Design, Prototyping, Validation, and Testing of a Wearable Surface Electromyography Acquisition System

by

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Abstract

Surface electromyography (sEMG) can provide clinicians an objective measure of muscle function. Despite strong evidence of its utility, clinical use of sEMG is limited because of the time, costs, and complexity associated with conventional acquisition systems. To address the shortcomings of conventional sEMG systems, we introduce the WEAR (Wearable EMG Analysis for Rehabilitation), a compact, wearable sEMG acquisition system with wireless capabilities.

In this thesis, a user-centred design (UCD) process is introduced as a means to research end-user (physiotherapist) needs and limitations, validate initial design concepts, and capture design requirements. A functional prototype WEAR system was implemented based on two novel concepts: 1) a wearable electrode mount housing a reusable polarizable electrode array, and 2) a multi-channel integrated analog front end solution, originally intended for use in electrocardiography and electroencephalography applications.

Functional performance of the WEAR prototype was compared against a conventional sEMG acquisition system, which employed a single pair of disposable pre-gelled Ag/AgCl electrodes and discreet component design. Data from isotonic, isometric contractions and walking trials from 10 participants were used to evaluate sEMG signal quality. Results suggest that sEMG output from the WEAR prototype was comparable to the conventional sEMG acquisition system output, even with the use of an array of reusable polarizable electrodes and the integrated analog front end.

Statement of Originality

This thesis describes the results of the author's research conducted at Carleton University and TOHRC during the course of the M.ASc. program. Results presented herein have been published in the conference proceedings – *34th Conference of the Canadian Medical & Biological Engineering Society and Festival of International Conferences on Caregiving, Disability, Aging and Technology and IEEE International Workshop on Medical Measurements and Applications* and have also been accepted to the *35th Conference of the Canadian Medical & Biological Engineering Society*. The details of the location in the thesis of the results of these publications are summarized below (along with a detailed description of the author's contributions to these publications).

A. Freed, A. Parush, A. D. C. Chan, and E. D. Lemaire, "A user-centered design case study: Design of a wearable sEMG system", 34th Conference of the Canadian Medical & Biological Engineering Society and Festival of International Conferences on Caregiving, Disability, Aging and Technology, Toronto, Canada, 69374, pp. 1-4, 2011.

The results of this conference paper constitute the first portion of Chapter 3. The author prepared all interview questions and focus group discussion topics, performed all user research, carried out the preliminary data analysis, prepared the manuscript for publication, and made all necessary revisions based on feedback from the co-authors.

A. Freed, A. D. C. Chan, E. D. Lemaire, A. Parush, "Wearable EMG analysis for rehabilitation (WEAR)", IEEE International Workshop on Medical Measurements and Applications, Bari, Italy, pp. 601-604, 2011.

The results of this conference paper constitute the first portion of Chapter 4. The author implemented the prototype WEAR system based on system concept by Dr. Chan and Dr. Lemaire, prepared the manuscript for publication, and made all necessary revisions based on feedback from the co-authors.

A. Freed, A. D. C. Chan, E .D. Lemaire, A. Parush, and E. Richard, "Pilot test of the prototype wearable EMG analysis for rehabilitation (WEAR) system", accepted to 35th Conference of the Canadian Medical & Biological Engineering Society, Halifax, Canada, 2012.

The results of this conference paper constitute the latter portion of Chapter 4. The author implemented the prototype WEAR system based on system concept by Dr. Chan and Dr. Lemaire, conducted system validation, carried out data analysis, prepared the manuscript for publication, and made all necessary revisions based on feedback from the co-authors.

To my wife

Acknowledgments

I would like to thank my supervisors, Adrian Chan, Ed Lemaire, and Avi Parush for their time, patience, and guidance throughout the course of my research. In particular, I would like to acknowledge their open mindedness in allowing me to take a multi-disciplinary approach with this thesis. In addition, I would like to thank Joao Thomas and Emile Richard for their technical assistance and advice.

Finally, I dedicate this thesis to Michelle, without whom this would never have become a reality. Her constant support and love inspired me to push through the hard times and propelled me to the completion of this journey.

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List of Abbreviations

A/D	Analog-to-Digital
ADC	Analog-to-Digital Converter
AFE	Analog Front End
COTS	Commercial Off-The-Shelf
EMG	Electromyography
FR	Functional Requirements
GUI	Graphics User Interface
IQR	Interquartile Range
MPU	Microprocessor Unit
MTRC	Modified TRC System
NG	NeuroGym Rehabilitation
OASIS	Open architecture for Accessible Services Integration and Standardization
PGA	Programmable Gain Amplifier
PSD	Power Spectral Density
PT	Physiotherapist
PVT	Private
RMS	Root Mean Square
sEMG	Surface Electromyography
SENIAM	Surface Electromyography for the Non-Invasive Assessment of Muscles
SNR	Signal-to-Noise Ratio

SPI	Serial Port Interface
SS	Signal Strength
TA	Tibialis Anterior
TOHRC	The Ottawa Hospital Rehabilitation Centre
TRC	Conventional sEMG Acquisition System Located in The Ottawa Hospital Rehabilitation Centre's Rehabilitation Technology Laboratory
UCD	User-Centred Design
UR	Usability Requirement
WEAR	Wearable EMG Analysis for Rehabilitation

1. Introduction

1.1. Motivation

For over 70 years, surface electromyography (sEMG) has been used in research and clinical rehabilitation to gain more insight into a participant or patient's muscle function patterns during motion [1]. Walking is commonly analyzed in a systematic process, called gait analysis, to assess the effects of injuries or neuromuscular diseases (i.e., cerebral palsy, muscular dystrophy, Parkinson's) [2]. Although observational gait analysis methods, without the aid of technology, can be highly efficient and cost-effective, they can also be subjective. Implementing technology into gait analysis can provide objective measures. By acquiring sEMG data from muscle groups activated throughout walking, relative strength and timing of the muscle contractions can be quantified [3].

sEMG acquisition is not without its drawbacks. sEMG acquisition systems can be complicated to operate and signals can be difficult to interpret, often requiring a specialized technician or engineer to assist in a gait analysis session. A whole session, including setup, system calibration and patient assessment can take from two to four hours [4]. In addition, the high equipment purchasing and operating costs tend to be prohibitive, especially for small, private rehabilitation clinics. Given the potential benefits of sEMG in rehabilitation, a need exists for a sEMG acquisition system that can address the drawbacks associated with conventional sEMG acquisition [5].

This thesis presents the Wearable EMG Analysis for Rehabilitation (WEAR) system, a wearable sEMG acquisition system that aims to improve upon cost and time factors,

enabling widespread availability of sEMG analysis at the point of patient care. The proposed system will be intuitive to learn and use, thus mitigating the need for support personnel and their associated fees. The WEAR system will also take advantage of leading-edge technology to reduce equipment costs.

1.2. Thesis Objectives

The overall objective for this ongoing research program is the developments of portable, wearable, and easy to use sEMG acquisition system that will support more widespread clinical use of sEMG. The objectives for this thesis are related to the development of the WEAR system, a prototype portable, wearable sEMG acquisition system that employs a dry electrode array. Specific objectives are:

1) Capture a set of functional and usability requirements for WEAR system development via a user-centred design (UCD) process [6][7][8].
2) Implement, validate and test a functional proof-of-concept WEAR prototype system.

1.3. Summary of Contributions

The following is a list of major contributions presented in this thesis:

1. **Overall WEAR system design, prototype implementation, validation, and testing**

   WEAR employs an array of dry surface electrodes in a reusable electrode mount, or sleeve, instead of conventional, self-adhesive wet electrodes. The reusable electrode mount hastens system set-up and reduces electrode placement complexity, since electrode placement based on measured distances

between anatomical markers would not be required. This is the first electrode array for clinical applications in biomechanical movement analysis. Additionally, by employing an integrated analog front end solution rather than using discrete components (i.e. bioamplifiers, analog-to-digital converters), the system will be compact in size, thus wearable.

Implementation of the WEAR prototype demonstrated both system feasibility and physical interface effectiveness. Prototype validation was carried out on one participant to compare the WEAR signal quality with two conventional sEMG acquisition systems. Further pilot testing was carried out on 10 participants. Results of validation and participant testing showed comparable performance between the WEAR prototype and conventional systems.

