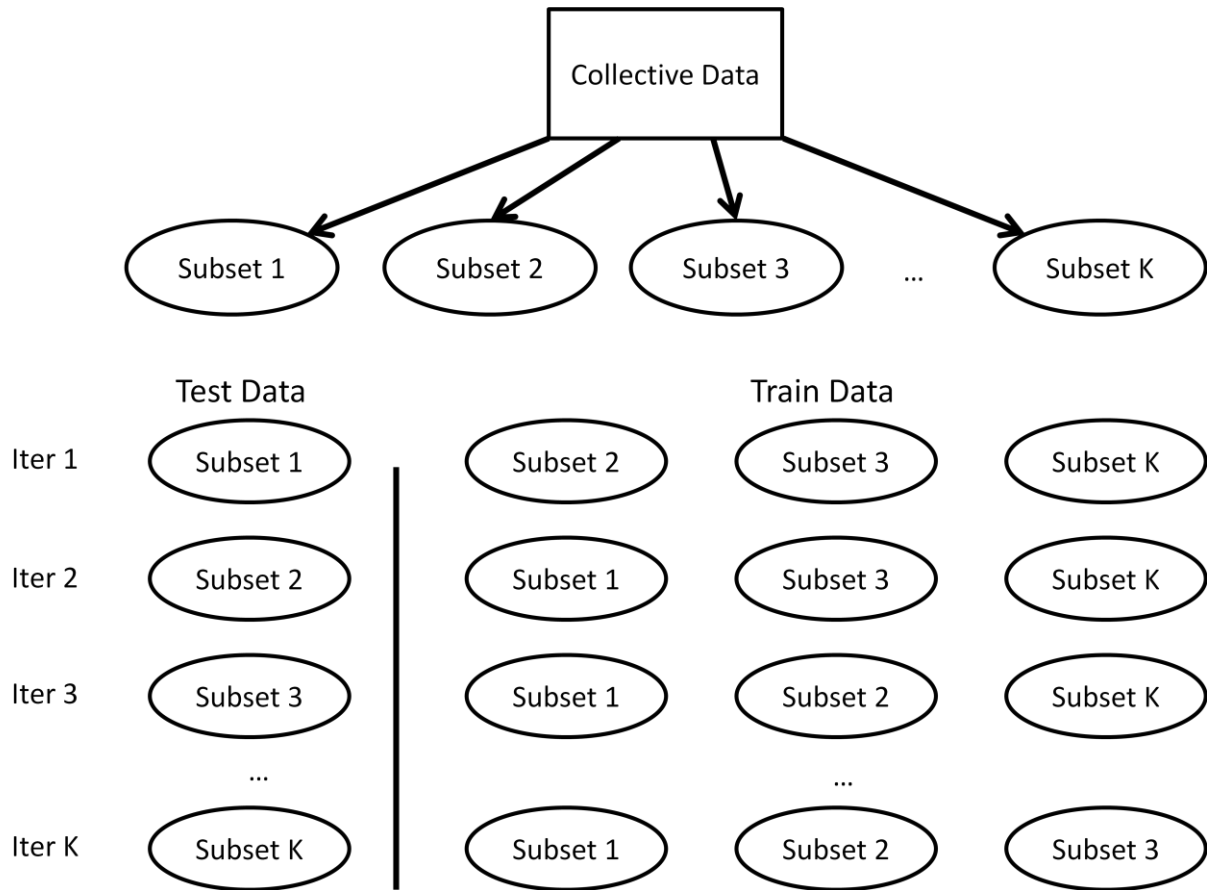


Figure 2-2. K-fold Cross Validation

between training and test data sets are operator defined with the only requirement being that training set must contain examples for all possible classes.

It is undesirable to select a static training and test data set to evaluate the accuracy of the classifier as it does not show the capabilities of the classifier when using a variety of training data sets. Additionally, with static separations it is possible that the classifier accuracy will either be over or under estimated based on a favorable or unfavorable separation of the data. Several iterations of training and test data sets are defined in order to mitigate this risk. The number of iterations, K , is based on the number of subsets the data is divided into. The final accuracy of the classifier is defined as the combined accuracies of the classifier when evaluating test data sets.

2.4 MYOELECTRIC CONTROL

Typical pattern recognition myoelectric controlled prosthetics contain four primary steps: signal segmentation, feature extraction, signal classification, and controlled response (Oskoei &

Hu, 2007). The first three are computational processes that will be discussed in some length. The final (controlled response) details how the intelligent prosthetic system responds to the EMG signal instructions. The goal of this study is to produce an algorithm that is generalizable across a variety of prosthetic systems. How the prosthetic responds will need to be decided based on the capabilities of prosthetic system that is being controlled and function of the healthy foot and ankle. As such, the controlled response phase will not be discussed. Previous myoelectric control algorithms will be detailed with a focus on limitations and potentials for improvement.

2.4.1 Signal Segmentation and Window Definition

The first step in pattern recognition based myoelectric control is segmenting the physiological signal. During segmenting, a window is defined as a period of time during which the signal is evaluated and relevant features are extracted (section 2.5.2). Traditional segmenting for continuous myoelectric classification algorithms takes one of two forms: adjacent windowing and overlapping windowing. Adjacent windowing segments the data into even time intervals with the following window beginning at the end of the previous. Alternatively, overlapping windows are windows of even length that are separated by a uniform change in time (aka. overlap window) which is less than the window length and results in windows that overlap each other. The time length of segment windows and overlap windows is defined by the designer based on practical considerations. Longer segment window lengths result in a longer post processing time delay and controller delay while shorter segment window lengths reduce accuracy of prediction (Englehart & Hudgins, 2003; Oskoei & Hu, 2007). A practical compromise is derived by choosing relatively long segment window lengths with short overlap windows. This provides the stability of long segment windows, but also provides fast response time as windows are analyzed more rapidly based on the short length of the overlap window. However, the computational power required for processing EMG signals increases for overlapping windows and further increases with longer segment windows and shorter overlapping windows. Regardless of computational power, the overlap window length is limited by the post-processing time delay in order to avoid simultaneous computing (Englehart & Hudgins, 2003; Oskoei & Hu, 2007).

In the case of lower limb myoelectric control algorithms, the cyclic nature of gait allows for different windowing options. Windows can instead be based on repeated, detectable events

within the gait cycle. The defined window in this case would be a constant time interval either before or after the chosen event. Example events include either heel strike or toe off (Huang, Kuiken, & Lipschutz, 2009) which can be detected based on contact or lack of contact of the prosthetic with the ground. This windowing scheme can be used to make classifications about the entire gait cycle which is more computationally efficient when compared to continuous classifications.

Additionally, window lengths must be chosen to avoid a noticeable delay from when the subject changes their motion intent until the active control of the prosthetic occurs. It is generally accepted for upper limb prosthetic system that time delays in excess of 300 ms result in a noticeable delay for the amputee (Oskoei & Hu, 2007). This requirement is unlikely to transfer over to lower limb myoelectric control applied to the gait cycle due to the short nature of each stride which is typically less than 1 sec per stride. The maximum feasible time delay for lower limb prosthetics has not been evaluated.

2.4.2 Feature Extraction

Dimensionality reduction of the EMG signals into representative features is required in myoelectric control schemes due to the complex structure of EMG signals. These features are meant to represent the original physiological signal to the classifier in a repeatable and focused manner. Extracted features have been categorized into three groups: time-domain, frequency-domain, and time-frequency domain (Englehart K. , Hudgins, Parker, & Stevenson, 1999). Time domain features are defined by the ability to be calculated from discrete time series values and are typically related to the magnitude of the EMG signal. Frequency domain features explore the frequency content of the EMG signal in order to determine predominant frequencies within the signal and typically utilizing Fourier transforms. Time-frequency features investigate the frequency content of the signal over distinct periods of time and evaluate how the frequency content of the signal changes over time. These representations are used as it has been observed that both the magnitude and frequency of EMG signals increase with increased muscle activation due to increased electrical stimulation of the muscle.

The complexity and computational costs of each feature tend to increase from time domain to frequency domain to time frequency domain features (Oskoei & Hu, 2007; Englehart K. , Hudgins, Parker, & Stevenson, 1999; Englehart, Hudgins, & Parker, 2001). In addition,

frequency and time-frequency signals require larger data window lengths in order to insure the stability of the features. This results in a longer response time between the change in signal and the actuation of the prosthetic (Oskoei & Hu, 2007). In the interest of fast response times, time domain features are highly favored for real-time applications although it has been shown that frequency and time-frequency realizations better represent the signal and result in better classifications (Englehart, Hudgins, & Parker, 2001). A list of prevalent time domain features from previous research, as well as how to calculate each feature is shown in Table 2-1.

In order to estimate the frequency change of EMG signals without Fourier transforms or similar analysis, time domain features are used such as wavelength, number of zero crossings, slope sign changes, and autoregressive coefficients. While these features do not provide exact frequency signals, they do modulate as the frequency of the signal changes and require significantly less computational power to calculate when compared to Fourier transforms (Englehart, Hudgins, & Parker, 2001). As a result it has been suggested previously that proper combination of these features along with magnitude based time domain features should be combined in order to best represent the EMG signal in an efficient manner for real time control (Englehart & Hudgins, 2003; Huang, Kuiken, & Lipschutz, 2009). Despite this recommendation,

Table 2-1. Time-domain EMG features from previous research

Feature Name (Abrev.)	Formula
Mean Absolute Value (MAV)	$\bar{x} = \sum_{k=1}^N x_k $
Variance (VAR)	$\hat{x} = \sum_{k=1}^N (x_k - \bar{x})^2$
Waveform Length (WAVL)	$x_w = \sum_{k=1}^{N-1} x_{k+1} - x_k $
Zero Crossings (NZero)	Increment NZero If $\{x_k > 0 \ \& \ x_{k+1} < 0\}$ or $\{x_k < 0 \ \& \ x_{k+1} > 0\}$
Slope Sign Changes (NSlope)	Increment NSlope If $\{x_k > x_{k-1} \ \& \ x_k > x_{k+1}\}$ or $\{x_k < x_{k-1} \ \& \ x_k < x_{k+1}\}$
Autoregressive Coefficients (ARC)	$x_e = \sum_{i=1}^{Order} a_i x_{e-i} + \epsilon \quad \forall x_e \ e = 1, 2, \dots, N$

the optimal combination of features has been explored in several publications and feature choice varies significantly (Oskoei & Hu, 2007). The stability of features with respect to sensor location, muscle activation magnitude, and muscle fatigue disturbances has been evaluated, revealing auto-regressive coefficients and wavelength features to be the most stable for upper limb myoelectric control schemes (Tkach, Huang, & Kuiken, 2010).

Neuro-fusion models have also been developed that augment myoelectric control by using multi-sensor fusion of EMG signals with more traditional mechanical measurements (i.e. force/moment profiles, lower limb inertial measurements, etc.) (Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011; Delis, Carvalho, F da Rocha, Ferreira, Rodrigues, & Borges, 2009). These methods will be discussed in more detail in Section 2.4.3. When these measurements are included, features must similarly be extracted from signals in order to match the windowing of the EMG signals. These features have been limited to more simplistic features such as mean value, variance, maximum, and minimum value over the segment window (Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011).

2.4.3 Signal Classification

During the signal classification phase, extracted features are used as part of pattern recognition or machine learning in order to determine the meaning behind the physiological measurements. The individual classes vary depending on the function of the prosthetic system. Examples of classifications incorporated into previous systems include discrete joint angle estimations (Au, Bonato, & Herr, 2005), joint flexion/extension separation (Ha, Varol, & Goldfarb, 2010; Ha, Varol, & Goldfarb, 2011), and functional mode classification (Huang, Kuiken, & Lipschutz, 2009; Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011). In addition, continuous magnitude based estimations of joint kinematics have been presented (Delis, Carvalho, F da Rocha, Ferreira, Rodrigues, & Borges, 2009) but are not as prevalent as finite class based separation.

Various machine learning and pattern recognition classifiers have been implemented for use in myoelectric control including (but not limited to) artificial neural networks (Delis, Carvalho, F da Rocha, Ferreira, Rodrigues, & Borges, 2009; Au, Bonato, & Herr, 2005; Au, Berniker, & Herr, 2008), linear discriminant analysis (Englehart & Hudgins, 2003; Huang, Kuiken, & Lipschutz, 2009), support vector machines (Huang, Zhang, Hargrove, Dou, Rogers, &

Englehart, 2011), fuzzy logic controllers (Ajiboye & Weir, 2005), neuro-fuzzy hybrids (Karlik, Tokhi, & Alci, 2003), Gaussian mixture models (Huang, Englehart, Hudgins, & Chan, 2005), and hidden Markov models (Chan & Englehart, 2005). Linear discriminant analysis and its extension, support vector machines, have been heavily investigated due to their high classification accuracy and quick computations (Oskoei & Hu, 2007). However, classification accuracies are observed to vary widely based on the application and it is unlikely that one algorithm will be most successful in all potential uses. Additional information about specific classifiers is provided in Section 2.3.

2.4.4 Previous Lower Limb Myoelectric Controllers

Myoelectric control of the lower limb has been provided in a variety of forms including volitional control (Ha, Varol, & Goldfarb, 2010; Ha, Varol, & Goldfarb, 2011; Au, Bonato, & Herr, 2005), proportional control (Ferris, Gordon, Sawicki, & Peethambaran, 2006; Wu, Waycaster, & Shen, 2011), and modal classifications (Huang, Kuiken, & Lipschutz, 2009; Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011). Volitional control focuses on allowing the amputee to voluntarily reposition their prosthesis based on the neural signals from controlled muscle contractions. For example, if a transfemoral amputee wanted to extend the prosthetic knee, the amputee would contract the extension muscles of the residual thigh. The intelligent prosthetic would then recognize this change in EMG signal and reposition the device accordingly. The potential for volitional control has been evaluated for both transfemoral and transtibial amputees with great success under non weight bearing conditions (Au, Bonato, & Herr, 2005; Ha, Varol, & Goldfarb, 2010). However, these control laws have not been evaluated during stance based locomotion tasks and are not designed or expected to continue to allow volitional control under these circumstances.

Proportional control has seen the least advancement for lower limb amputees. Proportional control relates the magnitude of the linear envelope EMG signal to torque, angle, or angular velocity of the prosthetic joint. Though successful for upper limb amputees (Oskoei & Hu, 2007), the difference in the EMG signals between lower limb amputee and healthy subjects (i.e. co-contraction and functional adaptations, see Sections 2.1.2 and 2.2.2) as well as the baseline muscle activations required by the lower limb during stance that is not observed for upper limb amputees make proportional control difficult for use in lower limb amputee

populations. Additionally, proportional control implies direct movement of the prosthetic according to increases in EMG muscular contraction. These changes could result in instability concerns for the lower limb amputee as well as require considerable power to actuate.

Modal control has seen the most promising use of myoelectric control of passive prosthetic devices during normal ambulation. The focus of modal control is to classify the motion intent of an amputee into a finite number of classes such as level ground walking, stair ascent/descent, ramp ascent/decent, and turning, among other possibilities. As previously stated in Section 2.2.1, the normal function of the knee and ankle vary significantly under these different modalities. Proper detection of these modes allows the passive prosthetic system to modulate its response in real time as the amputee transitions between these modes. Typical mode selection compresses the EMG signals into a finite number of features which represent the level of signal activation. These features along with additional inputs are used by machine learning algorithms to classify the amputee's modal intent. The prosthetic then responds accordingly.

Limited myoelectric modal control algorithms have been developed for transtibial amputees. Au et al. 2008 developed a transtibial prosthetic system that allowed selection between two ankle position modes. Modes were selected in order to allow the amputee to either enter heel strike in the neutral ankle angle orientation (angle angle = 0°) or plantar flexed orientation (angle angle = -20°), the latter of which is useful when descending stairs. Mode switching was generated by measuring EMG signals from the residual limb tibialis anterior, medial gastrocnemius, and lateral gastrocnemius. The variance of these signals over 100 ms windows were utilized in a feed forward neural network. Training of the network was completed through virtual visual feedback to the amputee subject as the subject attempted to independently contract either the gastrocnemius muscle group to signal plantar flexion or the tibialis anterior to signal the neutral position. The effectiveness of ankle angle mode switching was evaluated in a clinical trial. The amputee subject was required to consciously contract either muscle group during the swing phase of gait in order to change modes. The initial study showed that the amputee was able to choose the desired ankle angle at heel strike based solely on EMG signal inputs. However, the need for conscious activation of the residual limb muscle in this myoelectric algorithm is undesirable compared to a system that intuitively adapts based on the natural changes in EMG signals. Additionally, mode switching is only allowed between two modes. The ankle angle could be further adjusted at heel strike and the response of the ankle

through the following stance phase could be better tailored to terrain if additional modes were available.

A wider range of mode predicting has been completed for transfemoral amputees. The apparent focus on transfemoral amputees may be a result of the more dramatic changes in the knee systems for different modes when compared to the ankle. Huang et al 2009 and 2011 presented classification of transfemoral amputee signal into a wide range of modalities including level ground walking, stair ascent/descent, ramp ascent/descent, obstacle crossing, as well as two different forms of turning. In the original algorithm, modes were selected separately for two distinct events within gait: heel strike and toe-off from EMG signals collected at varying window lengths around the transition points. EMG signals from a wide range of muscles were recorded including the gluteus maximus, gluteus medius, sartorius, rectus femoris, vastus lateralis, vastus medialis, gracilis, biceps femoris long and short heads, and semitendinosus from which a wide range of features were extracted including the mean absolute value, number of zero crossings, waveform length, number of slope sign changes, as well as the coefficients of a 3rd order auto regression. A separate linear discriminate analysis model for each phase of gait was used to classify the different modes based on the feature set. Classification errors for this model ranged from 0-45% (Huang, Kuiken, & Lipschutz, 2009) and depended on the phase of gait and type of mode being classified. Higher classification errors were observed for turning modalities and during the weight acceptance phase of gait.