2. **Identification of a list of functional and usability requirements for a clinically feasible sEMG acquisition system**

   The thesis describes the UCD process undertaken to perform user research with a group of physiotherapists, who were identified as potential end-users of a sEMG acquisition system. Physiotherapist feedback in a series of one-on-one interviews and focus groups was analyzed and translated into a list of functional and usability design requirements. System design following the captured requirements should result in a system that addresses end-user needs and limitations in terms of muscle function analysis. Addressing end-user needs and limitations should aid in the acceptance of a new system by healthcare professionals.

3. **Demonstrated ADS1298 viability as an integrated analog front end in a wearable sEMG application**

   The ADS1298 is a compact, low-power, integrated analog front end solution intended for use in biosignal acquisition. Originally designed for electrocardiography and electroencephalography applications, the eight channels, programmable gain amplifiers, and high-resolution, 24-bit analog-to-digital converters proved to be highly effective for sEMG acquisition. The eight channels were particularly suited for the WEAR prototype to accommodate the electrode array.

Portions of the research have been disseminated as conference papers:

- A. Freed, A. Parush, A. D. C. Chan, and E. D. Lemaire, "A user-centered design case study: Design of a wearable sEMG system", *34th Conference of the Canadian Medical & Biological Engineering Society and Festival of International Conferences on Caregiving, Disability, Aging and Technology*, Toronto, Canada, 69374, pp. 1-4, 2011.
- A. Freed, A. D. C. Chan, E. D. Lemaire, A. Parush, "Wearable EMG analysis for rehabilitation (WEAR)", *IEEE International Workshop on Medical Measurements and Applications*, Bari, Italy, pp. 601-604, 2011.
- A. Freed, A. D. C. Chan, E .D. Lemaire, A. Parush, and E. Richard, "Pilot test of the prototype wearable EMG analysis for rehabilitation (WEAR) system", accepted to *35th Conference of the Canadian Medical & Biological Engineering Society*, Halifax, Canada, 2012.

1.4. Thesis Outline

The remaining chapters in this thesis are organized as follows. Chapter 2 presents a high-level review of the literature pertaining to gait analysis, sEMG, wearable systems, UCD, and practical applications of wearable systems for biosignal analysis. Chapter 3 discusses the user research performed to capture the list of functional and usability requirements. Chapter 4 discusses the overall WEAR system design, prototype implementation, and validation. Chapter 5 presents prototype testing with a group of 10 participants. Conclusions and recommendations for future work are presented in Chapter 6.

2. Literature Review

To understand the technical and usability issues with conventional sEMG systems for gait analysis, the following sections review and examine the relevant literature on clinical gait analysis, sEMG systems, wearable technology, and user-centred design (UCD). This literature review describes key issues for developing a clinically viable sEMG acquisition system.

2.1. Clinical Gait Analysis

Clinical gait analysis is the systematic study of human walking, using observational and measurable information to understand and implement treatment plans for gait abnormalities [2]. Clinicians strive to detect inconsistencies in a person's gait cycles, which can be divided into stance and swing phases. Stance phase begins with an initial heel strike and ends as the toe lifts off the ground (toe off), after the opposite foot has planted. The swing phase begins at toe off and ends at heel strike (Figure 2.1). The normal gait cycle can be disrupted by a number of factors; including, aging, stroke, neurological damage, joint injury, or muscle fatigue [9].

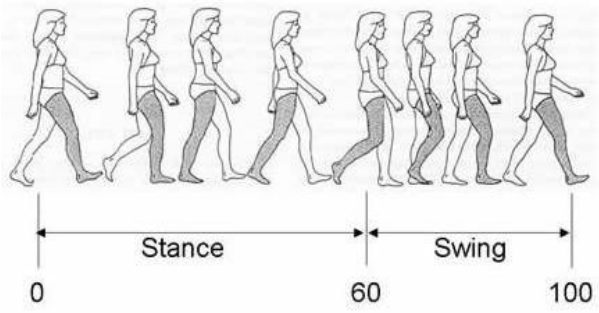

Figure 2.1: The gait cycle [10].

2.1.1. Gait Analysis Techniques

Observational gait analysis involves visual assessment by a clinician, coupled with patient oral feedback. While observational gait analysis is a relatively fast process and costs no more than a clinician's time, it is highly subjective, possibly resulting in biased results and missed information. In addition, a clinician lacking in experience or possessing certain biases due to recent training could misdiagnose gait deficiencies while performing an observational gait analysis [5]. To bypass some of this subjectivity, clinicians can perform technology aided gait analysis. Technology aided gait analysis can provide clinicians with objective information about the patient's gait and provide a means of storing data for a detailed analysis without the patient's presence [5].

Video recording can be combined with visual assessment to review gait cycles repeatedly and in slow motion. Quantifiable information can be obtained from video to improve assessment quality; such as stride length, stride event timing, velocity, cadence, and stance/swing proportion [9]. Advanced laboratories can use motion capture technology (e.g., passive, reflective marker systems) for body orientation analysis or compression foot switches to align motion information to the gait cycle [11]. Motion capture software, such as the Vicon 3D motion analysis system, generates 3D body orientation data that can be used to compare movements with previously published normal motion. 3D motion analysis can capture gait abnormalities that clinicians miss with observational gait analysis [12]. Force plates installed in a walkway are often used in conjunction with motion capture to measure reactionary torques and forces between the foot and the ground, providing an extra level of information [4]. Despite their

advantages, advanced technological modalities are quite expensive in terms of equipment purchases, the engineer or technologist operating the system, and the time for set up, data capture, and analysis.

2.2. Surface Electromyography

EMG signals are bioelectric signals associated with muscle contractions. Amplitudes of EMG signals vary in sympathy with the strength of muscle contractions. sEMG is a technique used to non-invasively acquire EMG signals, using electrodes placed on the skin, as opposed to needle or wire EMG electrodes that are inserted into the muscle of interest. Figure 2.2 shows the sEMG signal recorded from surface electrodes on the forearm during grip testing.

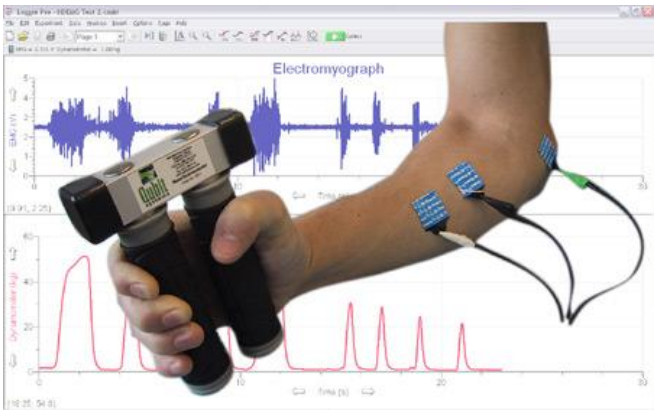

Figure 2.2: sEMG activity (blue line) captured through bipolar surface electrodes (white and black; green is ground) and dynamometer response (red line) during grip test [13].

sEMG can be used to determine the relationships between muscle activation signals and biomechanical variables [14]. These relationships are upheld throughout dynamic voluntary contractions and isometric contractions [14]. By acquiring sEMG data from muscle groups activated during the gait cycle, relative strength and timing of the muscle

contractions can be quantified, rather than simply estimated [3]. sEMG is useful for people rehabilitating from injury, adjusting to new prostheses, or suffering from neuromuscular diseases such as cerebral palsy, muscular dystrophy, and Parkinson's [2].

2.3. sEMG Acquisition Systems

sEMG signal amplitudes are small (in the order of a few mV) and can be affected by a variety of contaminants (e.g., power line interference, motion artifact) [14][15]. Therefore, sEMG acquisition requires specialized bioinstrumentation amplifiers with high input impedance, high common mode rejection ratio, and low noise to ensure a high signal-to-noise ratio [14]. sEMG signals often resemble filtered white Gaussian noise, making it difficult to verify signal quality [15]. As a result, sEMG is often limited to laboratory settings with specially trained personnel operating the acquisition system, verifying the signal quality, and interpreting the results.

sEMG acquisition also has a long set-up time that includes skin preparation (e.g., cleaning with alcohol and often shaving or abrading the area to reduce the electrode-skin impedance [16]) and electrode placement based on anatomical landmarks [17]. A whole session, including setup, system calibration, and patient assessment can take two to four hours [4]. Conventional sEMG systems also tend to be wired and bulky units, limiting the context of use to a particular area of a lab or clinic and to movements that do not interfere with the wires. Equipment and associated personnel costs can also be an issue. sEMG is not widely used in clinical gait analysis despite its proven ability to provide more detailed quantifiable information on muscle activation [5].