A revised algorithm (Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011) was later presented that provided continuous classification of modalities. In addition to EMG signals, a six axis load cell was implanted in the pylon of the prosthetic between the artificial ankle and knee to measure 3 dimensional force and moment data. Time series data were segmented into 150 ms sub windows which were incremented at 12 ms. Simpler EMG features were calculated over each window from each muscle: mean absolute value, waveform length, number of zero crossings, and number of slope sign changes. The maximum, minimum, and mean values from each kinetic measurement were also calculated from each window. Linear discriminant analysis and support vector machines with a radial basis function kernel were used to classify the mode of each segment based on the separate and combined EMG and kinetic features. Similar to the original algorithm, classification schemes were separated based on the phase of gait. Mean classification accuracies for this algorithm of steady gait cycles were in excess of 90% when

using EMG and kinetic features separately. Fusing the EMG and kinetic features in classification further increased the accuracy of classification. The support vector machine classification was observed to have higher classification accuracy with accuracy increase ranging from 1.5% - 5.9%. In addition, the classifier allowed for predictive classification of mode by detecting changes in the EMG and kinetic features of the amputee subject prior to the transition. When using support vector machines, fused data were capable of predicting all transitions for all 5 subjects (75 transition/subject) prior to the gait cycle where the new mode was observed. The predictive ability of the algorithm varied depending on the mode transition, but occurred between 200 to 600 ms before the new gait cycle which allows ample time for the prosthetic to switch functionalities.

2.4.5 Practical Considerations

Use of myoelectric control for the lower limb prosthetic has potentially more risk in application than upper limb applications. A misclassification could result in serious stability concerns for the already unstable lower limb amputee due to changes the prosthetic system would have to undergo in order to mimic healthy ankle function. Such stability concerns could lead to tripping which, depending on the health of the patient, could result in injury especially when performing a complex task such as ascending or descending stairs. As a result, in order for a myoelectric classifier to be useful in real world applications, the classifier must be near perfect in classification. Ideally, there would be a fail-safe in place in the event of a misclassification to either help stabilize the amputee or detect the potential for misclassification.

The observed variability of EMG signals is concerning for myoelectric control laws regardless of the application. Variability in EMG signals can be observed both within and between subjects. Intra subject variability in signals can result in misclassifications of the signal which results in decreased accuracy. The variability of EMG signals can either be the result of signal disturbances or changes in the way the amputee approaches different modalities. In order to overcome these concerns with amputee EMG signals, the model myoelectric controller would ideally allow for adaptive learning in order to adjust to changes in the amputee's walking pattern. Adaptive learning could also be used to overcome the sudden onset of poor classification accuracy from a signal disturbance.

Inter subject variability also provides interesting challenges. Since EMG signals can differ from subject to subject, the myoelectric classifier must be amputee specific in order to ensure the desired level of accuracy. When using a myoelectric classifier in real world situations the classifier must be trained to recognize each subject's EMG signals accordingly. Continuous training of machine learning algorithms is computationally demanding and requires information about the terrain the amputee is navigating. On the surface level this results in the circular logic of the need to detect terrain changes in order to train a myoelectric classifier designed to detect terrain changes.

An additional requirement is that the classifier should allow the prosthetic foot to behave similarly regardless of whether it is negotiating a terrain in a consistent mode or whether the amputee is transitioning between two different modes. Transient EMG signals between two modes may not be representative of EMG signals during consistent terrain locomotion. As a result, the most likely location for misclassifications will be during these transitions.

Chapter 3. METHODOLOGY

The first step towards the development of a myoelectric control algorithm is to collect and analyze EMG and IMU signals from a sample of the non-amputee and amputee population. These signals will be used to determine the capabilities of a myoelectric classifier (See Chapter 4). Such a collection requires an experimental set up that is compatible for use with both amputee and non-amputee populations. Specifically, for amputees, it requires recording EMG signals from within their socket for two muscle groups. These signals will be collected over a wide variety of walking modes.

3.1 SUBJECT RECRUITMENT

Research subjects were recruited from the healthy non-amputee and transtibial amputee populations. Potential subjects were excluded if they met the following criteria: 1) amputee subjects were congenital amputees 2) subjects were suffering from neuromuscular disorders and 3) subjects that were not healthy enough or considered active enough to complete the procedure. Congenital amputees (as opposed to traumatic amputees) were excluded due to lack of development in their residual limb and the resulting limited ability to record EMG signals. The institutional review board approved the protocol and informed consent was received from each subject prior to testing.

3.2 MEASUREMENT SYSTEM

In order to simulate the conditions that would be observed outside of the lab, a portable experimental set up was required that allowed for full range of lower limb motion and did not affect the gait of subjects. A schematic of the data collection system can be seen in Figure 3-1. The primary goal of collection was to record EMG signals from lower limb muscles during the selected modes. In order to use these signals, the timing of relevant gait events was needed to later separate the signals into distinct gait cycles. A Telemetry DTS wireless EMG system (Noraxon, Scottsdale, AZ) in a bipolar single differentiation configuration was used. Surface electrodes were placed on the skin and connected through short leads to a local transmitter. For this experiment, the electrodes were passive. For distal muscle groups (below the knee) low profile Ambu NF-50-K/US neonatal electrodes (Glen Burnie, Maryland) were used to allow for placement in the prosthetic socket between the residual limb and gel liner when the subject was

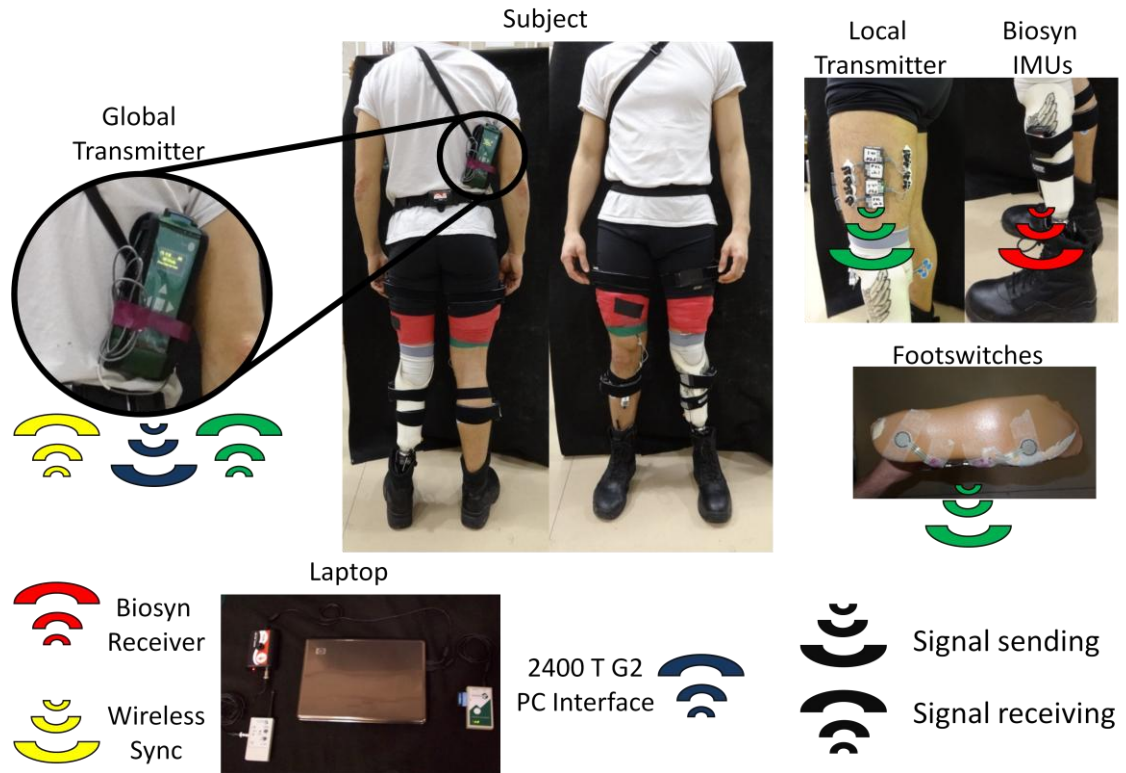


Figure 3-1. Experiment measurement system schematic

an amputee. This low profile configuration increased patient comfort and provided a realistic means of including EMG sensing in current prosthetic assemblies. For muscle groups above the knee, Noraxon Single Electrodes #272 (Scottsdale, AZ) were used. These electrodes had a higher profile with a thickness of 1.5 cm, but since the skin surface at this point was superior to the prosthetic socket, the profile of the electrode did not affect the comfort of the amputee patients. Identical electrodes were used for non-amputee subjects for consistency.

All electrodes were wire connected to a local transmitter. The local transmitter recorded the signal at 1500 Hz, amplified it by 100 dB, and routed the signal through a blue tooth connection to a Telemyo DTS Telemetry global transmitter the subject wore either around the waist or over the shoulder based on the subject's preference. This global transmitter then routed the time-synchronized signals to a Telemyo 2400 T G2 PC interface which connected to a laptop computer through a USB connection. Myoresearcher XP Master Edition software v1.07 (Noraxon, Scottsdale, AZ) was then used to view and record the signals in real time.

In addition to EMG signals, Noraxon Force Resistive Sensors (FRS) #FRS1 (Scottsdale, AZ) were used as foot switches on both feet and transmitted wireless through the Telemyo

system. Foot switches were placed on the surface of the heel directly inferior to the bony surface of the calcaneus and the first metatarsophalangeal joint on the plantar surface of the foot. These foot switches produce voltage signals when force on the sensors exceeds an adjustable tolerance and allow for marking periods of gait where either the heel or toe sections of the foot are in contact with the ground. With this information, it is possible to separate each gait cycle into four relevant phases: weight acceptance, stance, pre-toe off, and swing.

The secondary goal for each collection was to record inertial measurements of the lower limb segments simultaneous to the EMG and footswitch sensors. These inertial measurements were taken to assess whether they could aid in mode classifications based on the previously reported benefits of multi-sensor fusion for myoelectric classification (See Section 2.4.4). The commercial Biosyn system (FAB, Burnaby, BC) was utilized for these measurements. The small sensor boxes were placed on the predominant segments of the lower limb: right/left shank, right/left thigh, and pelvis. Each of these sensor boxes housed a three dimensional accelerometer and rate gyroscope. The raw measurements from each sensor were captured at 25 Hz through the Biosyn receiver which stored these signals based on a USB laptop connection.

With the use of both EMG and IMU measurements it was necessary to generate a synchronizing signal that could simultaneously start both systems and ensure that the time markings of each system were identical. This signal was generated by the Biosyn system when each test was started. This signal was then transmitted wirelessly using the Noraxon Wireless Sync Transmitter #232B (Scottsdale, AZ). The global transmitter received the sync signal and then sent it to the laptop recording system which triggered the Myoresearcher software to begin recording. Using such a connection allowed the start of EMG data collection to be within 7 ms of the Biosyn IMU system.

3.3 EXPERIMENTAL PROTOCOL

A protocol was developed that allowed for the consistent collection of myoelectric and inertial signals from both amputee and non-amputee subjects. In order to test a myoelectric control law's ability to distinguish between these signals over a variety of walking modes (level ground of varying speeds: self selected, slow, and fast, stair ascent/descent, and ramp ascent/descent) each subject completed a research protocol that allowed for similar signals to be collected from each subject while completing these modalities.

3.3.1 EMG and General Sensor Placement

Four lower-limb muscles were selected from which to record EMG signals based on relatively distal placement of electrodes, role in knee actuation, and presence in both non-amputee and transtibial amputee populations. These muscles included the tibialis anterior (TA), medial gastrocnemius (MG), vastus lateralis (VL), and bicep femoris (BF). Signals from these muscles were collected bilaterally for control and amputee subjects. Placement of EMG sensors was consistent with recommendations outlined in the “Anatomic Guide for the Electromyographer” (Delagi, Perotto, Iazzetti, & Morrison, 1975) , summarized in Table 3-1 and pictured in Figure 3-2. Slight adaptations of placement were at times necessary for amputee subjects due to abnormalities in musculature of transected muscles. When EMG signal was abnormal or weak for amputees at the outlined location, electrodes were shifted slightly based on tactile observations while the amputee flexed the affected muscles.

Table 3-1. Selected muscles for EMG collection and electrode placement, as described in Delagi et al. (1975).

Muscle (channel)	Electrode Placement
Tibialis Anterior (1)	4 fingers inferior to tibial tuberosity 1 finger lateral
Tibialis Anterior (2)	Directly proximal to Tibialis Anterior (1) along muscle body
Medial Gastrocnemius (1)	1 hand inferior to popliteal fossa Medial aspect of shank, angled with muscle fibers
Medial Gastrocnemius (2)	Directly proximal/lateral to Medial Gastrocnemius (1)
Vastus Lateralis (1)	1 hand superior to patella (knee extended) Lateral aspect of thigh (muscle visible)
Vastus Lateralis (2)	Directly distal to Vastus Lateralis (1) along muscle body
Biceps Femoris (1)	Midpoint of ischial tuberosity and fibular head while prone Placement was adjusted tactically
Biceps Femoris (2)	Directly distal to Biceps Femoris (1) along muscle body

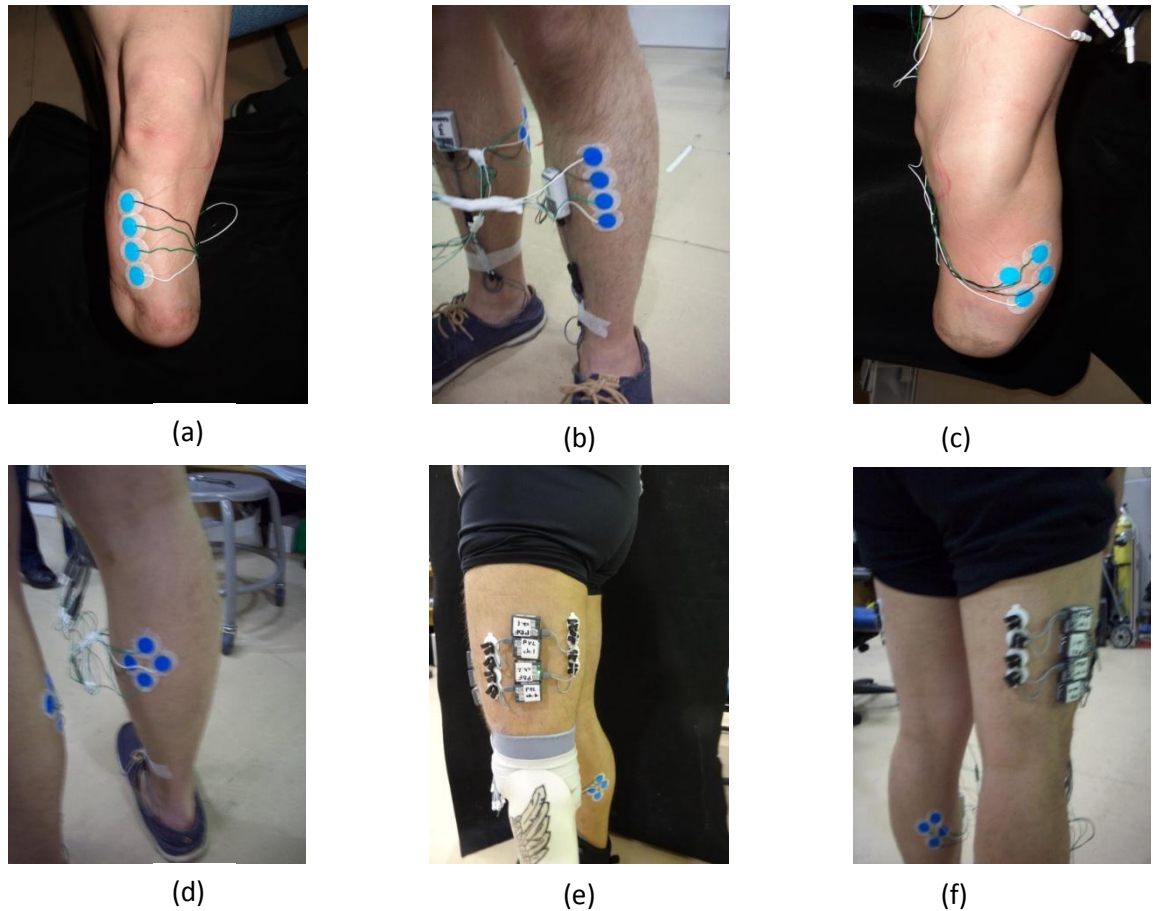


Figure 3-2. EMG electrode placements for the (a) Tibialis Anterior (amputee), (b) Tibialis Anterior (control), (c) Medial Gastrocnemius (amputee), (d) Medial Gastrocnemius (control), (e) Vastus Lateralis, and (f) Biceps Femoris.

Prior to placement, the skin surface was shaved of hair and cleaned with alcohol wipes in order to reduce the noise in the signal. Amputee residual limbs were not shaved due to the risk of ingrown hairs and skin irritation. Two EMG channels were collected from each muscle in order to observe changes in signal content when electrode locations are shifted. Due to the limited number of channels in the collection system, only a single channel of EMG signal was recorded on the thigh muscles (Vastus Lateralis and Biceps Femoris) on the sound limb for amputee subjects and the left limb for non-amputee subjects. For some amputee subjects, there was not enough surface area on the residual limb on the amputated side to record two quality signals from either the tibialis anterior or the medial gastrocnemius. When this was observed to be the case, only a single EMG signal was recorded. The “first” channel of each collection was the

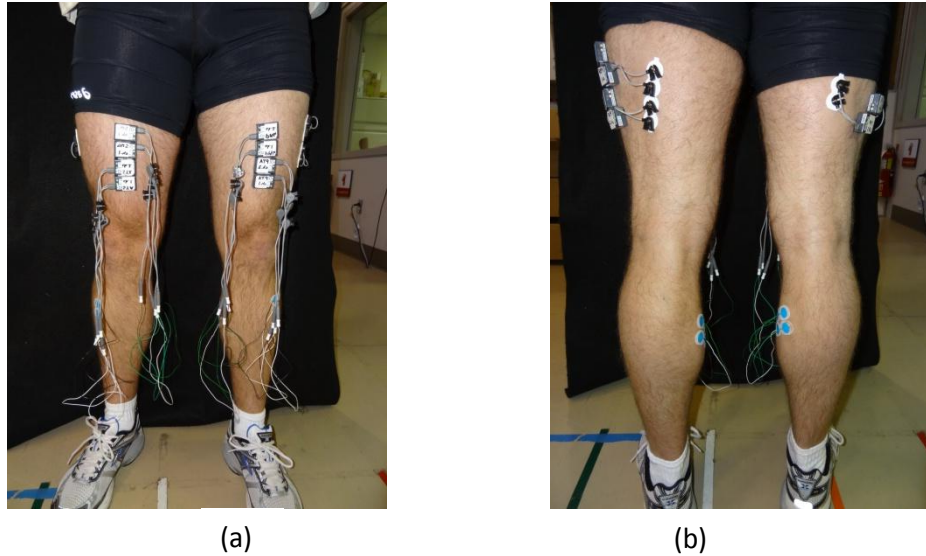


Figure 3-3. Placement of Telemyo local transmitters of EMG sensors from the (a) non-amputee anterior and (b) non-amputee posterior

primary EMG channel and the “second” channel was used to simulate a disturbance in the EMG signal that would be observed by a significant shift in electrode placement.

The ground electrode for the EMG signals was on the inner surface of the local transmitters for each channel. This required the transmitters to be in contact with the skin of each subject in order to record properly. Transmitter boxes for the thigh muscle EMG signals were placed on the lateral aspect of the thigh and transmitters for the shank muscles were placed on the anterior aspect of the thigh. Transmitter boxes were similarly placed for both amputee and control subjects. Both placements can be observed in Figure 3-3. No transmitter boxes were placed on the shank as this section is covered for amputee subjects. Wired connections allowed for transmission of signals from shank electrodes to transmitters on the thigh. The wires were grouped and immobilized against the surface of the skin in order to reduce noise from motion artifact. These wires did not affect the subject’s ability to fully bend the knee. Transmitter boxes were anchored to the subject using STIK IT GL-2 skin adherent produced by Gordon Laboratories (Upper Darby, PA). Similarly, wired connections were secured to the thigh using medical tape in order to reduce the motion of the cables and reduce potential motion artifact.

Biosyn IMUs were placed on the lateral aspect of the shank and thigh for each limb. The placement of the IMUs were relatively distal on each limb segment and in compliance with the manufacturer’s specifications. An additional IMU was placed on the lower back at the level of



(a)



(b)



(c)



(d)

Figure 3-4. Final placement of all sensors on control subject from the (a) anterior and (b) posterior and amputee subject from the (c) anterior and (d) posterior.

lumbar vertebrae 1 and 2. These five IMU were capable of capturing the kinematics of the major segments of the lower limb. Biosyn IMU placement can be observed in Figure 3-4 .

3.3.2 Experimental Course and Data Collections

After placement of electrodes and IMUs, maximum voluntary contraction (MVC) measurements were recorded from each subject. The measurements were used to verify significant signal from the EMG electrodes and are meant to provide an indication of the expected magnitude of the signal during collection. For the thigh muscles, MVCs were collected as the subject sat in the seated position on a surface that didn't allow the feet to touch the ground.

Depending on the muscle group, the subject either tried to bend (biceps femoris) or extend (vastus lateralis) their knee against resistance provided by one of the experimenters placing his/her hand on the anterior or poster aspect of the shank. For the shank muscles, subjects remained in the seated position and were told to either plantar flex or dorsiflex their foot with resistance provided as necessary. Amputee subjects were told to imagine flexing their phantom foot on the amputated side in order to get similar measurements.

During the experiment, both non-amputee and amputee subjects performed identical tasks. Each collection was initiated in a straight hallway outside of the lab with several level ground walking trials which were completed at three different walking speeds: self selected, slow, and fast. The speed of level ground walking was selected by the subject based on instructions provided prior to the experiment. Instructions included the use of either self selected, slow, or fast to describe the speed as well as a brief description of how the speed should feel (i.e. running late for a meeting, relaxed window shopping, etc.). In order to provide rough quantification of walking speed, the distance of level ground walking was recorded with a measuring tape placed along the direction of travel and the time duration of walking was recorded using a stop watch. These measurements were used to show that the subject was adjusting walking speed based on the instructions provided. For each level ground trial, data for at least eight gait cycles per limb were collected. Self selected walking speed tests were completed for five trials followed by two slow walking trials and two additional fast walking trails.

Following level ground walking, the subject was instructed to complete stair ascent/descent and ramp ascent/descent trials. Each stair and ramp trial was initiated and terminated with level ground walking in order to observe the transition cycles leading into the different modalities and transitioning back to level ground walking. For these trials, the subject began from the standing positions, completed 5 gait cycles of normal level ground walking, transitioned and completed the selected mode (ramp or stair), and transitioned back into level ground walking for at least five gait cycles before terminating gait. This procedure was identical for stair and ramp trials, with the exception of the stair ascent to level ground and level ground to stair descent transitions which only included three gait cycles of level ground walking based on space restrictions. Each of the possible transitions from level ground to either stair or ramp modes were initiated with both the left and right limbs for non-amputee and amputee subjects.

Three trials per transition leading limb were completed for each possible mode (stair ascent/descent and ramp ascent/descent) providing six trials for each modality. Collections for stair and ramp modalities were recorded in separate parts of the experiment while alternating between either stair/ramp ascent and stair/ramp descent. For each trial, four or five gait cycles (depending on the leading limb) were collected for stair ascent/descent modality and nine to ten gait cycles were collected for ramp ascent/descent modalities. In addition, each mode trial contained two example gait cycles of transitions between level ground and either stair or ramp modality or vice versa.

Both stairs and ramp surfaces were standard. For stair trials each stair was 6.5 in. high and 11 in. long. A total of eleven stairs were completed for each trial both when ascending and descending. Stairs did include handrails which both subject populations were allowed to use if they were determined to be necessary for safe completion or was typical behavior for the subject. For ramp trials, the ramp terrain consisted of two ramp surfaces separated by a short (5 ft.) level ground section. Each ramp was between 21 ft. and 24 ft. in length and was sloped at approximately 5 deg from horizontal. Gait cycles occurring on the level ground section between the two ramps were not used in any part of the analysis.

Following individual stair/ramp data collections, subjects completed a mode “course” which consisted of level ground walking, ramp, and stair terrains within close proximity. Stair

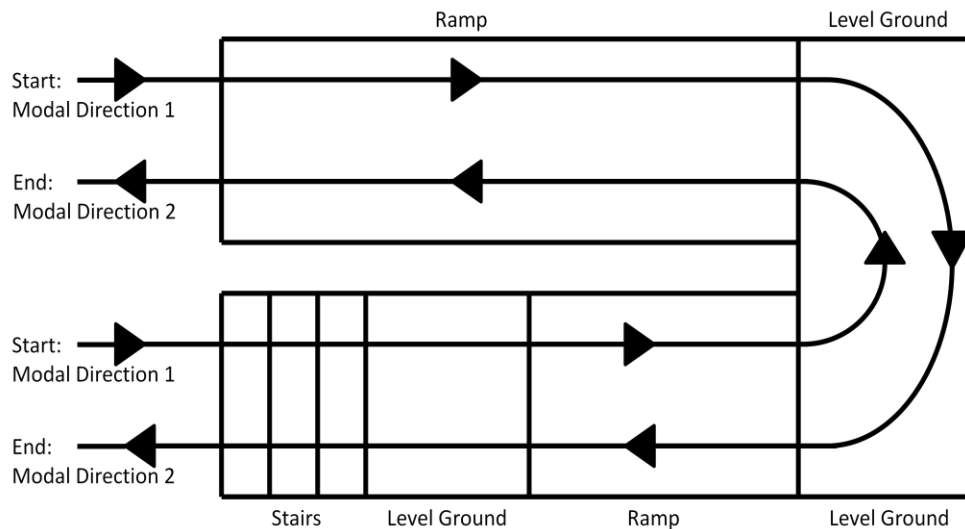


Figure 3-5. Modal course schematic

and ramp features during this mode course were similar to previous surfaces. The general path of the modal course can be seen in Figure 3-5. Each subject completed the mode course in both directions to capture all modalities previously tested. No instructions were given that would influence how the subject approached the course with the exception that subjects were told to take a wide turn when over the far level ground surface. This provided a realistic experiment that captured the subject's nature style of ambulation. Two trials were completed for each direction of the course.

3.4 SIGNAL PROCESSING

In an effort to develop an efficient myoelectric controller, it is desirable to use minimal signal processing steps in order to reduce the computational requirements and maintain a quick response time. The majority of signals taken are raw signals with only the necessary filtering to reduce motion artifact and noise in the signal.

With current methods utilizing a wireless EMG transmitting system as well as efforts to attach necessary wiring to the subject, the motion artifact was minimized. This removed the necessity for increasing the low pass filter above the recommended 20 Hz. The sole signal processing was a 4th order Butterworth band-pass filter between 20 and 500 Hz for EMG signals. The Telemetry system (Noraxon, Scottsdale, AZ) completed a 500 Hz low pass filter during collection and a 20 Hz high pass filter was completed during post processing in Matlab.

Inertial signals were recorded at 25 Hz. To reduce high frequency signal contact, these signals were low pass filtered with an 8 Hz cutoff frequency using a 4th order Butterworth filter. Filtering was completed as part of post processing in Matlab.

3.5 SUMMARY

A wireless recording system was created that allowed for myoelectric and inertial measurements of gait during a variety of different walking modes and within the real world environment. This system allowed for identical and safe use for both amputee and non-amputee subjects. Signals were recorded over a variety of different walking modes (level ground: self selected, slow and fast walking speeds, stair ascent/descent, and ramp ascent/descent). Collection over these modes provided a data set that included a vast range of myoelectric and inertial data from motions that would occur during normal walking. Minimal signal processing

was performed for both EMG and IMU measurements to reduce the computational cost of any classifier that is designed.

Chapter 4. MYOELECTRIC CLASSIFICATION AND PREDICTION

The myoelectric and inertial signals collected for both non-amputees and transtibial amputees were used to classify different walking modalities. Classification was designed to not only detect the current walking mode, but also to predict transitions between walking modes to allow for fluid adaptation of the prosthetic over different terrains. In addition to demonstrating the ability to make classification, the practicality of a myoelectric controller was evaluated within the limitations of the current data set. Specifically, a myoelectric classifier must be robust in response to potential EMG signal disturbances to not result in spontaneous misclassification during use. The effects of the most predominant and expectable disturbance (electrode shifting) were evaluated. A myoelectric classifier must also have a degree of generalizability among subjects. If generalizability of classification exists, it will allow for more intuitive use as part of a prosthetic system as the classifier will be able to begin making classifications for each subject from initial electrode placement as opposed to requiring time consuming training before classification can be functional.

4.1 RESEARCH SUBJECTS

The experimental procedure was completed on five subjects from each population group. For amputee subjects, four amputees were traumatic amputees and a single subject required amputation as a result of complications with diabetes (amputee subject 04). All subjects had normal walking patterns and were free from mobility issues with the exception of amputee subject 05. It was observed prior to experimentation that this particular subject was unable to plantar flex his sound side limb foot due to a subtalar fusion as a result of a previous injury. It was decided prior to testing that this would not affect myoelectric signals on the amputated side and as it did not affect the patient's ability to complete all walking modes experienced in the

Table 4-1. Test subject demographics and statistics

Subject Demographic	Control Subjects (n=5)	Amputee Subjects (n=5)
Age (years)	28.8 ± 5.40	39.2 ± 16.0
Height (cm)	174 ± 4.3	173 ± 3.0
Weight (kg)	78.9 ± 15.7	78.0 ± 5.1
Sex (F:M)	1:4	0:5
Dom/ Pros Limb (L:R)	0:5	3:2

experiment, should not result in exclusion from experiment. A summary of test subject demographics is presented in Table 4-1. No subjects were excluded because of gender, height, weight, or other non relevant physical characteristics.

4.2 FEATURE EXTRACTION

Heel strike (HS) and toe off (TO) events were identified by initial and final foot contact based on footswitch data. These events were used as reference points when defining sub-windows of the gait cycle over which classification would occur. Unlike in previous lower limb myoelectric control algorithms, windowing definitions are set up to include signals from the entire gait cycle. Current myoelectric algorithms capture a short window of the signal which provides limited information to the classifier. Misclassifications with this existing method are overcome through use of majority voting and other post decision algorithms in addition to classification. Defining fewer windows over each gait cycle will reduce the computational cost of classification and training as compared to current continuous classifiers (See Section 2.4.4).

Myoelectric data were segmented into three sub-windows: EMG1(from HS to HS + 200 ms), EMG2 (from TO-300 ms to TO), and EMG3 (from TO to TO+100 ms), Figure 4-1. The inertial data sub-window ranged from HS to TO. The longer window for IMU features was due to the low sampling rate of the inertial signals in order to ensure that enough data points were present to allow for stable and consistent features. Windows definitions and HS/TO reference

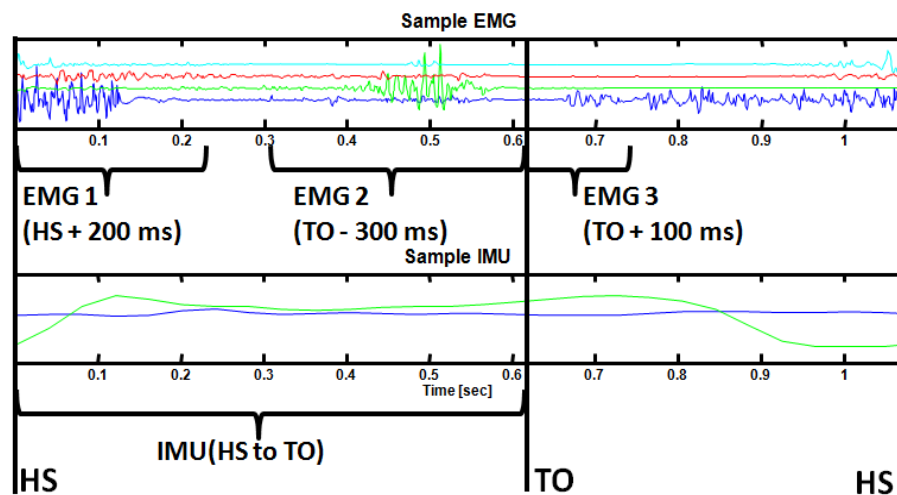


Figure 4-1. EMG and IMU sub-window definitions (HS – Heel Strike, TO- Toe Off)

points were identical for all walking modalities. Features from each sub-window were extracted to be used for classification based on definitions from literature. For myoelectric signals, these features included the mean absolute value (MAV), root mean square (RMS), wavelength (WAVL), Number of zero crossings (NZero), Number of slope sign changes (NSlope), and 6th order auto regressive coefficients (ARCs) model. Features from inertial signals included the MAV, RMS, and WAL in addition to the max and min of the signal over each window. More information about these features can be observed in Section 2.4.2. The total number of features was 44 (4 muscles x 11 features/channel) and 30 (6 IMU signals x 5 features/signal) for each EMG and IMU window, respectively.

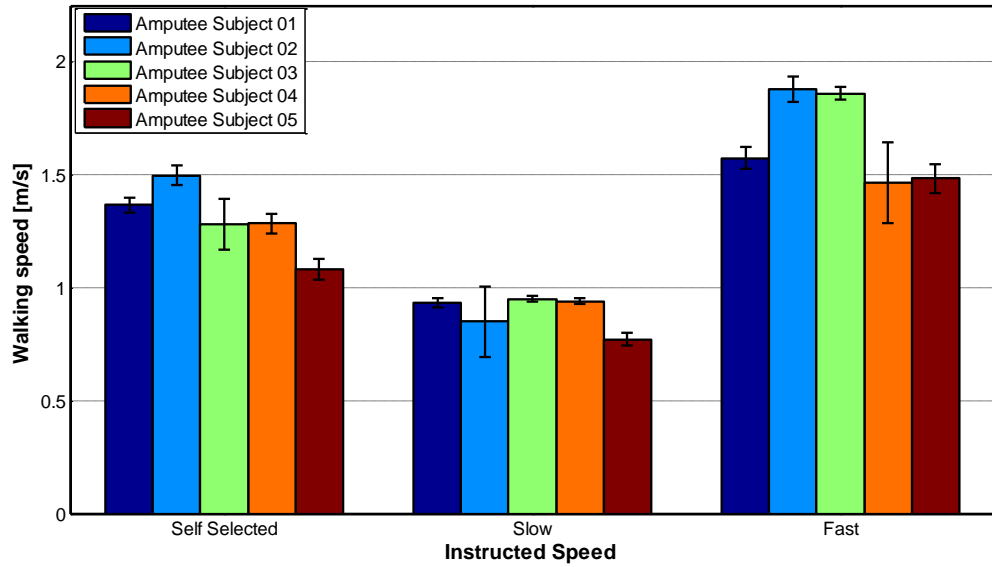
4.3 WALKING MODE CLASSIFICATIONS

It is desired that mode classification could be used as part of an active prosthetic system in order to adjust the response of the ankle foot prosthetic for different styles of walking. In order to test the ability of machine learning algorithms to distinguish between different modes solely on the features extracted from EMG signals, several trials of EMG patterns from the data collection were used as examples of different walking modes. The current classifier attempted to make distinctions between level ground walking at three speeds: self selected (SSW), slow (SLW), and fast (FTW), stair ascent/descent (SUP/SDW), and ramp ascent/descent (RUP/RDW). The experimental procedure and different trials were previously outlined (See Section 3.3.2). From these collections, a subset of example gait cycles for each mode was extracted. The different data subsets and amount of gait cycles used per trial are presented in Figure 4-2.