A need exists for an innovative sEMG acquisition system for gait analysis that is clinically feasible [5]. Such a system would employ portable, wearable, and wireless technology incorporating reusable dry electrodes as opposed to the standard disposable gelled electrodes [18]. A more flexible sEMG system could also be used in applications such as long term muscle fatigue detection [19] or home based movement analysis after a brain injury [20].

2.3.1. Electronic Hardware

Many conventional sEMG acquisition system setups follow the same basic configuration. A pre-amplifier located very close to the electrodes can help mitigate the effects of noise and motion artifact [14]. After pre-amplification, signals are sent through shielded wires to a central hub for further amplification (potentially adjustable) and signal filtering (e.g., high-pass filters can be used to eliminate low frequency noise, anti-aliasing filtering). Data are then sent through an analog-to-digital converter (ADC) and then to a computer for processing. With the advent of new technology, a similar approach can be taken to produce a compact, lightweight, and power-efficient sEMG system.

Manufacturers such as Texas Instruments (Dallas, TX, USA) and Analog Devices (Norwood, MA, USA) have recently developed integrated analog front end (AFE) solutions. For example, the ADS1298 (Texas Instruments) is a low-power, 8-channel biopotential amplifier with 24-bit analog-to-digital converters and a built in multiplexer to simplify data transfer [21]. Employing an AFE in the design of a novel, compact sEMG system would eliminate the need for a series of discrete components. In addition to the AFE, such a novel system would require a microprocessor for system configuration

and control, a data storage module (i.e. SD memory card reader/writer), a wireless data transmission module (i.e. Wi-Fi, Bluetooth), and a power source. These electronics could be housed in a compact package and placed close to the electrodes due to the small size and low power requirements. The proximity between the electronics and electrodes would reduce the noise associated with long wires between electrodes and amplification/analog-to-digital conversion.

2.3.2. Surface Electrodes

Surface electrodes can be grouped broadly into wet electrodes (e.g., Ag/AgCl) and dry electrodes (e.g., stainless steel). The advantages of wet electrodes are reduced motion artifact, reduced contact impedance, and typically low cost [22]. The main disadvantages of wet electrodes are that their performance can degrade over time, notably in the commonly used disposable, pre-gelled Ag/AgCl types. Dry electrodes, which are often reusable, have shown comparable performance to wet electrodes, including those made of steel [22] and more advanced flexible materials [23]. While dry electrodes tend to be expensive, cost differences could be realized over time since dry electrodes, such as those made of steel, could be cleaned and reused rather than disposed after each use. Figure 2.3 depicts a few of the electrodes that have been used for sEMG acquisition.

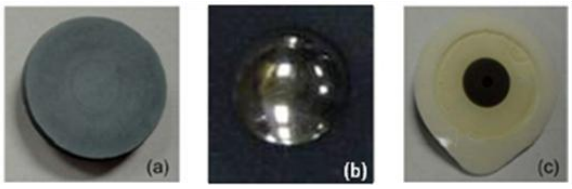

Figure 2.3: (a) Flexible material dry electrode; (b) steel dry electrode; (c) Ag/AgCl wet electrode.

Conventional sEMG analysis systems typically utilize disposable electrodes, affixed to areas related to the muscle being analyzed. Electrode placement schemes, such as the guidelines developed in the Surface Electromyography for the Non-Invasive Assessment of Muscles (SENIAM) project, use anatomical landmarks that must be precisely measured for each individual [16]. Although effective, electrode placement based on anatomical measurement can be time consuming and inconsistent between clinician and even between patients, since anatomical markers can be more difficult to discern on some patients [24]. To reduce the time for inconsistent placement of electrodes, an electrode array can be employed.

2.3.3. Electrode Array

Electrode arrays reduce the setup time and complexity of electrode placement because they use a series of evenly spaced electrodes. A two-dimensional electrode array, consisting of m rows and n columns, can be quickly placed over the muscle area to collect data from pairs across the whole array. Automated software can be used to analyze each pair based on time and frequency domain characteristics to determine the "optimal" electrode pair to be used in the motion analysis [24]. This array approach is in contrast with the time consuming conventional approach of a carefully placing a single electrode pair.

Different schemes can be employed to designate electrode pairs within an array. An easily implemented method uses dedicated pairs. Electrode pairs can also be designated in a more complex setup whereby electrodes are analyzed as bipolar pairs with any other electrode in the array. The advantage of the more complex method is that there are more

pair options within the array. Regardless of the method of pair designation, SENIAM guidelines specify an inter-electrode distance of 20mm (centre-to-centre) along the length of the muscle fibre [16].

2.4. Wearable Systems

Wearable systems in healthcare originated through physicians' need to gather long term information about their patients. By incorporating miniature sensors into non-obtrusive accessories attached to the body (i.e., clothing, rings, or straps) and integrating small handheld units to store data, wearable systems can always be ready to record adverse events. Data from handheld units or event loggers can be transmitted wirelessly, or via a docking station, to a computer for transfer to a central server where clinicians can access the information for analysis [25].

Health monitoring systems have advanced past the confines of point-of-care and home-based environments due in part to advances in materials and sensor technology. In addition to biosignals (i.e. heart rate, skin temperature, respiration rate, etc), information can be gathered and monitored in real-time on movement, posture, location, pressure, and fabric damage/ballistic penetration [26]. Monitoring technologies employing wearable sensors are being used in such fields as rehabilitation, emergency response, and athletics. Regardless of the domain, wearability is an essential factor to consider while designing wearable systems.

2.4.1. Wearability

Gemperle, et al. [27] defined wearability as the "interaction between the human body and the wearable object". Low weight, flexibility, and unobtrusiveness can have a

positive effective on wearability. Wearability can be rated on a number of levels. Knight and Baber [28] proposed six comfort rating scales to assess wearability:

1. Emotion: Does the wearer worry about how they look while wearing the device? If they feel tense or nervous, biometrics and movement patterns can be altered.
2. Attachment: Does the wearer feel the device moving around on their body (i.e. swinging, pulling, etc.)? This is important in terms of sensor placement.
3. Harm: Is the device painful to wear? Is it causing the wearer any type of physical damage?
4. Perceived change: Does wearing the device make the wearer feel physically different or weird in some way?
5. Movement: Does the device impede or restrict the movement of the wearer?
6. Anxiety: Does the wearer feel secure wearing the device?

Wearability considerations stem from the field of human factors, which concerns itself with the interactions between humans and technology. By following a process that incorporates end-users into design flow, usability goals, such as wearability, can be factored into the design requirements.

2.5. User-Centred Design

User-Centered Design (UCD), a process developed by researchers in the field of Human Factors, can improve productivity, reduce operator errors, reduce the amount of training and support required, and improve acceptance of a product or system by the users [7][8]. UCD is an iterative design process incorporating end-user feedback and

validation at each stage. UCD methodology has made deep inroads in sectors such as defense and aviation, where human factors or usability engineers are an integral part of design teams [29]. Multidisciplinary fields, such as biomedical engineering, lend themselves particularly well to UCD since the systems being designed must be used by people with varying levels of technology expertise.

2.5.1. UCD Methods

Figure 2.4 shows the five phases involved in the UCD process: 1) analyze, 2) design, 3) test, 4) re-design, and 5) re-test. During the analyze phase, end-users participate in field observations, questionnaires, interviews, and/or focus groups. Analyze phase information is used to generate a list of usability goals and design requirements to meet the end-users' needs and limitations. The system design phase can result in conceptual or physical prototypes based on a sub-set of the design requirements generated in the analyze phase. The test phase then involves end-users in usability testing to acquire direct feedback on the prototype that can be incorporated into the re-design and re-test phases [8]. UCD is an iterative process, where iterations continue until all, or the highest priority, requirements are met.