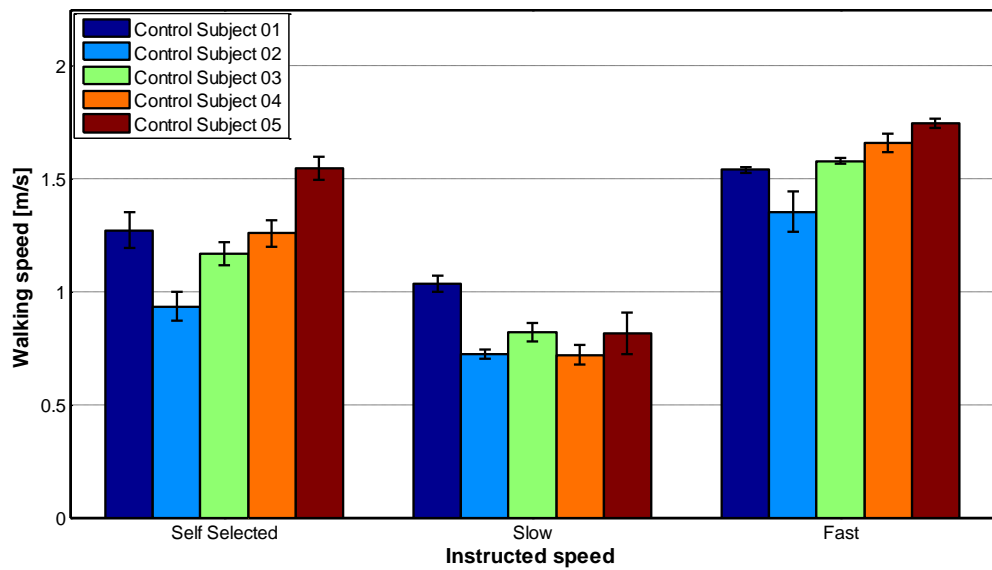
When testing a classifier, it is desired to collect data relating to different classes in a random sequence to reduce the potential that classification accuracy is artificially inflated due to

<p>Level ground Trials (7 cycles/trial) -Self selected speed (SSW - 5 trials) -Slow speed (SLW - 2 trials) -Fast speed (FTW - 2 trials)</p>	<p>Ramp Trials (8-10 cycles/trial) -Ramp Ascent (RUP - 6 trials) -Ramp Descent (RDW - 6 trials)</p>
<p>Stairs Trials (4-5 cycles/trial) -Stair Ascent (SUP - 6 trials) -Stair Descent (SDW - 6 trials)</p>	<p>Modal Trials(2 cycles/trial) -Ramp Ascent (RUP - 2 trials) -Stair Ascent (SUP - 2 trials) -Ramp Descent (RDW - 2 trials) -Stair Descent (SDW - 2 trials)</p>

Figure 4-2. Gait cycle subset from data collection to be included in classification



(a)



(b)

Figure 4-3. Average walking speed at each instructed speed for (a) amputee subjects and (b) non-amputee subjects

the classifier detecting changes to features in time as opposed to between different classes. Since the data collection for this experiment was taken on examples of each mode within the real world in separate locations, randomizing the different mode trials was not possible. However, “modal” trials were collected over a surface where all five modes were present (level ground, SUP/SDW,

and RUP/RDW) at the end of each collection (See Section 3.3.2). Examples of stair ascent/descent and ramp ascent/descent gait cycles from the modal trials in addition to the examples from stair and ramp trials were used to observe if classification was affected by the time of collection. It is believed that if a classifier is equally capable to classify modes at different times, time domain changes in the signal are not being used to make separations between different modes.

For each level ground walking speed trial, subjects were instructed to walk at one of three different speeds. Estimates of the average speed of each level ground walking trial were collected by recording the distance traveled and time of each trial to insure that subjects were modifying their walking speed as desired. In order to realistically expect a classifier to make separations between each speed, significant differences between each instructed speed must be observed for all subjects. As can be seen in Figure 4-3, though the subject's speed at each instruction varied, each subject can be observed to have individual modification of walking speed when changing from self selected to slow, and to fast. In general, the variance of walking speed between similarly grouped trials appears insignificant, showing the consistency of each subject's selected speed based on the instruction.

4.3.1 Mode Detection

The ability of a classifier to separate between the different modes and level ground walking speeds was first assessed using subject-specific classifiers. For subject-specific classification, a separate classifier is developed for each subject and does not use data from any of the other subjects in the study. Both Linear Discriminant Analysis (LDA) and Support Vector Machines (SVM) were used in classification. Both machine learning algorithms were executed in the Matlab v10.7.0 environment using a combination of custom coding and built in functions. When using SVM, a linear kernel was used for all classifications. Other kernels were explored as part of a preliminary assessment, but were repeatedly observed to present poor classifications (data not shown). Sequential minimum optimization (SMO) and the one-against-one (OAO) multiclass algorithms were used based on previous successes in literature (See Section 2.3.2). Features from all three EMG sub-windows (EMG1, EMG2, and EMG3) were combined towards classification (See Figure 4-1).

In order to evaluate the accuracy of classification for each subject with the finite data set available, a k-fold cross validation assessment was utilized (See Section 2.3.3). The available data were separated on a “leave one trial out” k-fold scheme. The only exception was that all modal trials were grouped together as a single fold since fewer gait cycles from the modal trials were used as compared to other trials. The total number of folds was 32 (5 SSW, 2 SLW, 2 FTW, 6 SUP, 6 SDW, 6 RUP, 6 RDW, 1 modal). For each fold a single trial was removed from the training set and set aside as the test set. The trained classifier was then used to classify the removed trial. The resulting classification for each test set after all iterations were complete was used to define the total accuracy of each classifier for each subject. K-fold methods were used in order to predict how the classifier will respond in a real world situation where only a finite set of data is provided and the classifier is then used to classify data sets that were not provided as part of the original training.

Of the EMG features used in detection, the auto regressive coefficients are the most computationally demanding to compute (See Section 2.4.2). Reducing the computational requirements of any classifier will improve the likelihood of its use in real world applications. Classification through both classifiers was performed using both a full feature set: mean absolute value (MAV), variance (VAR), wavelength (WAVL), number of zero crossings (NZero), number of slope sign changes (NSlope), and 6th order auto regressive coefficients (ARCs) as well as a limited feature set which included all the features with the exception of the ARCs. Classification without ARCs was tested as ARCs are the most computationally expensive feature to calculate. Classification accuracy averages and standard deviations were calculated for each individual subject using the k-fold methods. The overall classification accuracy for all seven classes (SSW, SLW, FTW, RUP, SUP, RDW, SDW) is presented in

Table 4-2. Comparison of classifier accuracy for both LDA and SVM using features sets that either include or exclude auto regressive coefficients

Amputee Subjects	LDA	SVM
EMG features (include ARCs)	96.7% (± 1.22)	97.7% (± 1.66)
EMG features (exclude ARCs)	97.9% (± 0.22)	97.9% (± 1.39)
Non-amputee Subjects	LDA	SVM
EMG features (include ARCs)	91.6% (± 4.92)	95.7% (± 3.22)
EMG features (exclude ARCs)	93.3% (± 2.62)	94.7% (± 2.82)

Table 4-2. As can be observed, the benefits of including ARCs for classification was limited or a negative result. ARCs were removed from the feature set as a result.

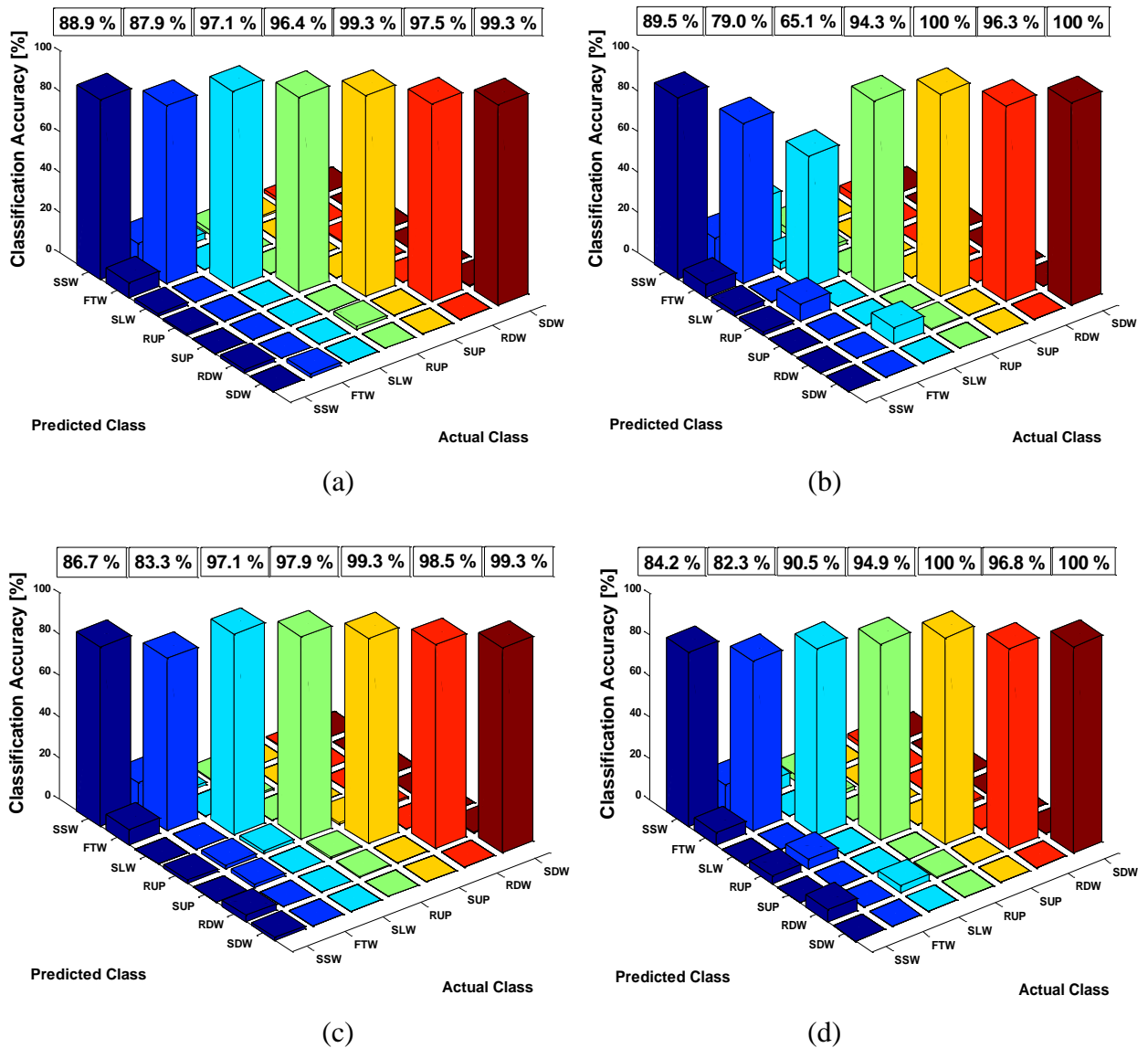


Figure 4-4. Combined confusion matrix for all amputee (LDA – (a), SVM – (c)) and non-amputee (LDA – (b), SVM – (d)) subjects for modal detection.

For control subjects, a slight increase in classification accuracy can be observed when using SVM as opposed to LDA (94.7% (± 2.82) compared to 93.3% (± 2.62), respectively). Alternatively, for amputee subjects this trend is not observed with classification accuracies of 97.9% (± 0.22) and 97.9% (± 1.39) observed for LDA and SVM, respectively. In order to better understand which modes are being misclassified, the confusion matrix which displays the

predicted mode relative to the actual mode for both amputee and control subjects using LDA and SVM is presented in Figure 4-4.

It can be observed that the worst classification accuracy regardless of the subject population or classification method is between the different level ground walking speeds. Even though several misclassifications are associated with speed, the misclassifications of one speed are typically incorrectly classified as one of the other two remaining speeds. These speed classifications are part of the larger level ground classification.

The summary of total misclassifications as well as the percentage of misclassifications relative to the total number of gait cycles is presented in Figure 4-4. This count highlights the large number of misclassifications associated with misclassifications between walking speed which was observed across different subject populations and for both classifiers. For amputee subjects, the accuracy of speed classification was 91.9% (± 14.1) and 91.5% (± 8.43) when using LDA and SVM, respectively. The next largest group of misclassifications was observed for misclassifications between level ground walking and either ramp ascent or ramp descent. Also, the number of misclassifications confusing ramp ascent and ramp descent is of a similar magnitude. In general, misclassification of stair ascent/descent against other modalities was very low for both amputee and non-amputee subject populations. Classification between the five major classes (level ground, RUP/RDW, and SUP/SDW) resulted in a reasonable classification accuracy of 98.5% (± 0.30) and 98.2% (± 0.71) for amputee subjects when using LDA and SVM, respectively.

4.3.2 Mode Prediction

In mode detection, the classifier is distinguishing between individual modes based on EMG and/or IMU (See Section 4.4) data collected while the prosthetic of the amputee is experiencing that mode. Even with accurate mode detection, the function of a prosthetic system will not necessarily be able to adapt to changing modes since by definition, detection of mode occurs after the mode has already been completed. Use of solely mode detection would result in a one gait cycle delay before adaptation. In order to allow for a smooth transition between different modes, the ideal classifier must also be able to detect changes in the EMG features before the transition occurs which is referred to here as ‘mode prediction’. It is desired that

<u>OTR</u>		<u>Trans1</u>		<u>Trans2</u>	
Self Selected Level Ground		Level Ground /Stair Ascent		Level Ground /Stair Descent	
Slow Level Ground					
Fast Level Ground					
Ramp Ascent					
Ramp Descent					
Ramp Ascent / Level Ground					
Ramp Descent /Level Ground					
Level Ground /Ramp Ascent					
Level Ground /Ramp Descent					
<u>SUP</u>		<u>Trans3</u>		<u>SDW</u>	
Stair Ascent		Stair Ascent / Level Ground		Stair Descent	
				<u>Trans4</u>	
				Stair Descent / Level Ground	

/ = Transition between modes

Figure 4-5. Redefinition of modes into other (OTR), stair ascent (SUP), stair descent (SDW) and transition modes (Trans1-4) from the previous data to specifically predict stair modality

prediction occur with enough time before the mode switch in order to allow the responsive prosthetic mechanisms enough time to adjust to the new modality.

The most critical transition to predict is when transitioning from level ground walking to either stair ascent or stair descent. For all the other modes explored in this effort, initial foot contact is made on the heel. The foot then follows a similar pattern with slight adjustments for all level ground walking speeds and ramp ascent/descent. However, for both stair ascent and descent, initial foot contact after the swing phase tends to be on the ball of the foot and the response of the healthy ankle is adjusted much more than for other modalities. As a result, the primary focus of mode prediction was detecting transitions leading into the stair modalities and transitioning back to level ground.

To evaluate the potential for mode prediction when transitioning between other modalities and into/out of stairs, the transition gait cycles from the data collection were included into the classification. Transition gait cycles were defined as gait cycles where the foot changed from one type of mode surface to another during the swing phase of gait. The stance phase of gait before this swing phase and the transition swing phase were grouped together as the transition gait cycle. Accordingly, a new definition of classes is presented in Figure 4-5. The new definition includes the transition cycles into and out of each modality from the stair trials during experimentation in addition to the previous data set. The other (OTR) mode under this new definition includes all modalities that were not either transitions into a stair mode or a stair mode. The ramp ascent and ramp descent modes in addition to level ground walking are included in

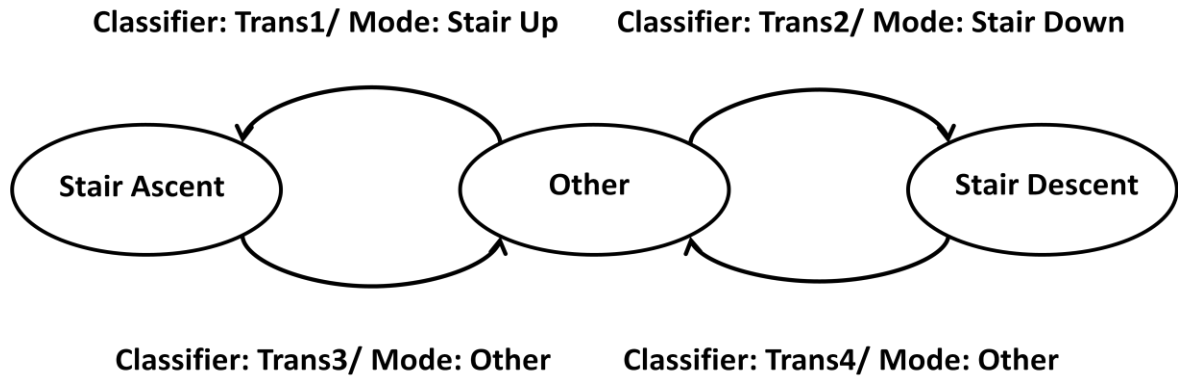


Figure 4-6. Finite state machine for switching between modalities when predicting transitions between level ground and stair surfaces

order to show that not only is the classifier capable of detecting transitions into stair modes from level ground gait cycles, but also able to separate a wide range of normal gait cycles that are experienced during every day walking including a wide range of speed and ramp modes from transitions into stairs.

Three different classifiers were trained in order to detect transitions. The classifier separations are defined in Figure 4-5 by the colored square separations. The first classification includes separation between all OTR modes and transitions into either stair ascent or stair descent. The other two classifications include distinguishing between stair ascent/descent and a transition into level ground walking. The idea behind these classifications is that they would be used as part of a finite state machine mode switching algorithm in order to predict changes between level ground walking and stair modes (See Figure 4-6). When an amputee walks normally at any speed or over ramp surfaces, the classifier identifies the class as an OTR mode. During the transition gait cycle, the classifier then detects the transition as either a Trans1 or a Trans2 classification which would allow the prosthetic controller to switch into either stair ascent or stair descent, respectively. The amputee would then complete the stair mode and a new classifier would continue to identify the current mode as a stair mode until the gait cycle that transitions back into level ground walking. The separate classifier would then either identify the gait cycle as a Trans3 or Trans4 classification which would signal to the prosthetic controller that it must switch back into the level ground state.