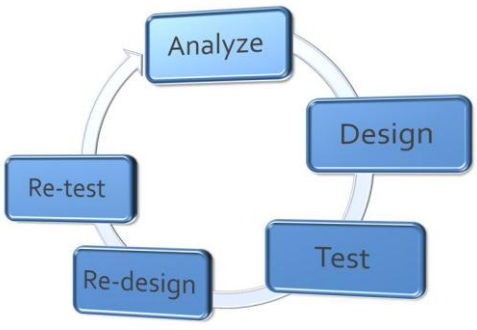

Figure 2.4: Iterative UCD lifecycle [33].

The following sub-sections provide an overview of each phase, but are not intended to be a comprehensive review of UCD. For a more in-depth knowledge, works such as those by Nielsen [31] and Norman [32] should be consulted.

2.5.1.1. Analyze

Effective use of UCD requires early user involvement since identification of context of use, specific end-user groups, and an initial set of usability goals can help steer development [30]. Context of use defines where the system will be used and under what conditions, while the end-users are those who will be most frequently employing the system within the usage context (e.g., farmers are the primary end-users of a plow). A system may also have a set of secondary end- users, a group that is affected by the system but not necessarily driving the system through its main workflow (e.g., passengers in an airplane are secondary end-users, but the pilot is the primary end-user) [34]. Usability goals are a set of measurable parameters such as effectiveness (i.e., can users successfully achieve their goals) [35], efficiency (i.e., time and effort it takes to successfully complete certain tasks) [35], and learnability (i.e., time required to learn to confidently use a system) [36]. Some UCD information can be derived during an initial planning stage involving members of the design team (i.e. technology experts) [8], however, subject matter experts [37] (end-users), can provide much greater depth of information.

Various methods can be employed to obtain detailed information on end-users and their needs and limitations. A *field observation* is a study during which the researcher silently observes work flow to gather contextual information for the system being designed [8]. *Questionnaires* can be developed from field observation information to get

direct feedback on researcher-perceived issues or difficulties [8]. While questionnaires may allow more users to be involved, one-on-one *interviews* in the user's place of work tend to be more informative. A semi-structured interview consisting of open-ended questions allows the interviewer to expand and to tease out more detailed information on current limitations and shortcomings [8]. Another way to gather information on needs, limitations, and requirements is through *focus groups* that allow a group of end-users to interact in a researcher-moderated forum. Focus groups encourage end-users to brainstorm on topics presented by the researcher who can then determine priority requirements based on converging or consensus opinions [8].

Information gathered during the analyze phase enables researchers to define an encompassing set of usability and technical requirements based on user needs. This information can also be used to develop task based scenarios (e.g. crane operator must move a shipping container from one place to another). Requirements generated from scenarios remain stable throughout the system design lifecycle as opposed to those generated by functions (e.g. crane arm must have variable speed) and are more universally understandable [37]. With a comprehensive set of requirements outlining how the system can satisfy usability goals, system design can begin.

2.5.1.2. Design/Re-design

The UCD design phase combines technical requirements with usability requirements. The outcome of an early design phase can take many forms, since prototypes are not necessarily physical or functional. Paper prototypes or mock-ups based on the scenarios generated from the gathered requirements can be implemented for early usability testing

[8]. Paper prototypes are inexpensive, quick to create, and help ensure that analysis of user needs and limitations was done effectively prior to practical development [30].

After early usability testing, a practical and functional proof-of-concept prototype can be developed during the re-design phase. A proof-of-concept prototype does not necessarily incorporate all usability requirements gathered during the analyze phase. Whether mock-ups or practical prototypes are developed, usability tests conducted at each development stage can help to confirm the usability goals and define further technical or usability requirements.

2.5.1.3. Test/Re-test

During usability tests, end-users interact with the system to accomplish prescribed tasks [8]. Usability tests can be conducted in a silent or think-aloud manner, with the subject expressing his/her thoughts on what they are seeing, doing, and feeling [8]. The researcher should not guide the user, but encourage them to express their thoughts during a think-aloud test or to continue trying different options in the event of difficulties [8]. Information gathered during usability testing can include the time required to complete the tasks, number of times the subject expresses frustration, and different paths to success [8].

Usability tests results can be used to further refine the design specifications for the next design iteration. Usability testing performed in early UCD iterations is referred to as formative testing and improves the system during development, while testing in later iterations is referred to as summative testing to determine if the system can be used successfully [38]. Frequent early testing can be relatively inexpensive to implement,

since system development is more flexible early on. Focusing end-user testing on one large, summative test just before, or just after the completion of system development tends to be more expensive and takes longer to implement, thus delaying time to market [31].

2.5.2. UCD in Biomedical Applications

UCD has been proven to provide benefits in a variety of fields and biomedical technology is among them. Healthcare is a multi-disciplinary field where clinicians are not only expected to maintain an up-to-date knowledge base of medical conditions related to their specializations, but also expected to be current with treatment methods and medical technology. Given the time pressures placed on clinicians, it is important to design technology that can address clinicians' needs in a way that is intuitive to them. The following case studies demonstrate where UCD could have made a difference or has been used to implement a new technology.

2.5.2.1. UCD Case Study #1: Patient Safety in Hospitals

Ensuring patient safety is a requirement in hospitals. Gosbee [39] described a particular case in which a patient with an abnormal ECG was connected to an ambulatory monitor on the way to the ICU. With a reported blood pressure of 120/80 mm Hg and a heart rate of 72 bpm, clinicians did not assume any immediate risk to the patient. Upon arrival at the ICU, a 4th year medical student remarked on the lack of correlation between the readings on the monitor and the fact that the patient had a respiratory rate of 24 bpm. Inspection of the monitor revealed that it was in demonstration mode, indicated by a small 'D' on the screen. It turned out that the patient had a "real" blood pressure of 80/60

and heart rate of 140 bpm. After implementing emergency procedures, the patient was stabilized after a few hours of treatment.

Blame could have been shared by a number of parties in Gosbee's case study and more detailed training and procedures could have been implemented to avoid similar situations. Analysis of the situation revealed that certain equipment employed in that hospital was "tricky" to use and specialty teams were informally created to operate specific devices. On the day of the incident involving the monitor in demo mode, the specialty team was not available and the healthcare team was using the equipment for the first time. Also, the equipment could be set in demo mode indefinitely and several unclear steps were necessary to switch it into or out of demo mode.

Early implementation of UCD could have helped avoid patient risk. By understanding the end-user's technological knowledge and the distractions and pressures placed on clinicians using the monitors, system designers may have taken another approach. For example, demo mode could have been exited automatically after 15 minutes, or similar tactics from aviation could have been implemented, with displays in simulation mode showing a large 'X' in the background [39].

2.5.2.2. UCD Case Study #2: Rehabilitation Technology

Cerebral palsy is a condition that occurs in children due to brain injuries in the womb and is the most common cause of physical disability in children [40]. Children with CP show muscle weakness, a lack of dexterity, and coordination difficulties, among other symptoms. Many CP sufferers have problems reaching for and grasping objects, in addition to being unable to use their arms to properly brace for a fall. Therapeutic

exercises have been developed to increase arm strength and dexterity in CP patients. While the treatments have proven effective, children do not perform the repetitive, difficult routines often enough for full benefit [40].

Weightman *et al*. [40] employed a UCD methodology to develop a new home-based rehabilitation system for children with CP. The system incorporated a computer game with a force feedback interface aimed at 5-12 year olds to help them complete therapeutic routines to improve arm strength and dexterity. They employed a three stage approach: a requirements capture stage, an iterative design/test stage including multiple formative usability testing sessions with pre- and post- test user interviews, and a summative test involving long term home use by subjects followed by interviews and questionnaires.

After the third development stage, Weightman *et al.* [40] concluded that they had achieved a much higher level of user acceptance by employing the UCD process during rehabilitation system development. In addition to the positive usage statistics, feedback from parents and children involved in the study showed that the technology was perceived to be beneficial and that the process was enjoyable.

2.6. Wearable Biosignal Monitoring Systems

Bringing the concept of wearability to biosignal (i.e. EMG and ECG) monitoring has generated a number of innovative systems. Sensors have been integrated into thin materials, gigabytes of information can be stored in postage-stamp sized cards, and energy storage has decreased in size while increasing in efficiency. Designers have combined different design techniques, including UCD, to develop a number of wearable systems for biosignal monitoring.