Two different types of transition cycles are identified: lead and follow transitions. Lead transitions are defined as the transitions when the prosthetic limb transitions from one mode to

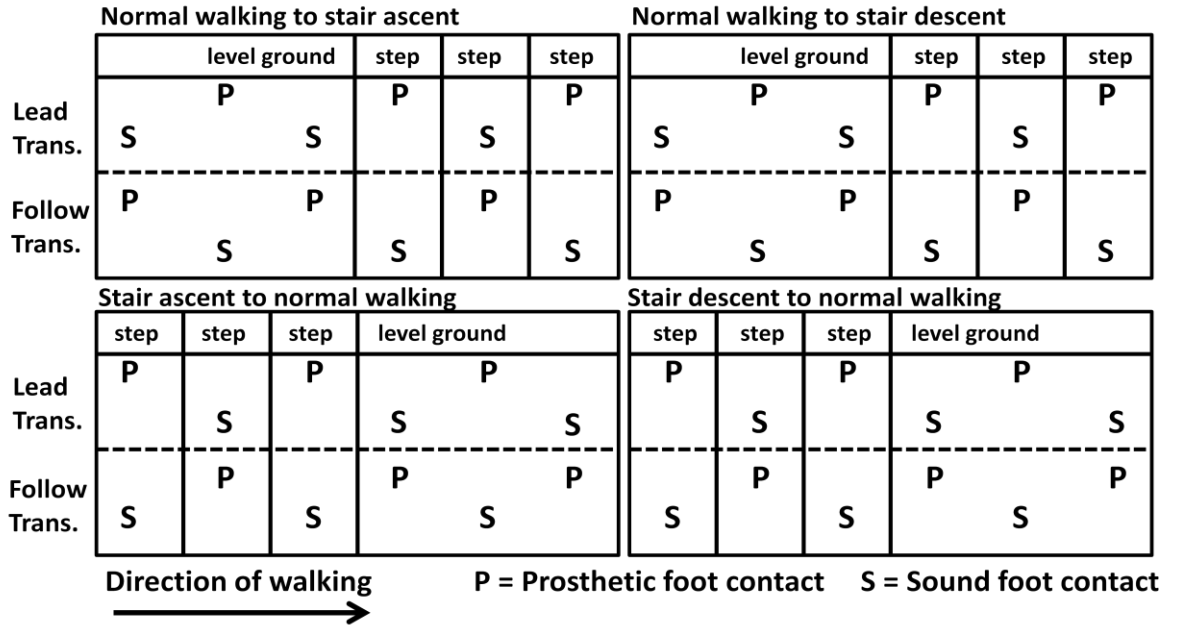


Figure 4-7. Definition of lead and follow transitions for all mode transitions considered

another while the sound limb is still in the previous mode (i.e. the prosthetic limb transitions from level ground to stair ascent while the sound limb is on a level ground surface). Alternatively, a follow transition occurs when the prosthetic limb transitions from one mode to another after the sound limb has already made a similar transition (i.e. the prosthetic limb transitions from stair ascent to a level ground surface after the sound foot has already transitioned to level ground). Lead and follow transitions are demonstrated for all transitions considered in Figure 4-7. The prediction of both types of transitions was explored in the current study.

If detection of the transitions into and out of the stair mode is possible, there would ideally be a period of time between the EMG data window from which features are extracted until the heel strike when the prosthetic first contacts the stairs. This would allow the prosthetic controller time to adapt its function to position the foot in the correct orientation for initial foot contact and respond appropriately to the stair surface. The features from EMG sub windows EMG1 and EMG2 (See Figure 4-1) were used in order to make the defined classifications. This leaves the entire swing phase of gait to process the signals, make the classification, and adjust to prosthetic system when eventually applied to an online real-time system. K-fold cross validation “leave one trial out” strategies similar to mode detection and LDA and SVM classifier identical to mode detection algorithms (See Section 4.3.1) were used for classification.

Table 4-3. Error of classification (%; mean \pm SD (count)) for predictive detection of **follow** transitions between (a) level ground to stair ascent/descent, (b) stair ascent to level ground, and (c) stair descent to level ground.

	LDA	SVM
(a)		
Amputee Subjects		
- False Positive	1.3 \pm 2.2 (12)	0.1 \pm 0.4 (1)
- False Negative	3.3 \pm 8.4 (1)	6.7 \pm 9.1 (2)
- Transition Confusion	0.0 \pm 0.0 (0)	3.3 \pm 6.8 (1)
Non-amputee Subjects		
- False Positive	1.3 \pm 1.6 (9)	0.1 \pm 0.3 (1)
- False Negative	0.0 \pm 0.0 (0)	6.7 \pm 9.1 (2)
- Transition Confusion	0.0 \pm 0.0 (0)	0.0 \pm 0.0 (0)
(b)		
	LDA	SVM
Amputee Subjects		
- False Positive	1.5 \pm 1.9 (2)	0.0 \pm 0.0 (0)
- False Negative	6.7 \pm 16.7 (1)	13.3 \pm 18.2 (2)
Non-amputee Subjects		
- False Positive	0.0 \pm 0.0 (0)	0.0 \pm 0.0 (0)
- False Negative	0.0 \pm 0.0 (0)	0.0 \pm 0.0 (0)
(c)		
	LDA	SVM
Amputee Subjects		
- False Positive	0.7 \pm 1.9 (1)	0.0 \pm 0.0 (0)
- False Negative	6.7 \pm 14.9 (1)	6.7 \pm 14.9 (1)
Non-amputee Subjects		
- False Positive	0.0 \pm 0.0 (0)	0.0 \pm 0.0 (0)
- False Negative	0.0 \pm 0.0 (0)	0.0 \pm 0.0 (0)

The error rates for transition detection and mode prediction is outlined in terms of false positive and false negatives. A false positive is associated with a steady state mode being incorrectly classified as a transition into another modality. Alternatively, a false negative is associated with missing the detection of a transition and instead classifying the transition cycle as a steady state gait cycle. Both false positive and false negative percentages are relative to the number of examples in the correct class (i.e. a false negative percentage is the ratio of missed transition detection relative to the total number of example transitions provided). If the subject is in the OTR modality, there exists a third possibility; when the classifier predicts a transition is

Table 4-4. Accuracy of classification for predictive detection of **lead and follow** transitions between (a) level ground to stair ascent/descent, (b) stair ascent to level ground, and (c) stair descent to level ground.

	LDA	SVM
Amputee Subjects		
- False Positive	3.1 ± 2.7 % (19)	0.5 ± 0.5 % (6)
- False Negative	33.3 ± 4.8 % (17)	20.0 ± 12.5 % (12)
- Transition Confusion	0.0 ± 0.0 % (0)	5.0 ± 7.5 % (3)
Non-amputee Subjects		
- False Positive	4.1 ± 4.0 % (28)	1.3 ± 1.3 % (10)
- False Negative	48.3 ± 21.9 % (29)	25.0 ± 8.3 % (15)
- Transition Confusion	0.0 ± 0.0 % (0)	3.3 ± 7.5 % (2)
(a)		
	LDA	SVM
Amputee Subjects		
- False Positive	5.6 ± 7.7 % (6)	2.2 ± 3.3 % (3)
- False Negative	37.5 ± 16.7 % (9)	36.6 ± 7.5 % (11)
Non-amputee Subjects		
- False Positive	3.7 ± 3.0 % (5)	1.5 ± 2.0 % (2)
- False Negative	26.7 ± 9.6 % (8)	16.7 ± 11.8 % (5)
(b)		
	LDA	SVM
Amputee Subjects		
- False Positive	3.7 ± 2.1 % (4)	2.2 ± 3.3 % (3)
- False Negative	25.0 ± 19.2 % (6)	33.3 ± 20.4 % (10)
Non-amputee Subjects		
- False Positive	9.6 ± 15.8 % (13)	3.0 ± 4.8 % (4)
- False Negative	33.3 ± 40.8 % (10)	13.3 ± 13.9 % (4)
(c)		

occurring, but predicts the wrong transition (i.e. transition out of level ground walking detected, but the next modality is incorrectly identified as stair ascent instead of stair descent). These types of error are identified as transition confusion. The error of transition detection for follow transitions is presented in Table 4-3 and for lead and follow transitions combined in Table 4-4.

Separation of transition gait cycles from steady state gait cycles is observed to be possible with a low error rate. The detection of follow transitions is more accurate than detecting both lead and follow transitions. For amputee subjects, the highest false positive rate during follow transition detection was $1.5 \pm 1.9 \%$ and $0.1 \pm 0.4 \%$ when using LDA and SVM, respectively.

The highest false negative rate for similar detection was $6.7 \pm 16.7 \%$ and $13.3 \pm 18.2 \%$ for LDA and SVM, respectively. Unlike in steady state mode detection, the use of different classifiers affected the accuracy of classification. When using LDA, the accuracy of detecting transitions was increased as compared to SVM. Alternatively, LDA experienced a higher false positive rate than SVM.

4.4 EMG AND IMU SENSOR FUSION

Based on the previous advantages of fusing mechanical measurements with myoelectric signals in intent classification algorithms in both upper and lower limb prosthetics (See Section 2.4.4), inertial signals were collected along with myoelectric signals during experimentation. The fusion of inertial measurements and myoelectric signals had not been explored for lower limb prosthetics previously (though recent efforts have utilized these signals for upper limb prosthetics with significant benefits). Sensor placement and inertial signals collected can be observed in greater detail in Section 3.3. The signal channels included in this fusion effort were a three dimensional accelerometer and rate gyroscopes placed on the lateral aspect of the shank. These signals were chosen because this placement resulted in sensors mounted on the lateral aspect of the prosthetic socket for transtibial amputees. It was believed that if this detection algorithm were to be used in a prosthetic system that this placement would be a safe and repeatable location for the sensors to be placed. Inertial signals were sampled at 25 Hz. From

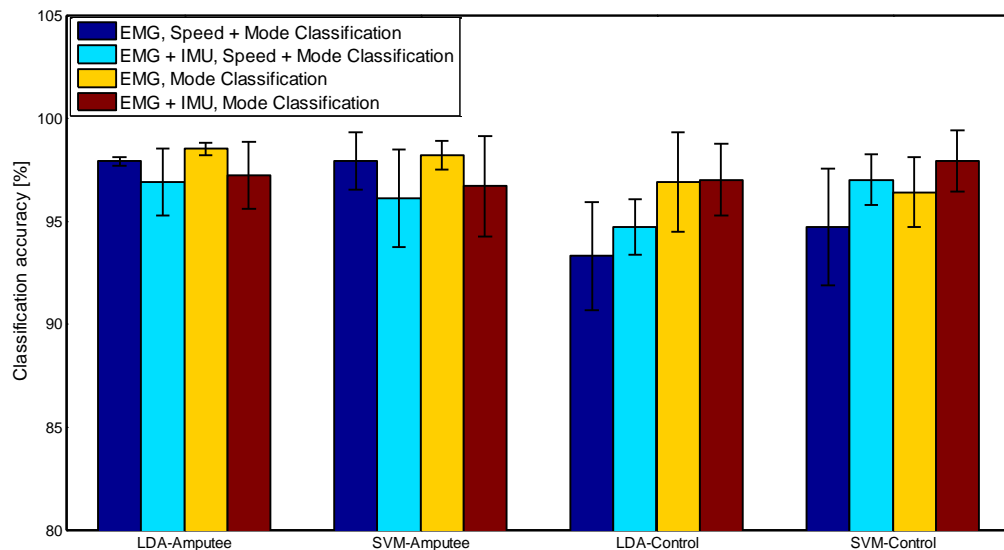


Figure 4-8. Comparison of myoelectric and myoelectric – inertial fusion for both classifiers and subject populations

these signals, similar features to the myoelectric were extracted from the signal. These features included the MAV, RMS, and WAVL. NZero and NSlope sign changes were not considered since inertial signals follow a much more repeatable pattern than EMG and no changes were observed in these features for the different modalities. In their place, the maximum and minimum of the signal over the sample window were used to capture information about the range of each inertial signal. These features were observed to be more relevant to classification.

A comparison of classification accuracy when using only myoelectric signals and with the fusion of myoelectric and inertial signals using all EMG windows (EMG1, EMG2, EMG3) and the single IMU window is presented in Figure 4-8 for both classification algorithms and subject populations. While a slight increase in classification accuracy was observed for control subjects using both classifiers, the same trend was not observed for amputee subjects. The fusion of myoelectric and inertial sensors for amputee subjects had a negative effect on classification accuracy when compared to solely using myoelectric signals. When making classification for all seven classes (including separations between speed) for amputee subjects the classification accuracy was reduced from 97.9% (± 0.22) to 96.9% (± 1.63) and 97.9% (± 1.39) to 96.1% (± 2.37) when including inertial signals with LDA and SVM, respectively.

4.5 GENERALIZABILITY OF CLASSIFICATION

In order for a myoelectric classifier to be used in a real prosthetic system, it is desirable to develop a classifier that is general enough to be used over a wide range of patients. This will allow the classifier to engage immediately when the prosthetic is donned. The alternative would be subject specific training of the classifier, which would be time consuming and potentially unrealistic for the clinical setting. Even if the general classifier is not as accurate as the subject specific model, it can provide a starting point for which to further train a classifier. Starting from a general classifier, the myoelectric controller could be incrementally adapted into a subject specific system that more closely matches the subject specific classifiers outlined previously.

Since the voltage range of EMG signal varies for different subjects and placement, the subject-specific signals were first normalized for all amputees. The normalization was based on the largest value recorded during the maximum voluntary contraction (MVC) collection before the experiment after band pass filtering the myoelectric signals between 20 – 500 Hz. Each

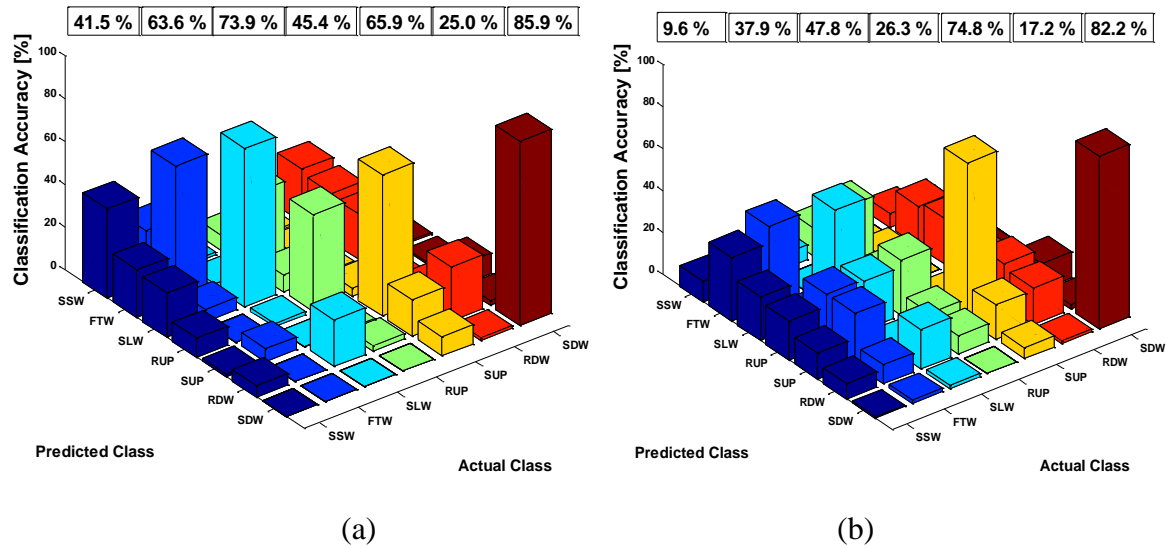


Figure 4-9. Generalized classifier accuracy for all amputee subjects when using (a) LDA and (b) SVM

myoelectric signal was then divided by the maximum value of the signals during MVC. This results in a myoelectric range between -1 and 1.

A generalized myoelectric control algorithm would use example data from previous subjects in order to make predictions for a subject whose myoelectric signals it has not been exposed to. A 5-fold cross validation scheme was set up where each classifier was trained using features from all three EMG windows (EMG1, EMG2, and EMG3) from all amputee subjects except for one. The subject excluded from the training was the test subject. Multiple iterations were completed so that each subject was used as the test subject once. Each iteration of the 5-fold cross validation was used to evaluate the overall accuracy of the generalized classifier. The combined confusion matrices for the general classifier are presented in Figure 4-9.

The classification accuracy of the general classifier was significantly reduced from the subject-specific classifier with average classification accuracies of 52.8% (± 23.6) and 39.5% (± 14.2) compared to 97.9% (± 0.22) and 97.9% (± 1.39) when using a subject-specific classifier for LDA and SVM, respectively. Despite the large decrease in classification accuracy for the general classifier, certain modes exhibited better generalizability than others. Specifically, stair ascent and descent modes were better able to generalize classification for both LDA and SVM classification. If separations are only desired between other modalities and stair ascent/descent, the generalized model is capable of correctly separating 90.9 % and 83.2 % of the total example

gait cycles for LDA and SVM, respectively, without using any gait cycle examples from the test subject.

4.6 CLASSIFIER SENSITIVITY TO DISTURBANCE

During real world use, a prosthetic is donned and doffed on a regular basis. This presents a challenge to myoelectric control algorithms as the myoelectric signals are measured through direct contact of the electrode with the surface of the skin. Different placements of the electrodes can result in varying signals even when the electrode is placed over the same muscle body. This is partly due to the non-uniform stimulation of the muscle during activation. It is desirable to have a myoelectric classifier that is robust in its ability to handle different electrode placements as repeated removal and reattachment of the prosthetic is likely to result in a slight shift in electrode contact with the skin each time the prosthetic is reattached.

To simulate a shifted electrode, a k-fold cross-validation technique was utilized similar to that used in the walking mode detection (See Section 4.3.1) including 32 folds for each subject. For each instance, the classifier was trained on features extracted from the first normalized EMG channel for each muscle. After training, the test data set was used to determine the accuracy of the classifier. The test set data was composed of a sample of data which contained features from a secondary normalized EMG channel for one of the four muscles investigated: tibialis anterior (TA), medial gastrocnemius (MG), vastus lateralis (VL), and biceps femoris (BF). Secondary EMG channels were recorded adjacent to the primary channel along the muscle body and were placed as close as possible to the original channel without electrode overlap. The offset of placement was between 1 to 2 inches from the primary channel. This setup allowed simulation of the effect on the classifier when trained with myoelectric signals from muscles with an initial electrode placement and applied after a single electrode has been shifted. Simulations were conducted for shifting the electrode for each of the four muscles and compared to the original cross validation assessment of mode detection.