In 2004, Pozzo *et al.* [41] developed a 64-channel wearable sEMG acquisition system for a European project called 'Neuromuscular Assessment in the Elderly Worker' (NEW). The NEW searched for a user-friendly, small-sized EMG acquisition system for field use, but no commercial system met all the requirements. The system developed by Pozzo *et al.* [41] was successfully implemented in field studies, but given the reduced size of electronics, memory storage, and batteries, the NEW system would seem bulky by today's standards.

Another European project called the Open architecture for Accessible Services Integration and Standardization (OASIS) began in 2008 and was scheduled to run for four years [42]. OASIS was a large scale project using UCD to develop a common open architecture platform to integrate information from a variety of plug-and-play systems to enable independent and autonomous living for the elderly. As one of the plug-and-play technologies, Piogga *et al.* [42] developed a wearable system to monitor posture and kinematic information along with acquiring sEMG data. Using sensors integrated into a lycra garment, the collected data was merged into a dynamic measure. By implementing a Predictive Dynamic Model, the single dynamic measure was used to determine muscular fatigue and physiological conditions.

Innovative approaches to the design of wearable biosignal monitors have been employed in a variety of domains. A wearable computing platform called wearIT@work was developed for use in multiple fields, including emergency response [43]. By monitoring information such as EMG, heart rate, and location, firemen can be kept safer during emergency situations. The wearIT@work system for emergency response used a

UCD process to develop simulation environments to properly test the equipment. Through simple board games, the researchers obtained detailed information on scenarios commonly faced by firemen, which were then used to create virtual environments. The virtual environments were effective enough that the efficacy of the wearIT@work system could be thoroughly tested in a controlled environment [43].

3. User Research

Previous research on electrode arrays [24] and reusable dry electrodes [44] demonstrated the technical potential for sEMG muscle analysis in a clinical setting. However, despite the technical feasibility, a sEMG system developed without direct input from target end-users could fail to gain acceptance. A UCD methodology was implemented to engage end-users in the design of a wearable sEMG system.

Employing a UCD process in this thesis entailed additional planning, participant recruitment, and data gathering and analysis. Since the project timeline was limited, UCD activities were restricted to performing user-research to obtain a comprehensive list of end-user needs and associated design requirements. Further steps of a UCD approach would have included an iterative design stage to incorporate the list of design requirements, followed by end-user testing. The end-user testing would then provide another list of requirements to be analyzed and incorporated into subsequent design iterations. The user research conducted for this thesis focused on planning sessions, semi-structured one-on-one interviews, and focus groups. The goals of each stage directly affected the strategy applied to the subsequent stage, ultimately leading to a list of usability and functional design requirements.

The user-research planning stage had three main goals: 1) identification of end-user groups (i.e., who will use the system), 2) defining the contextual variables (i.e., where, why, and how the system will be used), and 3) defining the WEAR system usability goals. The appropriate end-user group was identified during the planning stage and was recruited for the interviews and focus groups. The semi-structured interviews were

conducted in the end-user's work environment to allow the researchers to gain more insight into the space and tools currently available to the end-users (i.e. to verify some assumptions made about the contextual variables). The interviews provided a preliminary list of user needs based on the perceived limitations and frustrations of the end-users. The list of needs generated with the interview results was then used to create three discussion topics about implementing the WEAR system in a clinical setting. The three topics were discussed openly between participants in the subsequent focus groups. Participant feedback was analyzed using non-parametric frequency oriented statistics by associating the discovered needs with potential system features and generating a set of end-user requirements, with a focus on usability design goals. The final list of end-user requirements was also used to validate the original usability goals derived in the planning meeting.

3.1. Planning Stage

User research planning was conducted by the research team (Adam Freed, Dr. Adrian D.C. Chan, Dr. Avi Parush, and Dr. Edward D. Lemaire) prior to participant recruitment to specify target end-users, preliminary contextual variables, and to determine the main usability goals for the system. Additionally, the end-user requirements gathering strategy was developed. Decisions made regarding the high level system specifications can be seen in Table 3.1.

Table 3.1: High level system specifications.

Primary end-user	**Secondary end-user**	**Contextual variables**	**Usability goals**
Physiotherapist	Rehabilitation patient	•Where: Physiotherapy Clinic •Why: sEMG muscle analysis •How: Gait analysis in rehabilitation	•Effectiveness •Efficiency •Learnability •Wearability

Various clinical groups could have been identified as target end-users for the WEAR system (i.e., physicians, occupational therapists, etc.). By leading and participating in a number of other research projects with physiotherapists (PT) at TOHRC, Dr. Lemaire learned of the importance of motion analysis in PTs' patient assessment and treatment plans. Given that PTs currently employ motion analysis and the availability of a participant pool at the TOHRC physiotherapy service clinic, they were designated as the primary end-user of the nascent WEAR system for the purpose of this thesis. PT patients, being the ones who would be wearing the system were then identified as secondary end-users. Since statistical significance was not required in this type of qualitative research, a decision was made to follow sample size criteria often used in qualitative methods [45][46].

Since the intent of the WEAR system was to increase the accessibility of sEMG analysis, the expected context of use was a physiotherapy clinic. Based on the knowledge of TOHRC PT processes, we expected that the WEAR would be used to obtain quantitative measures of muscle function during motion analysis for clinical rehabilitation. Gait analysis is a common task performed by PTs and the tibialis anterior

(TA) is active throughout much of the gait cycle, thus the TA was selected as the target test site.

Analysis of conventional sEMG acquisition systems showed that, while they provide important information, set-up is long, they are complicated to use and learn, and free movement can be affected by cables and wires. To transition sEMG analysis from a lab to a clinical setting, the usability goals were set to achieve effectiveness, efficiency, learnability, and wearability. The effectiveness goal can be achieved through error free system operation and proven quality results [35]. Efficiency is defined in terms of speed of use when compared with the average time required to setup and operate a conventional sEMG system [35]. In terms of learnability, WEAR should require little time (~20-30 minutes) for new users to confidently use the system, including error avoidance/recovery [36]. Finally, secondary end-users must be able to maintain natural movement patterns throughout data acquisition [27]. Aside from learnability, measurable goals of usability were not defined during the planning meetings.

A two step process of requirements gathering was planned: 1) one-on-one interviews with a volunteer participant group of PTs, and 2) focus group discussions with the same group of participants. Since system development in this thesis was to the functional prototype stage, the requirements derived from the interviews and focus groups were documented for implementation in subsequent design iterations of the WEAR system.

3.2. One-on-One Interviews

3.2.1. Materials and Methods

As the planning stage neared an end, a group of PTs was recruited for requirements gathering purposes and to validate the decisions made in the planning meetings (Table 3.1). Eight PTs were recruited from various clinics throughout Ottawa, Canada (5 from private clinics and 3 from the publicly funded TOHRC). The selection criteria included PTs who routinely worked with clients exhibiting neuromuscular abnormalities in the lower leg and were familiar with industry accepted assessment and rehabilitation techniques for such deficiencies. Since the goal for this qualitative and exploratory approach was to reach a point of data saturation in the generation of ideas to support the design process, more subjects could have been recruited if data saturation had not been reached.

The exploratory, one-on-one interviews were conducted between March 16th and April 26th, 2011 at the PTs' clinics. The interview goals were to gain familiarity with the PTs' work environments, standard workflows, commonly used tools and methods, roots of their frustration, and to gauge the level of their understanding of EMG. The interviews were also used to gather information on the PTs' high level needs and their limitations in muscle function analysis. Audio recordings of the interviews were taken and detailed notes were inscribed. At the conclusion of each interview, the responses were reviewed with the participant to ensure that they were understood and to provide an opportunity for them to expand on or alter their responses.

After reading and signing the information and consent forms, the participants were asked to fill out a short questionnaire (Appendix A). The questionnaire was designed to get a brief overview of the participants' level of experience in the healthcare industry and

in their current role, as well as a snapshot of their patient populations and experience with EMG. Once the questionnaire was completed, the 14 question semi-structured interview was conducted through a series of open ended questions (Appendix B). Interview questions were designed to encourage the participants to describe their roles and provide scenarios that detailed their muscle function assessment procedures.