Shifted electrode results are presented in Table 4-5. For the majority of subjects, shifting the thigh muscle electrode locations had little effect on classification accuracy. Classification accuracy was much more sensitive to electrode location of the tibialis anterior or the medial gastrocnemius. Across all subjects, shifting the medial gastrocnemius electrode resulted in the most degradation in classification accuracy.

Table 4-5. The difference in classification accuracy for a shifted electrode compared to the original placement for all amputee (LDA – (a), SVM – (b)) and non-amputee (LDA – (c), SVM – (d)) subjects for all four muscles used by the myoelectric algorithm: Tibialis Anterior (TA), Medial Gastrocnemius (MG), Vastus Lateralis (VL), and Biceps Femoris (BF)

	No Shift	Shifted TA	Shift MG	Shifted VL	Shifted BF
Amputee 01	90.0 %	-17.7 %	-3.0 %	1.4 %	1.9 %
Amputee 02	98.0 %	NA	-46.3 %	-10.5 %	-0.8 %
Amputee 03	97.9 %	NA	-4.1 %	1.1 %	0.0 %
Amputee 04	97.7 %	-1.9 %	-9.8 %	-0.3 %	-0.3 %
Amputee 05	98.2 %	NA	-15.6 %	-4.4 %	-0.2 %

(a)

	No Shift	Shifted TA	Shift MG	Shifted VL	Shifted BF
Amputee 01	89.6 %	-21.8 %	-5.3 %	2.3 %	0.7 %
Amputee 02	95.8 %	NA	-50.3 %	-11.7 %	0.2 %
Amputee 03	97.9 %	NA	0.5 %	0.5 %	0.0 %
Amputee 04	98.4 %	-1.6 %	-41.6 %	-0.5 %	-1.1 %
Amputee 05	98.7 %	NA	-17.7 %	-5.9 %	-1.8 %

(b)

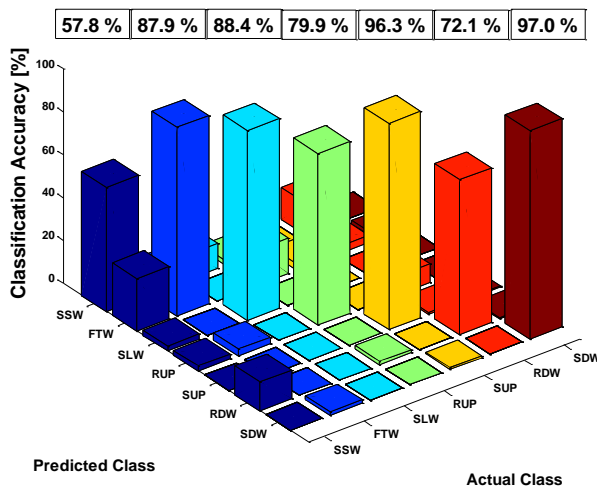
	No Shift	Shifted TA	Shift MG	Shifted VL	Shifted BF
Control 01	93.0 %	0.1 %	-17.6 %	-2.1 %	-0.4 %
Control 02	94.0 %	0.1 %	0.1 %	0.6 %	0.6 %
Control 03	95.4 %	-62.0 %	-67.6 %	-5.1 %	-1.3 %
Control 04	95.3 %	-4.0 %	-15.5 %	-4.0 %	-0.5 %
Control 05	89.0 %	-0.3 %	-11.0 %	-3.1 %	-1.4 %

(c)

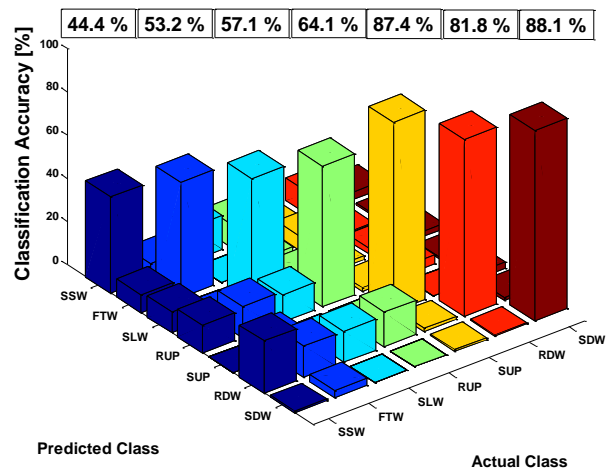
	No Shift	Shifted TA	Shift MG	Shifted VL	Shifted BF
Control 01	91.4 %	-5.7%	-40.5 %	-16.0 %	0.6 %
Control 02	96.4 %	-6.7%	-9.4 %	-4.0 %	-3.4 %
Control 03	97.7 %	-58.3%	-63.8 %	-3.0 %	-1.0 %
Control 04	96.1 %	-0.7%	-7.7 %	-7.1 %	-0.7 %
Control 05	92.0 %	-2.2%	-12.3 %	0.1 %	-2.2 %

(d)

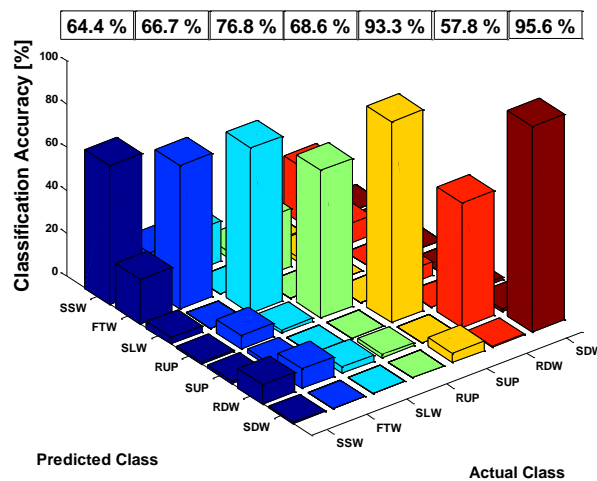
Shifting the electrode location on the medial gastrocnemius was observed to have the greatest effect on classification accuracy. Confusion matrices for all amputee and non-amputee subjects when using both classification methods are presented in Figure 4-10 when the medial gastrocnemius muscle electrode was shifted. As can be observed, classification of stair ascent and descent compared to other modes was not much affected despite decreases in classification accuracy of up to 50% for some subjects. For amputee subjects, classifications between stair



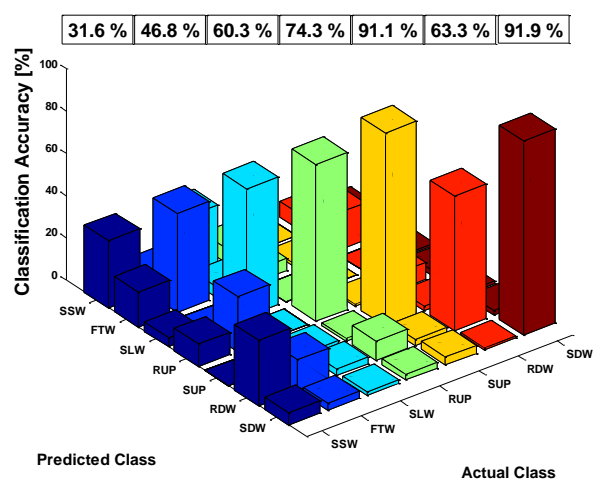
(a)



(b)



(c)



(d)

Figure 4-10. Combined confusion matrix for all amputee (LDA – (a), SVM – (c)) and non-amputee (LDA – (b), SVM – (d)) subjects for modal detection when medial gastrocnemius electrode location is shifted

ascent/descent and other modes after shifting an electrode was 98.7% and 97.9% when using LDA and SVM, respectively. High classification accuracy for stair ascent/descent against other modes was preserved because decreases in accuracy when electrodes were shifted were either due to misclassifications between different level ground walking speed classes or between level ground and ramp ascent/descent.

4.7 SUMMARY

Five transtibial amputees and five non-amputee subjects were recruited for this study. Each subject completed an experimental protocol during which the subjects performed different walking modes including level ground walking at various speeds, stair ascent/descent, and ramp ascent/descent. From the collected data, a windowing scheme was developed based on repeatable events in the gait cycle (heel strike and toe off). From these windows, relevant features were extracted that represented the level of activation of each muscle in order to decompose the signal. These features were a subset of features explored in previous myoelectric control literature.

The capability of myoelectric walking mode detection has been explored in this study. The classifier is computationally simplistic requiring the use of only a few, short windows of EMG data from each gait cycle. In addition, the feature set utilized for classification is computationally simplistic, using time domain features. The most computationally expensive feature explored (6th order autoregressive coefficients) was observed to have no discernible benefit towards classification and as a result was not used in this study. For transtibial amputees, mode detection accuracy was 97.9% (\pm 0.22) and 97.9% (\pm 1.39) for LDA and SVM, respectively. No benefits were observed for one classification algorithm over the other. The fusion of myoelectric and inertial signals was observed to have a negative effect on classification accuracy compared to solely using myoelectric features for amputee subjects.

The ability to predict transitions between modes was also considered. Prediction of modes focused on detecting when the subject was transitioning from any other mode into stair ascent/descent or from a stair mode into a normal walking mode. Such detection was observed to be possible when transitions were “follow transitions” (See Figure 4-7). Of the 60 total example transitions, 57 and 54 (95% and 90%) of the transitions were detectable for amputee subjects when using LDA and SVM, respectively. A trade-off was observed between a low false positive rate when using SVM and the accuracy of transition detection when using LDA. Very few transitions were observed as part of the current study with three examples available for each transition type. The inclusion of more examples may increase the ability of the classifier to make these predictions.

An examination of the generalizability of the myoelectric classifier was completed in order to determine the classifier’s potential limitations during real world use. Classification accuracy was decreased to 52.8% (\pm 23.6) and 39.5% (\pm 14.2) compared to 97.9% (\pm 0.22) and

97.9% (± 1.39) when using a generalized classifier for LDA and SVM, respectively. This reveals a limited ability to use the classifier without subject-specific training prior to use if the desired application of the classifier is to distinguish between the seven modes explored in this study. Separations between stair ascent/descent and other modalities showed the highest level of generalizability with accuracies of 90.9% and 83.2% when using a generalized model for LDA and SVM, respectively. A more generalized model may be possible with the inclusion of more subjects.

The robusticity of the classifier in response to shifts in electrode location was also examined in this study. For both amputee and non-amputee subjects, the classification accuracy was most sensitive to shifts in the medial gastrocnemius electrode location. When this and other electrodes were shifted, the classifier showed a decreased ability to make separations between level ground walking speeds and also between the level ground and ramp ascent/descent modes. The effects of electrode location shifting on the ability of the classifier to separate between stair ascent/descent and other modalities were minimal for all muscles.

Chapter 5. DISCUSSION

Based on the results presented in this study, a discussion of the major limitations of the current work is outlined. The overall goal of this study was to develop a myoelectric control algorithm that could be used as part of a real world prosthetic system. The most realistic use of this classifier will be discussed.

5.1 EXPERIMENTAL SYSTEM AND PROCEDURE LIMITATIONS

Use of the current measurement system did have slight technical limitations. Most notably, use of the synchronization signal malfunctioned during a small subset of the experimental data. The rare instances where the synchronization signal did not operate properly were easily observable as the time length of data collection between the two systems did not match. For these trials, it was observed that the signal either failed at the beginning or the end of the data collection. When at the end of collection, no changes to the time stamps were needed as they were identical, with one system recording for slightly longer. Alternatively, when the time synchronization failed at the beginning of the data collection, the IMU data were time shifted to match the time recordings of the EMG and footswitch signals. For the few trials where this was necessary, IMU signals were observed to match the cyclic footswitch data and showed consistent profiles.

The IMU sensors used in this study had a relatively low sampling rate at 25 Hz. Due to the relatively short duration of each gait cycle, this restricted the data points available for modal classification using IMU signals. Future studies would likely benefit from the use of an IMU system with higher sampling frequencies.

All measurement devices have the potential to influence the system that they are being used on. The system used in this study is no exception. The light weight of the current system and placement of wiring was specifically designed to provide minimal influence on the gait of both control and amputee subjects. All wiring spanning between limb segments was given enough slack to allow for full range of joint motion.

5.2 CLASSIFIER LIMITATIONS

The potential does exist that the classification accuracies observed in this study were inflated compared to what they would be in real world situations based on the limited

experimental data collected. Specifically, all myoelectric and inertial signals were recorded over a short period of time (under 3 hours). The use of this data set for each subject ignores the potential time dependence of the signals and assumes that signals are constant enough that a classifier trained on a subset of signals will still be viable at a later time. It is unknown to what extent these signals may change over time and how this will affect the classifier.

The stair and ramp surfaces for all the data collection were kept constant for the data collection. During real world use, the prosthetic would need to make accurate classifications for these modalities regardless of the uniformity of the terrain. Ramp and stair surfaces are expected to change in either angle or height of step depending on the modality. These physical variations were not taken into consideration in the present study and as a result their effect on the classifier is unknown.

The current classifier assumes that all possible terrains fit well into the different modes experienced during this experiment. However, the amputee subject is not bound by these modalities and is expected to experience other ambulation conditions such as sharp turns, jumping, stutter steps, and abrupt stops among others. How these more chaotic walking styles would be classified is unknown. Future efforts should evaluate how a more diverse set of walking modalities may affect the operation and safety of a prosthetic system which utilizes a myoelectric classifier.

5.3 WALKING MODE CLASSIFICATION

5.3.1 Mode Detection

In previous literature, ARCs were observed to benefit classification accuracy (Huang, Kuiken, & Lipschutz, 2009; Tkach, Huang, & Kuiken, 2010). With the exception of using SVM for control subjects, excluding ARCs from the feature set increases the average classification accuracy for all subjects and reduces the standard deviation of the classification accuracy in the current study. This implies a more accurate and stable classifier without the use of ARCs. Due to the combination of the increased computational demand of calculating the ARCs and the observed reduction in classification accuracy, ARCs were considered to not benefit classification and were removed for analysis. The EMG feature set included only the MAV, VAR, WAVL, NZero, and NSlope. These features were standard from literature for use in myoelectric control algorithms.

The amount of misclassification between different speeds is likely due to the similarity between gait patterns and is less concerning than other misclassifications especially since the misclassifications within speed still fall under the larger level ground classification. Alternatively, very few misclassifications were observed between stair ascent/descent and all other modalities. The function of the lower limb during stair ambulation is dramatically different than level ground or ramp modalities. This is believed to result in the better classification accuracy observed for these select modes.

If this style of detection were to be used in a prosthetic system, there would likely be a tradeoff between the number of modalities the system is able to detect, the computational demand of the classification, and the accuracy of the classifier. The increased number of classes results in an increase in the computational demand of the detection algorithm. Speed classifications would not likely be used due to the similar desired response of the prosthetic and the low classification accuracy.

As previously stated, stairs had a low misclassification rate when compared to other modalities. Due to the extreme change in the function of the ankle when ascending/descending stairs compared to other modes, it may be the case that a significant advantage to the amputee would be present if the prosthetic were only able to adjust its function to handle stairs more similarly to the natural foot ankle system. If classifications are only desired between all other modalities and stair ascent/descent, the classification accuracy is 100% (± 0.00) and 99.8% (± 0.29) for amputee subjects when using LDA and SVM, respectively. This is considered extremely accurate and highlights the potential for such classification in real world prosthetic systems.

In general, unlike previously observed (Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011), no consistent advantage was observed for the use of SVM when compared to LDA in modal classification. While a slight increase in the classification accuracy was observed when using SVM for the non-amputee subjects, this increase in accuracy was due to an increase in the classification of different walking speeds (See Figure 4-4). Such classifications are unlikely to be used in future applications due to the relatively lower classification rate and the similar function of the foot ankle system during these different speeds relative to other modalities. No increase in classification accuracy was observed for amputee subjects when using SVM over LDA.

5.3.2 Mode Prediction

The only myoelectric controller that allowed for detection of transitions between modes for transtibial amputees accounted for transitions between two modes: level ground walking and stair descent (Au, Bonato, & Herr, 2005). The transition detection algorithm outlined in the current study detects transitions between three modes. The previous myoelectric controller required conscience contraction of the muscles on the residual limb and was only evaluated on a single subject. The conscience muscle contraction required to switch modes does have benefits. It provides more direct control of the prosthetic by the amputee.

Another myoelectric controller law for transfemoral amputees detected a wider range of transitions between modes, focused only on “follow” transitions, and required continuous classification with increased computational cost (Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011). The presence of errors in transition detection is much higher when including both “lead” and “follow” transition types together. This is likely due to the actual changes the classifier is detecting when predicting a transition between two modes. Presumably, the classifier is detecting a change in muscle activation that is present due to a different motion pattern in that limb or due to stabilization associated with a different motion pattern in the contralateral limb. The outlined classifier only uses EMG signals from the stance phase of gait. For lead transitions, the change in muscle activation associated with transitions will likely not occur until mid to late swing phase. Any changes in muscle activation before this point would likely be slight and difficult to detect. As a result, many lead transitions may not be detectable using the current classifier. The inclusion of EMG signals from the swing phase of gait could be used to detect these transitions, but the benefit would likely be lost as detection at this point wouldn’t allow a prosthetic controller enough time to classify and respond to the detected transition.

Unlike mode detection, there are observable differences between the classification results when using LDA and SVM. Neither classifier is convincingly more accurate, but each classifier demonstrates certain advantages. When using LDA, there is a general trend towards a reduction in false positives, especially when focusing on follow transitions only. This means that LDA would likely predict more transitions than SVM. In previous literature, SVM showed an increased ability to detect transitions between modes (Huang, Zhang, Hargrove, Dou, Rogers, & Englehart, 2011). Alternatively, the presence of false positives is increased when using LDA compared to SVM. This would result in increased misclassification of OTR or normal gait cycles

as transition cycles when no transition is about to occur. If this detection were to be used as part of a responsive prosthetic system, such false positives would likely result in unexpected action of the prosthetic which could be potentially dangerous to the amputee. Alternatively, the opposite is true when predicting transitions with SVM. Transitions are less likely to be detected, but the false positive rate is much lower. This would result in a safer use of the prosthetic with SVM, but would also be less useful as fewer transitions would successfully be detected.

A missed transition from one modality to another does not necessarily mean the adaptive nature of the prosthetic will be lost. In the event that a transition is not predicted through the myoelectric signals, the high rate of stair modality detection of steady state gait cycles means that a stair will be detected after the transition is completed when the prosthetic completes the first gait cycle in the new mode. The prosthetic will then be able to adapt its function with a one gait cycle delay. Current passive, commercial systems provide no change in function as changing into and out of stair ascent/descent and other modalities. This lack of immediate adaptation of the prosthetic should not produce instability concerns. Though not optimal, it is a sufficient back up in the event of missed transitions.

5.4 EMG AND IMU SENSOR FUSION

The inclusion of IMU features in classification was observed to negatively affect classification accuracy which differs from results observed for similar fusion techniques for the upper limb (Fougner, Scheme, Chan, Englehart, & Stavdohl, 2011). The lack of an increase in classification accuracy when including features from IMU signals for amputees may be due to the different kinematics of the shank for transtibial amputees. The amputee is less likely to experience the full range of movement when using a prosthetic system. This reduction in motion may result in an inability of the classifier to detect changes between different modes for amputee subjects. Since any developed classifier would be used solely on amputee subjects when developing a real world prosthetic system, the influence of inertial signals on amputee classification is the more important observation. As a result, the fusion of myoelectric and inertial signals appears to have negative effects on motion classification based on the current data set and will be removed from immediate consideration. There is the possibility that the sampling rate of the inertial signals was too low to capture enough information to properly classify the different walking modes, particularly since the IMU window over which features were sampled

was so short (~ 400 to 600 ms depending on the mode). Increasing the sampling rate in future development efforts may improve these results.

5.5 GENERALIZABILITY OF CLASSIFICATION

The accuracy of classification was significantly reduced for the detection of all seven walking modes when using a generalized classifier. This is due to the strong variation between signals for different subjects that is expected when working with myoelectric signals. However, certain modes were more generalizable than others. A reasonable accuracy of classification can be obtained for the detection of stair modalities without knowledge of the myoelectric signals from an individual amputee. This presents the possibility of a generalized myoelectric control law that is capable of detecting stairs for the instance the prosthetic is donned on.

Greater accuracy may be possible with a larger test sample to better train the generalized classifier. A larger population would provide more information to be used in classification which would likely result in clearer trends in signals among different subjects. In the current sample of amputees, only four subjects were used to train the generalized classifier at a time. This is a small number and provides possibility that a single non conforming subject could skew the trained classifier away from a better generalized model. A larger sample would likely increase the generalizability of the classifier.

5.6 CLASSIFIER SENSITIVITY TO DISTURBANCE

The medial gastrocnemius muscle was observed to experience the worst degradation in classification accuracy when an electrode was shifted. This is believed to be due in part to this muscle's role in powered plantar flexion. Decreases in accuracy of classification for shifted electrodes were primarily the result of misclassifications between level ground walking speeds and ramp ascent/descent modalities. For different walking speeds, the magnitude of powered plantar flexion increases with different walking speeds (Hansen, Childress, Miff, Gard, & Mesplay, 2004). Similarly, powered plantar flexion is expected to be adjusted when completing ramp modalities. This suggests that during the training process the classifier was using the magnitude of medial gastrocnemius excitation as an important indicator between speed separations and ramp ascent/descent classification. These separations appear to have a narrow distinction between the different classes. When the electrode was shifted and resulted in a slight

change in magnitude of the myoelectric features, the classifier lost part of its ability to make these key separations.

It was observed similar to other tests that stair ascent/descent detection was particularly robust against electrode shifting disturbance. This is likely due to the large changes in muscle activations between stair ascent/descent modes for which changes in all myoelectric signals is observed when experiencing a stair modality.

5.7 SUMMARY

The major limitations of the current study include the low sampling rate of the IMU signals and the short period of time over which myoelectric signals were collected (< 3 hrs). This study was a proof of concept in order to determine the capability of myoelectric classification for transtibial amputees. These limitations will be addressed as part of future efforts.

For both mode detection and prediction, stair ascent/descent classification was more accurate than any other separation. This is believed to be due to the large changes in muscle activation for these modalities when compared to any other modes that share more similar gait patterns. This gave the classifier the ability to make more distinct separations between other modes, stair ascent, and stair descent. This strength of separation was observed during myoelectric control law robustness tests for generalizability and resistance to the electrode shift disturbance. For both of these tests, stair ascent/descent classifications were observed to be particularly accurate despite the lack of accuracy among other modes.

Chapter 6. CONCLUSIONS AND FUTURE WORK

6.1 LDA AND SVM COMPARISON

In previous myoelectric control literature, using SVM as a classifier was reported to be superior to LDA. Increased classification accuracy was reported when using the radial basis function kernel for SVM (the linear kernel was not considered for that particular study). For the current study, neither classifier showed consistent advantages for all capabilities and limitations of the myoelectric classifier that were explored. When detecting between the seven different modes, SVM and LDA performed equally well as a classifier for the amputee subjects in this study. It is of interest that when comparing classification accuracy between the two machine learning algorithms on a per subject basis that SVM showed a reduction in classification accuracy for three of the ten subjects considered in this effort: two amputee subjects and one control subject. This reduction ranged from .2 - 2.2% in decreased classification accuracy.

When predicting transitions between modes, each classifier presented its own advantage. The SVM classifier experienced a much lower false positive rate while the LDA classifier was able to predict more of the example transitions. While the increased prediction of transitions when using LDA may seem more advantageous initially, the lower false positive rate when using SVM may be more important during real world use. If a transition is incorrectly detected during level ground walking, the prosthetic would change its function before the next heel strike, potentially without the subject's observation. This could prove dangerous to the amputee subject and lead to increased tripping of the amputee. If a transition is missed, the high classification accuracy observed when detecting stair modes indicates that the prosthetic would be able to detect the stair modality after the missed transition and adjust its function with a one gait cycle delay. Alternatively, the LDA approach exhibited a better ability to generalize between research subjects. The generalizability of LDA was also observed with in a classifier that was slightly more robust against disturbances in electrode location.

Based on the different benefits of each classifier, the real distinction between them may not be based on accuracy of detection but on other features of the classifier. Specifically, LDA uses regression analysis to train the classifier as opposed to the iterative methods for SVM. This makes LDA a more computationally simplistic classifier to train. A real world myoelectric algorithm would likely need to perform adaptive training to continue to evolve with the

differences in myoelectric signals and gait patterns of the patient. The reduced computational cost of training LDA makes it a more desirable classification method when accuracies are not definitively better for SVM.

In addition, it is noted that current comparisons between LDA and SVM may be limited due to the small subject sample in this study. For this limited sample, trends may have occurred that are not representative of all individuals in the general population. Different trends may develop with a larger sample of subjects.

6.2 MYOELECTRIC CLASSIFICATION FOR STAIR DETECTION AND PREDICTION

While classification between all seven modes explored in this study was determined to be possible, the highest accuracy in classification was observed when making separations between all other modalities and stair ascent or stair descent. For this separation the classification accuracy is 100% (± 0.00) and 99.8% (± 0.29) for amputee subjects when using LDA and SVM, respectively. In addition, the ability to predict transitions between all other modalities and either stair ascent or descent provides the potential for the prosthetic system to smoothly adapt between these three modes. Of the total 60 example transitions, 57 and 54 (95% and 90%) of the transitions were detectable for amputee subjects when using LDA and SVM, respectively, while still maintaining a low false positive rate. In addition, separation between stair modes and other modes showed good performance for both generalizability of classification and robusticity of classification with shifting electrodes (See Sections 4.5 and 4.6).

This observation opens the potential for the use of a myoelectric classifier that solely makes distinctions between the three classes of stair ascent, stair descent, and all other modalities. The ultimate goal of prosthetic engineering is to develop a foot ankle system that completely replicates all functions of the natural foot ankle system. The natural ankle makes more substantial adjustments for stair modes compared than it does when varying speed and completing ramp modes. This emphasizes the importance of developing a foot ankle system that specifically adapts its function when the subject is completing a flight of stairs. The current study's results for classification of stair ascent/descent against other modalities show that such a stair-specific myoelectric control law for transtibial amputees may be possible with the current methods.

6.3 FUTURE WORK

The long term goal of this project is to include a similar myoelectric control law as part of a responsive lower limb prosthetic system. Before this can become a reality, several unanswered questions relating to the use of myoelectric algorithm need to be considered. The current effort focused on making classifications from a finite data set after an experimental collection. This collection occurred over a short time period (< 3 hrs) and with consistent stairs and ramps. With the observed proof of concept for myoelectric classification, a real-time classifier could be developed in order to test the ability of the myoelectric control law to make separations between different walking modes in real time. This would provide an understanding of the amount of time required to make classifications and the feasibility of making classification quickly enough to allow for prosthetic adaptation. This real time classification system could also be used in a wider variety of walking terrains (i.e. ramps of varying inclines, uneven surfaces, turning, during initiation and termination of gait, etc) in order to observe how robust the classifier is when detecting walking modes over surfaces that are not identical to surfaces that it was trained with. Since any myoelectric control algorithm for a prosthetic would be used over several years, the time dependency of consistency also needs to be evaluated. Towards real-time classification, any reduction in computation cost when calculating features or making classifications would benefit the classifier. This could be investigated through a systematic evaluation of the optimum feature set in classification as well as investigating the effects to classification when individual features are removed from the feature set.

Myoelectric signals were collected from amputee subjects when using their currently prescribed passive, non responsive prosthetics. With the inclusion of a myoelectric control algorithm, it is expected that any prosthetic the algorithm is used in would respond to different walking modes. This adaptation will affect the gait patterns of the amputee and as a result, their muscle activations which will be reflected in the myoelectric signals. It is unknown how these changes to the myoelectric signal will affect the accuracy of classification. This will need to be investigated prior to use of such a prosthetic system.

REFERENCES

- Abe, S. (2005). *Support Vector Machines of Pattern Classification*. London: Springer-Verlag.
- Ajiboye, A. B., & Weir, R. F. (2005). A heuristic fuzzy logic approach to EMG pattern recognition for multifunction prosthesis control. *Transactions on Neural Systems and Rehabilitation Engineering* , 280-291.
- Au, S. K., Bonato, P., & Herr, H. (2005). An EMG-position controlled system for an active ankle-foot prosthesis: An initial experimental study. *9th International Conference on Rehabilitation Robotics*, (pp. 375-379). Chicago, IL, USA.
- Au, S., Berniker, M., & Herr, H. (2008). Powered ankle-foot prosthesis to assist level-ground and stair-descent gaits. *Nueral Networks* , 654-666.
- Beyart, C., Grumillier, C., Martinet, N., Paysant, J., & Andre, J. (2008). Compensatory mechanism involving the knee joint of the intact limb during gait in unilateral below-knee amputees. *Gait and Posture* , 278-284.
- Broman, H., Bilotto, G., & De Luca, C. (1985). Myoelectric signal conduction velocity and spectral parameters: influence of force and time. *Journal of Applied Physiology* , 1428-1437.
- Calbourne, G. R., Naumann, S., Longmuir, P., & Berbrayer, D. (1992). Analysis of meachanical and metabolic factors in the gait of contenital below knee amputees. *American Journal of Physiology and Medical Rehabilitation* , 272-278.
- Chan, A. D., & Englehart, K. B. (2005). Continuous Myoelectric Control for Powered Prostheses using Hidden Markov Models. *Transactions on Biomedical Engineering* , 121-124.
- Clancy, E., Morin, E., & Merletti, R. (2002). Sampling, noise reduction and amplitude estimation issues in surface electromyography. *Journal of Electromyography and Kinesiology* , 1-16.
- Delagi, E. F., Perotto, A., Iazzetti, J., & Morrison, D. (1975). *Anatomic Guide for the Electromyographer*. Springfield, Illinois: Charles C Thomas.
- Delis, A., Carvalho, J., F da Rocha, A., Ferreira, R., R. S., & Borges, G. (2009). Estimation of the knee joint angle from surface electromyographic signals for active control of leg prostheses. *Physiological Measurement* , 931-946.
- Eilenberg, M., Geyer, H., & Herr, H. (2010). Control of a Powered Ankle-Foot Prosthesis Based on a Neuromuscular Model. *Transactions on Neural Systems and REhabilitation Engineering* , 164-173.
- Englehart, K., & Hudgins, B. (2003). A robust, real-time control scheme for multifunction myoelectric control. *Transactions on biomedical engineering* , 848-854.

- Englehart, K., Hudgins, B., & Parker, P. A. (2001). A wavelet-based continuous classification scheme for multifunction myoelectric control. *Transactions on biomedical engineering* , 302-311.
- Englehart, K., Hudgins, B., Parker, P., & Stevenson, M. (1999). Classification of the myoelectric signal using time-frequency based representations. *Medical Engineering and Physics* , 431-438.
- Ferris, D. P., Gordon, K. E., Sawicki, G. S., & Peethambaran, A. (2006). An improved powered ankle-foot orthosis using proportional myoelectric control. *Gait and Posture* , 425-428.
- Fougner, A., Scheme, E., Chan, D., Englehart, K., & Stavdohl, O. (2011). A multi-modal approach for hand motion classification using surface EMG and accelerometers. *33rd Annual International Conference of the IEEE EMBS*, (pp. 4247-4250). Boston, MA.
- Fridlund, A. J., & Cacioppo, J. T. (1986). Guidelines for Human Electromyographic Research. *Psychophysiology* , 567-589.
- Ha, K. H., Varol, H. A., & Goldfarb, M. (2010). Myoelectric control of a powered knee prosthesis for volitional movement during non-weight-bearing activities. *Engineering in Medicine and Biology*, (pp. 3515-3518). Buenos Aires, Argentina.
- Ha, K. H., Varol, H. A., & Goldfarb, M. (2011). Volitional Control of a Prosthetic Knee Using Surface Electromyography. *Transactions on Biomedical Engineering* , 144-151.
- Hansen, A. H., Childress, D. S., Miff, S. C., Gard, S. A., & Mesplay, K. P. (2004). The human ankle during walking: implications for design of biomimetic ankle prostheses. *Journal of Biomechanics* , 1467-1474.
- Hsu, C.-W., & Lin, C.-J. (2002). A comparison of methods for multiclass support vector machines. *Transactions on neural networks* , 415-425.
- Huang, H., Kuiken, T. A., & Lipschutz, R. D. (2009). A Strategy for Identifying Locomotion Modes Using Surface Electromyography. *Transactions on Biomedical Engineering* , 65-73.
- Huang, H., Zhang, F., Hargrove, L., Dou, Z., Rogers, D. R., & Englehart, K. B. (2011). Continuous Locomotion Mode Identification for Prosthetic Legs based on Neuromuscular Mechanical Fusion. *Transactions on Biomedical Engineering* , 2867-2875.
- Huang, Y., Englehart, K. B., Hudgins, B., & Chan, A. D. (2005). A gaussian mixture model based classification scheme for myoelectric control of powered upper limb prostheses. *Transactions on Biomedical Engineering* , 1801-1811.
- Karlik, B., Tokhi, O., & Alci, M. (2003). A fuzzy clustering neural network architecture for multifunction upper-limb prosthesis. *Transactions on Biomedical Engineering* , 1255-1261.

- Lawson, B. E., Varol, H. A., Sup, F., & Goldfarb, M. (2010). Stumble detection and classification for an intelligent transfemoral prosthesis. *32nd Annual International Conference of the IEEE EMBS*, (pp. 511-514). Buenos Aires, Argentina.
- Mayagoitia, R. E., Nene, A. V., & Veltink, P. H. (2002). Accelerometer and rate gyroscope measurement of kinematics: an inexpensive alternative to optical motion analysis systems. *Journal of Biomechanics* , 537-542.
- Mayagoitia, R. E., Nene, A. V., & Veltink, P. H. (2002). Accelerometer and rate gyroscope measurement of kinematics: an inexpensive alternative to optical motion analysis systems. *Journal of Biomechanics* , 537-542.
- Moreno, J., Rocon de Lima, E., Ruiz, A., Brunetti, F., & Pons, J. L. (2006). Design and implementation of an inertial measurement unit for control of artificial limbs: Application on leg orthoses. *Sensors and actuators* , 333-337.
- Oliveria, A. S., Yamaguti, E. Y., Mochizuki, L., Amadio, A. C., & Serrao, J. C. (2009). Biomechanical parameters of gait among transtibial amputees: a review. *Sao Paulo Medical Journal* , 302-309.
- Oskoei, M. A., & Hu, H. (2007). Myoelectric control systems--A survey. *Biomedical Signal Processing and Control* , 275-294.
- Postema, K., Hermans, H., Vries, J. D., Koopman, H., & Eisma, W. (1997). Energy storage and release of prosthetic feet Part 1: biomechanical analysis related to user benefits. *Prosthetics and Orthotics International* , 17-27.
- Powers, C. M., Rao, S., & Perry, J. (1998). Knee kinetics in trans-tibial amputee gait. *Gait and Posture* , 1-7.
- Prentice, S. D., Hasler, E. N., Groves, J. J., & Frank, J. S. (2004). Locomotor adaptations for changes in the slope of the walking surface. *Gait and Posture* , 255-265.
- Protopapadaki, A., Drechsler, W. I., Cramp, M. C., Coutts, F. J., & Scott, O. M. (2007). Hip, knee, ankle kinematics and kinetics during stair ascent and descent in healthy young individuals. *Clinical Biomechanics* , 203-210.
- Redfern, M. S., & DiPasquale, J. (1997). Biomechanics of descending ramps. *Gait and Posture* , 119-125.
- Tkach, D., Huang, H., & Kuiken, T. A. (2010). Study of stability of time-domain features for electromyographic pattern recognition. *Journal of Neuroengineering and rehabilitation* .
- Vigreux, B., Cnockaert, J., & Pertuzon, E. (1979). Factors influencing quantified surface EMGs. *European Journal of Applied Physiology and Occupational Physiology* , 119-129.