The open-endedness of the questions and semi-structured nature of the interviews allowed for follow-on questioning to further expand on new points of interest, which could help in the discovery of different facets of the participants' role. The overall goal of the interviews was to identify the needs of the PTs with regards to functional muscle assessment. The interview was designed to allow the research team to obtain greater insight into the work environment, workflow, restrictions/limitations and technical knowledge level of the end users. The line of questioning started with general inquiries about how they assess patients and then lead towards EMG and EMG technology. Aspects of their daily tasks that cause frustration were explored; such as, time delays, level of complexity, and functional limitations.

By grouping common elements from the questionnaires and answers from interview questions 1-4, general descriptions of the physiotherapists and their respective workdays were constructed. Information gathered from questions 5-14 was compiled and a list of high priority needs was produced to develop discussion topics for the focus groups.

3.2.1.1. Demographics

The participants consisted of two groups: 1) four PTs working in long-term rehabilitation of more complex/chronic issues either at the TOHRC, or at NeuroGym

(NG) Rehabilitation in Ottawa ON (TOHRC/NG), and 2) four PTs from private out-patient clinics whose patient populations presented a more typical level of deficiency (PVT). Table 3.2 shows comparisons of the two groups in terms of their experience levels and how they use their time throughout the day. The TOHRC/NG PTs spent more years in the healthcare industry, specifically in their current roles than the PVT PTs and reported that their level of experience gave them a high degree of confidence in their skills and observational abilities. The PT from NG fit with the group of PVT PTs in terms of the clinic's business model and his years of experience but, due to the patient populations associated with NG, the modalities and strategies used were closer to those used at the TOHRC.

Table 3.2: Demographic comparison of PT groups (mean and standard deviation).

	TOHRC/NG	**PVT**
Years in Healthcare	13.5 +/- 10.8	6.2 +/- 3.8
Years in Current Role	10.0 +/- 9.4	3.5 +/- 3.8
Average Level of Comfort with Technology (1 = Uncomfortable, 5 = Very comfortable)	3.0 +/- 0.0	4.5 +/- 1.0
Time with clients (min)	53.1 +/- 9.4	24.4 +/- 8.3
Time spent on muscle function testing (min)	21.7 +/- 8.8	5.1 +/- 1.8
Time outside patient contact (min/day)	51.8 +/- 18.2	59.6 +/- 19.0
Clients/day	6.1 +/- 1.3	13.5 +/- 4.7

TOHRC/NG therapists spent approximately twice as long with their clients as the PVT PTs. Within a patient visit, TOHRC/NG PTs spent approximately four times the number of minutes assessing muscle function (Table 3.2). The extra time per patient was required due to the complexity for typical TOHRC/NG patients (i.e. complex orthopedic, neurologic, long-term pain). The TOHRC/NG group had access to a large array of tools

and facilities (i.e. rehab pool, gym, sit-to-stand machines, sEMG/biofeedback equipment, etc.). However, TOHRC/NG PTs indicated that they only had a moderate level of comfort with new technology. Finally, also due to the nature of their patients' conditions, TOHRC/NG PTs worked in a more interdisciplinary/team environment, often dealing with other healthcare providers (i.e. occupational therapists, physicians, etc.), as well as their fellow PTs to contribute to an overall rehabilitation plan.

Although the four PVT PTs were less experienced than the TOHRC/NG group, they indicated a greater inclination towards obtaining further education and training. Given the simpler nature of their patients' conditions (i.e. simple orthopedic, musculoskeletal, amateur athletes) PVT PTs were generally dealing with a greater number of patients in a given day (Table 3.2). PVT PTs rarely had the advantage of large facilities to store extra equipment. New technology acquisitions at PVT clinics, as with TOHRC/NG facilities, had to show proven benefits over traditional methods to justify the added cost, but the limited budgets and low overhead of the PVT clinics further restricted such purchases. In contrast to the TOHRC/NG PTs, the PVT PTs indicated a high level of comfort with new technology. Along with the smaller facilities, the private clinics tended to have smaller staffs who were often the only clinician working with a particular patient, many of whom did not come to the facility through a doctor's prescription.

3.2.2. Results

3.2.2.1. Needs and Limitations

A number of common needs and limitations between the two groups became evident through analysis of the one-on-one interviews. By the sixth interview, information from

the interviews grew more repetitive and data saturation had been reached by the eighth interview (e.g., all participants discussed how objective measures of muscle function could satisfy one or more of their need/limitations). See Table 3.3 for a list of key findings from the interviews, listed in order of the total number of PTs that touched on the particular topic. An overview of individual interview question results is reported in Appendix C. Due to the open-endedness of the interviews, certain information was brought out as conversations branched from the initial interview questions

Table 3.3: High level participant needs and limitations based on interview outcomes.

Key interview findings (End-user needs/limitations)	TOHRC/NG	PVT	Total
Lack of modalities that provide objective measures	4	4	8
PTs possess little to no EMG knowledge	3	4	7
Time restrictions	4	3	7
Small operating budgets	1	3	4
Difficulty communicating with other healthcare providers, patients and insurance companies	2	1	3

A common theme throughout all eight interviews was the lack of objective measures in the PTs' testing methodology. The following quotes show that physiotherapy is a subjective field and that while experience can lead to dependable opinions, hard numbers are desired by therapists, patients, and private and public insurance companies:

- *"How do we really know? There's nothing to prove our assumptions. We need tools to give us more precision."*
- *"With our current objective muscle measures, we can see range of motion and symmetry, but muscle testing is not precise."*

- *"I don't want to administer a treatment for no reason. I need an indicator to justify my choices."*

Except for the one participant from NG, the lack of sEMG knowledge was evident. Some of the participants recalled getting a very basic overview of EMG during their education, had seen it briefly in their professional career, or had read articles on the subject. The following quotes show the general lack of PT EMG knowledge:

- *"I had one class on what it is, but not about its use."*
- *"I don't know anything [about EMG]."*
- *"I know that it's a way to get objective information on muscle activation used in research, but I never thought of it as a clinical tool."*

Another heavily emphasized factor across both groups of PTs was the lack of time. Despite having just under an hour with each patient, the complex nature of the TOHRC/NG PTs' patients' conditions meant that they had to rehabilitate multiple muscles/joints in an effort to help them regain a functional quality of life. The PVT PTs were under pressure to see as many patients as possible while still providing a high level of care, so despite the shorter time per patient, they were seeing more than twice as many patients as the TOHRC/NG PTs. As can be seen in Table 3.2, neither group of PTs was left with very much time in their day for any paperwork (i.e. charting, reporting, research, etc.). The following illustrate the PTs' lack of time, specifically in the use of new tools and equipment:

- *"Time is money in private clinics"*
- *"We don't use a lot of tools because it takes too long to use them."*

- *"EMG takes too long to set up."*

The low overhead and small operating budgets, specifically in private clinics were also common elements from the interviews. Even though there were no questions specifically addressing clinic budgets in the interviews, the following quotes are samples of budget issues mentioned throughout the interviews:.

- *"New technologies cost too much for our clinic."*
- *"We would need evidence of the value for the money. How useful is it to our patient population?"*
- *"It's all about getting the best bang for your buck. A high cost has to be justified."*

The last common element on Table 3.3 is the inability to communicate with other healthcare providers, the patients, and insurance providers. PTs expressed difficulties with conveying their message to the different parties involved with their patients' rehab programs and thought that having objective measures could enable smoother communication. The following quotes show the PTs' frustration in communicating with different parties:

- *"Manual muscle testing is subjective and can lead to differences of opinion between therapists."*
- *"Subjective feedback is very important, but some patients are less aware of patternings and how to describe their issues."*
- *"WSIB (Workplace Safety and Insurance Board) needs good measures. A tool that could show baselining and improvement would be of major value."*

When asked about the potential beneficiaries of muscle function analysis technology within their clinics, both groups indicated that a majority of their staffs would be able to make use of such technology with almost all their patient populations. PVT PTs indicated a higher rate of potential use than the TOHRC/NG PTs, but as can be seen in Table 3.4, muscle function analysis technology could be widely used by both groups. The following quotes illustrate how many staff and patients the participants believed would benefit from objective measures of muscle function:

- *"Most of the staff would use it and at least 50-60% of lower extremity patients, but all groups could benefit since rehab is better surgery most of the time."*
- *"Most of the PTs, any clients with motor control issues, the elderly since it would be more interesting than simply resistive training. For neuro patients, it would be gold!"*
- *"Half of the staff and half of the patients."*

Table 3.4: Percentage of total staff and patients per clinic who would benefit from muscle function analysis (mean and standard deviation).