- Waters, R., & Mulroy, S. (1999). The energy expenditure of normal and pathologic gait. *Gait and posture* , 207-231.
- West, W., Hicks, A., Clements, L., & Dowling, J. (1995). The relationship between voluntary electromyogram, endurance time and intensity of effort in isometric handgrip exercise. *European Journal of Applied Physiology and Occupational Physiology* , 301-305.
- Winter, D., & Sienko, S. E. (1988). Biomechanics of below-knee amputee gait. *Journal of biomechanics* , 361-367.
- Wu, S.-K., Waycaster, G., & Shen, X. (2011). Electromyography-based control of active above-knee prostheses. *Control Engineering Practice* , 875-882.
- Ziegler-Graham, K., Mackenzie, E., Ephraim, P., Travison, T., & Brookmeyer, R. (2007). Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Archives of Physical Medical and Rehabilitation* , 422-429.
- Zlatnik, D., Steiner, B., & Schweitzer, G. (2002). Finit-state control of a trans-femoral (TF) prosthesis. *Transactions on Control Systems Technology* , 408-420.

APPENDIX A: SUBJECT CONSENT FORM



SUBJECT NAME		SSN:
TITLE OF STUDY	Prosthetic knee-ankle-foot system with biomechatronic sensing, control, and power generation	
PRINCIPAL INVESTIGATOR	Glenn K. Klute, PhD	

LAY TITLE: Prosthetic knee-ankle-foot system with biomechatronic sensing, control, and power generation

Researchers:

Glenn Klute, PhD	Principal Investigator, Rehabilitation R&D Center	(206) 277-6724
Michael Hahn, PhD	Research Scientist, Rehabilitation R&D Center	(206) 277-6310
Joseph Czerniecki, MD	Associate Director, Rehabilitation R&D Center	(206) 277-1812
David Morgenroth, MD	Research Scientist, Rehabilitation R&D Center	(206) 277-1982
Wayne Biggs, CPO	Research Prosthetist, Rehabilitation R&D Center	(206) 277-6951
Ava Segal, MS	Research Specialist, Rehabilitation R&D Center	(206) 277-3089
Jan Pecoraro, RN	Research Coordinator, Rehabilitation R&D Center	(206) 764-2962
Elise Wright, BS	Research Specialist, Rehabilitation R&D Center	(206) 277-1001

24-hour emergency contact: Janice Pecoraro's pager at (206) 416-4143.

Pager Instructions: Dial in the area code and phone number you wish to be called back on then press the pound sign (#).

You are being invited to participate in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide whether you want to be in the study. You are free to discuss this with friends or family. This process is called "informed consent." We will give you a copy of this form once it is signed for your records.

1. Purpose of research study and how long it will last: The purpose of this research study is to develop a new prosthetic knee-ankle-foot system for lower-limb amputees. This new prosthesis will be actively controlled by an onboard computer, which will coordinate the knee and ankle joint

SUBJECT'S IDENTIFICATION (I.D. plate or give name-last, first, middle)

IRB APPROVED

VAPSHCS Consent template (doc #695; version 3.0; 09/30/10)
Prosthetic knee-ankle-foot system with biomechatronic sensing,
control, and power generation
Study Consent form version 4.0; June, 2011

JUL 28 2011 VA FORM MAR 2006

10-1086

VA Puget Sound Health Care System



STUDY TITLE: Prosthetic knee-ankle-foot system with biomechatronic sensing, control, and power generation

motions by using sensory data to detect user intent, to provide appropriate control, and to understand how lower-limb amputees use their prosthesis. The overall prosthetic knee-ankle-foot system is intended to improve comfort and endurance for active amputees who wish to work in demanding environments or who wish to enjoy active lifestyles.

This study is sponsored by the Department of Veterans Affairs Rehabilitation Research and Development Service and Department of Defense Deployment-Related Medical Research Program of the Office of the Congressionally Directed Medical Research Programs. We intend to enroll 198 lower-limb amputees and 54 non-amputees for a total of 252 participants.

2. Description of the study including procedures to be used: The procedures which you are asked to participate in are marked below with an "X." The total time will vary on the number of tests you are asked to, and agree to, participate in. You will not spend more than 3 hours in the lab at any one time. If you agree to wear a portable monitoring instrument, you may be asked to wear it for up to a month.

All procedures will be performed at the Veterans Affairs Puget Sound Health Care System, Seattle Division. Each study visit will take up to 3 hours.

If you are a lower-limb amputee, we will first check the fit and suspension of your prosthesis. If our prosthetist believes the fit is not satisfactory, we will ask your permission to make attempts to modify the fit as necessary. We may even make a new limb for you to use in the study. If a satisfactory fit cannot be achieved, you will not be able to participate in the study.

Novel Prosthetic Device (lower limb amputees only)

You will be asked to wear one or several different prosthetic devices. If there is more than one, the order in which you will be asked to wear them will be randomly determined, much like flipping a coin. You will be asked to wear each device until you feel confident and stable enough to perform the protocols checked below. If you are not able to obtain confidence and stability on any of the devices, we will stop the session. To control the prosthetic device, we may ask you to wear a lightweight vest containing a very small computer. To provide power to this computer or the prosthetic device itself, we may need to connect the vest to an electronic system with a small cable. If this is necessary, we will have a person mobilize the cable while you walk around.

Novel Prosthetic Device (non-amputees only)

You will be asked to wear one or several different prosthetic device(s). Since you are not a lower-limb amputee, we will fit you with special boots that will allow you to walk on a prosthetic foot. These boots are like platform shoes and you will be several inches taller when you are wearing them. One of the boots will be fitted with one or more prosthetic devices. If there is more than one prosthetic device, the order in which you will be asked to wear them will be randomly determined, much like flipping a coin. You will be asked to wear each device until you feel confident and stable enough to perform the protocols checked below. If you are not able to



STUDY TITLE: Prosthetic knee-ankle-foot system with biomechatronic sensing, control, and power generation

obtain confidence and stability on any of the devices, we will stop the session. To control the prosthetic device, we may ask you to wear a lightweight vest containing a very small computer. To provide power to this computer or the prosthetic device itself, we may need to connect the vest to an electronic system with a small cable. If this is necessary, we will have a person mobilize the cable while you walk around.

- Self-Selected Walking Speed Measurement.** We will ask you to walk straight to the end of a 60-foot hallway at your normal speed. You will do this three times or so while we time how long it takes you to walk this distance. This procedure will take less than 10 minutes to complete.
- Ground Reaction Force Measurement.** We will ask you to stand on and walk back and forth across force measuring platforms that are mounted flush with the floor or on a treadmill. You can stop and rest if you get tired. This procedure will take about 30 minutes to complete.
- Motion Measurement Using Optical Motion Detection System.** First, you will be asked to change into a tight-fitting pair of shorts and shirt that we will provide. Next, we will take a standard set of body measurements (height, weight, leg length, foot length) using calipers, a measuring tape, and a scale. We will then attach small reflective markers to your body using double-sided tape and ask you to stand and walk back and forth across the lab or on a treadmill while the motion of each marker is recorded by infrared cameras. You can stop and rest if you get tired. Video cameras will also record the movement. The video will serve as a qualitative visual record to aid in the analysis and interpretation of the data. This procedure will take about 1 hour to complete.
- Metabolic Energy Measurement.** The air you breathe will be measured to find out how much energy it takes for you to sit, stand, walk overground, or walk on a treadmill. To do this, we will ask you to wear a mask to measure the air you breathe and a lightweight vest. The mask will be adjusted so it fits snug on your face but will not obstruct your vision. Wearing the mask will muffle your voice a bit, but we will still be able to hear you talk.

We will first measure the air you breathe for 3-10 minutes while you rest quietly. Then, we will measure the air you breathe while you walk overground or on a treadmill for another 3-10 minutes. The resting and walking sequence may be repeated up to five times. The entire procedure will take about 1½ hours to complete.

- Telemetered Surface Electromyography.** The muscles in your body produce faint electrical signals when you use them. To measure these signals, we will place small electrodes on your skin. We may need to shave the hair from the places where we will put the electrodes. We may also rub your skin and wipe it clean with a sterile alcohol swab. We will only do this for the particular spot on your skin where we will place an electrode. The electrodes will be attached to your skin using a medical double-sided tape in a way that is similar to putting on a bandage. A total of _____ (number of electrodes) electrodes will be attached to your skin at the following places on your body:

IRB APPROVED

JUL 28 2011

VA FORM
MAR 2008

VA Puget Sound
Health Care System

10-1086



STUDY TITLE: Prosthetic knee-ankle-foot system with biomechatronic sensing, control, and power generation

Places of electrode attachment:

Cables will be used to connect the electrodes to a portable transmitter that you will wear around your waist using a belt. We will secure these cables to your body using Velcro straps, elastic bandages, or the like. The faint electrical signals measured by the system will then be continuously transmitted and recorded via radio waves to a computer-connected receiver. This protocol will be in conjunction with other protocols listed above and may take up to 1½ hours to complete. The electrodes will be removed at the end of the procedure.

- Video and/or Photographic Recording.** A video recording and/or photograph will be made to document your movements. This will help us to make sure the sensors were in the right place and your movement was correct. If this record is used in a scientific presentation or publication, your identity will be obscured.
- Portable Monitoring Device.** We will mount a small plastic box about the size of a candy bar to your prosthesis or strap it to your leg near your ankle. This box houses a very small portable computer that we will use to record how you use your prosthesis and the terrain upon which you walk; for example, the number of steps you take, how long and how fast you walk, the distance you travelled, the number and direction of turns you make, the slope of the ground that you walk on, and how many stairs, if any, you go up and down. We might also measure the temperature and humidity of the environment that you walk in. To help us understand how your prosthesis is operating, we may also measure the ankle and knee motions, how much electrical power is generated while you walk, and how much electrical power is required to operate the prosthesis. Finally, to help us explore ways to improve getting your prosthesis to do what you want, we might also measure the electrical activity of some of your leg muscles.

We will fit this portable monitoring device to you in our laboratory at the VAPSHCS. This will take about 30 minutes. Depending on the storage capacity of the device and how many measurements we will need to record, we may ask you to wear the device for up to 1 month. At the end of this time, we will ask you to return to the laboratory where we will remove the device. This will take also take about 30 minutes.

IRB APPROVED

JUL 28 2011

STUDY TITLE: Prosthetic knee-ankle-foot system with biomechatronic sensing, control, and power generation

3. Description of any procedures that may result in discomfort or inconvenience: The study procedures that take place in our laboratory may be an inconvenience to you since we will ask you to travel to and from our location to participate.

Novel Prosthetic Device(s): You may feel some discomfort on your residual limb or leg while wearing the novel prosthesis. In the event of significant discomfort, tissue irritation, joint pain, or any other problem you feel is related to the new limb, please let us know immediately. If you are an amputee, it may feel different than your current prescription when walking. If you are a non-amputee, the boot system we will ask you to wear may also result in some discomfort. You may also experience unwanted attention from individuals who notice the device you are wearing. You should notify the investigators immediately if you feel uncomfortable with the novel device during the protocols.

Motion Measurement Using Optical Motion Detection System: You may experience slight skin irritation or discomfort when we remove the tape used to attach the reflective markers to your skin. This discomfort will feel similar to removing a bandage from your skin. You may also experience some embarrassment while wearing the tight-fitting clothing we provide for the study procedures. To protect your privacy, only study investigators will be in the immediate area during the procedures unless you specifically give approval for other observers.

Metabolic Energy Measurement: You may experience slight discomfort while wearing this instrument. This instrument includes a mask that is strapped to your head but can be adjusted to make it as comfortable as possible. It is similar to a mask you might wear to keep you from breathing paint fumes while painting. You may experience some embarrassment while wearing the instrument mask. To protect your privacy, only study investigators will be in the immediate area during the procedures unless you specifically give approval for other observers or you specifically say it is okay to walk outside the laboratory.

Telemetered Surface Electromyography: You may experience slight skin irritation or small cuts from the shaving, the abrading, alcohol wipes used to clean your skin, and/or from the removal of the tape. This discomfort will feel similar to removing a bandage from your skin. You may have small patches of shaved skin which may cause some embarrassment.

Self-Selected Walking Speed Measurement: You should experience little or no discomfort during this procedure. This procedure is performed in a hallway at the VAPSHCS, so other people may see you walking back and forth. You will be wearing your street clothes while doing this rather than the tight-fitting clothes that we provide for laboratory measurements.

Ground Reaction Force Measurement: You should experience little or no discomfort during this procedure.

Video and/or Photographic Recording: You should experience little or no discomfort during this procedure.

IRB APPROVED



STUDY TITLE: Prosthetic knee-ankle-foot system with biomechatronic sensing, control, and power generation

Portable Monitoring Device: You may experience unwanted attention from individuals who notice the device on your leg or prosthetic limb.

4. Potential risks of the study: The particular procedures in this study may involve risks that are currently unforeseeable. We will contact you as soon as possible if new findings occur during this research that may pose a risk to you.

Novel Prosthetic Devices: As you adjust to wearing the novel prosthetic device, you may be at a slight risk of losing your balance or falling. We urge you to be very careful until you feel stable on your limb. There is also a slight risk of a component of the novel prosthetic device breaking during these procedures. This may increase your risk of falling or becoming injured. Every effort will be made to monitor the prosthetic device and your gait to reduce these risks.

5. Potential benefits of study: There will be no direct benefit to you by participating in this study. However, people who have undergone a lower-limb amputation may benefit as a result of the work we are doing to develop new prosthetic limbs.

6. Other treatment available: This is not a treatment study. Your alternative to participating in this study is to not participate.

7. Use of research results / Confidentiality: The information obtained about you will be held confidential. However, for purposes of this study, the following list of people or groups may know that you are in this study. They will have access to your records, which may include your medical records:

- Research team members
- The Department of Defense (study sponsor)
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research)
- Federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), and the VA Office of the Inspector General (OIG), Government Accountability Office (GAO)
- The VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies
- The VAPSHCS Fiscal Department will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study

The purpose of this access is to review the study and make sure that it meets all legal, compliance, and administrative requirements. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy.

IRB APPROVED



STUDY TITLE: Prosthetic knee-ankle-foot system with biomechatronic sensing, control, and power generation

Information we collect about you will be stored with a study code, not your name. The master list linking your name to the study code will be stored separately from the study data. Only study investigators and parties named in this consent form will have access to the master list.

Once this study is completed, we will not use your data (or the code linking it to you) for any additional research. Your data and code will be held in a secure database until VA receives authorization to destroy the code in accordance with federal records regulations. It may be several years before the data and code are actually destroyed, but they will not be used for research after this study is completed.

Your data will be stored in a locked office at the VAPSHCS to protect your privacy. Your recruitment and reimbursement identifying data will be stored on a VA-secure computer onsite at the VAPSHCS. This data will be erased approximately 8 weeks after your study participation and reimbursement has occurred. Only study investigators and parties named in this consent form will have access to this data.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to appropriate authorities.

There may be publications about this study in the future. If so, your identity will be held confidential. No personal information will be given in a publication without your approval in writing.

Your study information will be used only for research purposes and will not be sold. Information gained from this research may be used commercially for the development of new ways to diagnose or treat diseases. However, neither you nor your family will gain financially from discoveries made using the information that you provide.

8. Special circumstances: The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study.

You will be paid \$20 an hour for your time participating in study procedures in the laboratory. Additionally, you will be paid \$100 for wearing the portable monitoring device. Payments of \$50 or below will be paid in cash through the VA agent cashier. Payments over \$50 will be paid by check from the Department of the Treasury (6-8 weeks) following your study participation.

In order to reimburse you for these expenses, your name will be provided to the VA. If you participate in multiple studies and receive payments totaling \$600 or more in a calendar year, the VA is required to report this to the Internal Revenue Service as taxable income. If the VA reports this income to the IRS, you may receive a 1099 tax form from the VA at the end of the year for being in this study. The information that the VA would be required to report would include your name, social security number, address, and amount of payments. However, participation in this

IRB APPROVED



STUDY TITLE: Prosthetic knee-ankle-foot system with biomechatronic sensing, control, and power generation

study alone will not result in enough income to require the VA to report it to the IRS as taxable income.

If you are a VA patient, you already have a VA medical record. If you are not a VA patient, we will create a VA medical record for you. We will put information about you from this study into your medical record. All authorized users of the national VA medical records system can have access to your medical record. This may include health insurance companies who are being billed for medical costs. This record will be kept forever.

9. Withdrawal from the study: You do not have to take part in this study. If you are in this study, you can withdraw at any time. You will not be penalized for your decision to not participate or withdraw nor will you lose your VA or other benefits if you decide to do so.

Your doctor has the right to terminate your participation in this study if he or she feels that it is not in your best interest. This termination will not require your consent.

If you decide to withdraw, or if you are terminated from the study, the study physician will then need to meet with you to discuss the necessary steps that you may need to take to end your participation in the study.

10. Questions or concerns related to the study: The study researchers (listed below) *must* be contacted immediately if:

- You think you may have been harmed or injured as a direct result of this research; and/or
- You have any questions regarding your medical care issues.

During business hours (8:00 a.m. — 4:30 p.m.) Call Dr. Glenn Klute at (206) 277-6724

After business hours (nights and weekends) Call Jan Pecoraro, RN, at pager (206) 416-4143

You may contact the Institutional Review Board (IRB) – VA Office at (206) 277-1715 if you:

- Would like to speak with a neutral party who is not involved with this study;
- Have questions, concerns, or complaints about the research;
- Would like to verify the validity of the study; or
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, whose job it is to ensure the protection of the rights, safety, and well-being of human subjects involved in research.

IRB APPROVED



STUDY TITLE: Prosthetic knee-ankle-foot system with biomechatronic sensing, control, and power generation

11. Research-related injury: Medical treatment will be provided, if necessary, by the VA if you are injured by being in this study. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act.

Neither the Department of Defense nor the VA is obligated to reimburse medical expenses due to your non-compliance with study procedures as described in this consent form or otherwise communicated to you by study personnel.

You do not waive any legal rights by signing this consent form.

12. Research subject's rights: I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts, possible benefits of the study, and other choices of treatment available to me. My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

I agree to participate in this research study as you have explained it in this document.

Subject Signature

Date

Print Name of Subject

Signature of Person Obtaining Consent

Date

Print Name of Person Obtaining Consent

IRB APPROVED

JUL 28 2011