Participant Group	Staff Usage	Patient Usage
TOHRC/NG	59.1% +/- 27.5	56.3% +/- 7.5
PVT	100.0% +/- 0.0	87.5% +/- 25.0

3.2.3. Discussion

3.2.3.1. Verification of Initial Requirements

Based on the key interview findings (Table 3.3) an efficient, cost-effective sEMG acquisition system could be implemented in a clinical physiotherapy environment. Of the

four initial usability requirements, efficiency, effectiveness, and learnability were verified in the interviews and matched to identified needs and limitations (Table 3.5). Wearability was not discussed during the interviews since the focus was placed on gaining an increased understanding of the PTs and how they use current modalities and tools as primary end-users.

Table 3.5: Verification of initial requirements through interview outcomes.

Requirement	**Verified Need/Limitation**
Effective	• Lack of modalities that provide objective measures
Efficient	• Time restrictions
Learnable	• PTs possess little to no EMG knowledge • Time restrictions
Wearable	• Not yet verified

As previously discussed, Bevan defined effectiveness as error free system operation and proven quality results [35]. Although the nature of the information provided by sEMG would implicitly satisfy the need for objective muscle activation information, an ineffective system would not be adopted by PTs for clinical use. Throughout the interviews the need for reliability, accuracy, and/or precision in muscle function analysis was mentioned seven times. A system that operates error free and produces proven quality results would provide the effectiveness required by PTs to satisfy their need for modalities that provide objective measures

Efficiency was also verified as a usability requirement by the emphasized lack of time in a PT's work day. Any new modality could not take more time than a modality it would be replacing. A sEMG system that could provide a greater amount of quality information

in a shorter time span than current methods of muscle function analysis could be highly adoptable.

Learnability was previously stated to be the measure of time for new users to confidently use a system, including error avoidance/recovery [36]. The PTs indicated their level of comfort with technology to be average to high (Table 3.2), therefore, they should not intimidated by the thought of learning to use a new system in a short time. However, since PTs possess little to no understanding of EMG, new sEMG system should require little to no previous subject knowledge to make learning effective and efficient. As such, it may prove important to limit the usage of technical terminology pertaining to sEMG (i.e., gain, filtering, and quantization levels) in any system documentation to avoid confusion or discouragement.

3.2.3.2. Emerging Requirements

By associating certain common themes from the interviews with various identified needs and limitations, a list of new requirements was compiled (Table 3.6). Simple and easy to read output reports are essential to the success of a new system and that has been identified as one of the emerging requirements. An application frequently mentioned in the interviews was biofeedback, defined by Gartha in [47] as "any techniques using instrumentation to give a person moment to moment information about a specific physiologic process which is under the control of the autonomic nervous system, but not clearly or accurately perceived," which has also been identified as an emerging requirement to provide added value to the WEAR system. Finally, cost-effectiveness was identified as a requirement, since budgetary constraints were expressed in the interviews.

Table 3.6: Emerging requirements based on interview outcomes.

Emerging requirement	Need/Limitation
Simple and easy to read output reports	• PTs possess little to no EMG knowledge • Difficulty communicating with other healthcare providers, patients and insurance companies • Time restrictions
Biofeedback feature which requires little to no PT supervision	• Lack of modalities that provide objective measures • Difficulty communicating with other healthcare providers, patients and insurance companies • Time restrictions
Cost effective system	• Small operating budgets

With regards to the lack of EMG knowledge and lack of time, output screens and reports from the WEAR system must provide information that is meaningful to the end-users. Raw EMG data would have little meaning to PTs and it would take too long for them to attempt to analyze the data. A data set that shows relative change in muscle activation (i.e., compared to the patient's baseline/previous results, statistical norms, bilaterally, etc.) could be understood at a glance.

Simplified data representation could also satisfy the need to improve communication between healthcare providers who could use the quantitative information to discuss their patients' improvements in more absolute terms rather than attempting to understand each other's interpretation of subjective test results (i.e. manual muscle tests). The hard numbers could also help PTs provide information to their patients and their patients' insurance companies. Patients could get a better understanding of how they are improving and the insurance companies could get specific measures of improvement to help them decide whether or not to continue providing reimbursements in the case of an accident claim, for example.

In an effort to satisfy the need to quantify functional improvements, a biofeedback feature could be included. Biofeedback could provide muscle activation information in real-time for activities and motions, rather than simply specific isometric muscle contractions. Use of real-time biofeedback was a feature deemed a necessity by the therapists in order for the system to be attractive to them and their practices. Six out of eight participants specifically mentioned biofeedback at some point in their interviews. The PTs discussed how biofeedback could allow them to spend more time making use of the system, how they would definitely employ a system that their patients could take home and use every day, and how it could help to educate their patients in locating particular muscles and ensuring that they are exercising properly. Of the two participants who did not specifically mention biofeedback, one spoke of needing objective measures for functional activities, a requirement addressable with biofeedback.

Walking is a basic functional activity for which biofeedback could be used; however, other functional motions that could be quantified include climbing and descending stairs, carrying grocery bags, swinging a golf club, or riding a bicycle. Biofeedback could also be used to educate patients how to properly perform certain motions by enabling them to see the co-contractions occurring throughout the action. With this type of visual feedback, patients could be taught to perform a particular exercise correctly, thus improving the PT's ability to communicate with the patient. Finally, with a biofeedback system that enables the patient to perform exercises and self-monitor their performance, the PTs would not have to supervise for the duration of the exercises and would be free to see other patients, perform other duties, or take a break.

The last requirement derived from the interview feedback is a system that is cost effective. PTs, especially those from private clinics, deal with low overheads and limited budgets. Design complexity and component selection must allow for a system that would prove economically feasible and provide enough "bang for their buck", which ties back in with the efficiency and effectiveness requirements.

3.3. Focus Groups

Using the key findings and associated requirements derived from the one-on-one interviews, three main topics for discussion in the focus groups were developed: 1) a discussion on the pros and cons of purely observational gait analysis and those of technology aided gait analysis, 2) how the PTs would incorporate a new sEMG analysis system into their assessment process, and 3) a discussion on the potential role of biofeedback the PTs' rehab programs (Table 3.7). Most of the focus group's time was used for the three main discussion topics. Due to time constraints, three other requirement topics (referred to as "extras") were only briefly discussed: system appearance, hygienic implications, and cost (Table 3.7).

To ease focus group facilitation, two sessions were conducted at TOHRC. Each session was on a separate day, was scheduled to take approximately 1.5 hours, and was recorded for quality purposes. By involving multiple participants in the discussions, rather than one-on-one sessions, the hope was to have them expand on ideas as the conversations progressed. The goals of the focus groups were to expand on the needs and limitations discovered in the interviews as well as to obtain a more comprehensive list of design requirements for the WEAR system.

Table 3.7: Focus group discussion topics.

Topic	Description
Observational and technology aided gait analysis	You are going to conduct a gait analysis on a patient. You have the option of performing it observationally (purely subjective), or by using a combination of observation and technology (EMG, Video/Motion capture, force plates, etc.). Explain your reasoning behind using one or the other.
sEMG and assessment processes	A new patient comes into your clinic complaining of problems in her left leg. She doesn't remember how they started, but feels weaker in the lower part of her leg when she jogs. It's time to assess your new patient and in addition to your conventional tools and methods, you have a system to quickly and easily get EMG based information. Let's discuss how you would use such a system in your assessment process.
Biofeedback	You are working with a patient on a long-term rehabilitation program. He has had a stroke and is very slowly regaining mobility in his right forearm. You have a biofeedback system in your clinic which you would like to use as a modality in this patient's rehab. Discuss how you would see your patient and yourself interacting with such a system.
Extras	System appearance, hygienic implications, cost

3.3.1. Materials and Methods

3.3.1.1. Demographics

. The first focus group session consisted of three participants (2 TOHRC, 1 NG). A fourth participant from the PVT group could not attend due to a scheduling conflict. One participant arrived 15 minutes late and another advised the facilitator that she had to leave approximately 30 minutes early, but ended up staying until the end of the session. While it took extra prompting to initiate interaction, once the conversation began to flow, the PTs became quite talkative. The first focus group was dominated by the most experienced participant, but all participants were active. The climate and culture of the second session, which consisted of five participants (4 PVT, 1 TOHRC) was more enthusiastic. There

was a high level of participation from all participants and even though the demographics skewed towards PVT PTs, the single TOHRC participant was a consistent contributor.

3.3.1.2. Data Collection

The sessions began with a brief overview of sEMG, followed by a short presentation of the main discoveries from the one-on-one interviews. The bulk of the time during each focus group session was spent on interactive conversations based around the three main discussion topics (Table 3.7). The "extras" were only briefly covered after the main topic discussions had been completed since the scheduled time had been elapsed.

After presenting a discussion topic, the facilitator displayed an associated spreadsheet on the screen (Appendix D). The spreadsheets contained headings used to guide the discussions towards particular end-user needs or system requirements (Table 3.7). As consensus on particular points of interest was reached, the facilitator would record the point on the spreadsheet. This enabled the participants to see what had already been discussed, kept the discussions on topic, allowed dispute or re-examination of particular points, and helped when building on particular topics.

The interviews revealed that current technologies were considered to be too time consuming for the amount of extra information they provided. In addition, experienced PTs reported that they had developed strong observational skills, which allowed them to accurately analyze their patients' motions in a short time. Therefore, discussion topic #1 was created to gain greater insight into the PTs' impressions of purely observational versus technology aided gait analysis in order to discover more of their needs in terms of making technology-based gait/motion analysis usable for PTs.

Topic #2 was intended to allow a discussion of how a wearable sEMG acquisition system would be used by the PTs in a functional assessment. Since the main intent was to develop a set of requirements for a highly usable sEMG system, topic #2 was created to focus a discussion on three types of interactions with the system: 1) calibration (i.e. the process of setting up the system for use on a patient and then verifying that it was applied correctly and is ready to capture EMG data), 2) using the system during a patient assessment, 3) and results reporting.

Topic #2 initially focused on the calibration procedure for a wearable sEMG acquisition system. Details of calibration discussed were:

- System application: how to affix the system on the patient's leg.
- Interaction: how the PT could physically control the system during calibration.
- Feedback: how the system could communicate with the PT.
- Time: how long it could take to perform a calibration.

After calibration, topic #2 covered performing an initial patient assessment with the WEAR system. Topics discussed were:

- Interaction: how the PT could interact with the system during an assessment.
- Feedback: how the system could communicate with the PT during an assessment.
- Type of tests: could the PT use the system for the same tests he/she would otherwise use in an assessment, or would he/she use it for additional/different tests.

- Frequency of reassessment: how often the PT could use the system to reassess their patients.
- Time: how long it could take to use the system.

Finally, topic #2 covered the results analysis phase of the initial assessment. Details of the discussion addressed:

- Wireless vs. physical data transfer: would the PTs need the data to be transferred wirelessly to a PC or laptop, or could they be amenable to physically transferring a memory card.
- Real-time vs. offline data visualization: would the PTs need to see assessment data in real-time, or could it be sufficient to simply analyze offline at a later time.
- Images/charts/numbers: how the PTs would need to see the data.
- Decision support system: would they want a system to suggest treatment based on assessment results.
- Reports: what information would have to be on the output reports.
- Time: how long it could take for output reports to be generated and analyzed.

Six of the eight PTs specifically mentioned biofeedback as an important feature for a sEMG system to be useful, thus biofeedback was deemed an important feature to investigate. As one of the emerging features from the interviews, biofeedback was the focus of discussion topic #3. Topic #3 covered the aspects patient use and of PT use of a biofeedback feature as part of the WEAR system.

In terms of patient use of biofeedback, details discussed in topic #3 were:

- When: the time frame in the rehabilitation process that biofeedback could be used.
- Patient population: which types of patients could make use of such a feature.
- Game based vs. functional: the preference of a game based system (i.e. patient performs a particular movement in response to a situation occurring on a screen and accumulates a score for success/failure to properly perform the movement) or a "functional" system (i.e. patient performs a particular movement a certain number of times at their own pace and observes an outcome measure).
- Standalone vs. GUI: Could the system be self contained for purposes of biofeedback, or would it require a graphics user interface (GUI) on a monitor/screen.
- Take home vs. clinic: Would the biofeedback system be best employed in the clinic or at home.
- Time: Amount of time the PTs would want their patients using a biofeedback system.

For PT use of biofeedback, topic #3 focused on the setup of a potential biofeedback feature:

- Custom vs. Generic programs: Would PTs create their own biofeedback programs, or would they stick to a set of generic pre-programmed ones.

- Custom vs. generic thresholds: For generic biofeedback programs/games, would thresholds/parameters for success or failure be standard or customizable based on the patients' ability levels.
- Decision support system: Would the PTs make use of a pre-programmed decision support system to guide them through a biofeedback system setup.
- Time: Amount of time that would be acceptable for biofeedback system setup.

Due to time restrictions, only a brief portion of each session was dedicated to cover the "extras". This portion of the discussion delved into the user needs and system requirements associated with the appearance, cleaning and cost of the system. Although system appearance was not discussed in the interviews, it was an aspect of wearability that merited investigation. Cleaning of the WEAR system was included since the system could be used by multiple patients, therefore it was important to discover the concerns the PTs had in terms of transfer of germs and bacteria in their clinics. Finally, cost effectiveness was an emerging system requirement from the interviews. Since some of the participants were also involved in ownership or management of their clinics, they had a good view of the clinics' budgets and were able to help provide direction for a potential system cost.

3.3.2. Results

The outcomes from each focus group topic are summarized in this section. The summary tables from each topic show the details that received the most attention during the respective discussions, listed in the order of emphasis given during the focus groups.

Complete spreadsheets of raw results compiled from both focus group sessions can be found in Appendix E.

3.3.2.1. Key Focus Group Findings (End-User Needs and Limitations)

Outcomes from the focus groups were analyzed and amalgamated into a list of additional needs and limitations in order of participant emphasis:

1. Lack of trust in new modalities/technologies.
2. Less experienced PTs have trouble recognizing visual cues.
3. Clinics have limited space.
4. Personal biases can affect PTs' judgment.
5. Functional testing unrestricted by environment or activity level.
6. Circumstantial/External factors affect performance of patients.
7. Greatest gains achieved through frequency and intensity of exercise.
8. Patients not always motivated.
9. Inability of patients to frequently access clinic.
10. People come in all shapes and sizes.
11. Hospital privacy regulations.
12. Limited washing facilities.
13. Certain populations afraid of unfamiliar technology.
14. Need means to generate extra income.

3.3.2.2. Topic #1 – Observational and Technology Aided Gait Analysis

Discussion topic #1 covered the pros and cons of technology aided gait analysis (Table 3.8) and the pros and cons of purely observational gait analysis (Table 3.9). In

both tables, the pros were placed opposite corresponding cons where possible. Where no direct contrast for a pro or con was discussed, the opposite box in the table has been greyed out. Among the new needs and limitations discovered were trust issues with technology performing as advertised and the effect of external or circumstantial factors on patients' movement patterns, such as white coat syndrome (a psychological factor that causes increased tension in people being observed in a clinical setting [48]).

Table 3.8: Summary of pros and cons of technology-aided gait analysis.

Pros	Cons
Provides objective measures to guide the rehab process	Added financial and time costs are not worth the amount of information provided
Can provide a measure of even small improvements	Very difficult to get normalization of results (mechanics vary from person to person)
Motivation - Concrete way to show improvement	With no improvement, objective measures can be de-motivating
Improved feedback between therapist and patient (and insurers)	Incorrectly applied or faulty technology could result in misdiagnoses
Biofeedback as teaching tool	White coat syndrome
Can generate extra income from patients and private insurers	Can't charge more to WSIB for extra information

3.3.2.3. Topic #2 – sEMG and Assessment Processes

The discussion of topic #2 brought out more specific design requirements, rather than new needs or limitations. Outcomes from the calibration discussion included sizing, hygienic requirements, and effective sEMG recording when sweating due to rigorous activity. Requirements included a simple, basic display with obvious calibration success/failure indicators. The time issues facing PTs were reinforced and guidelines for how long system calibration could take were requested (Table 3.10). Discussion of the assessment process revealed that the PTs would need to gain trust of the system through

evidence of effective operation and that the frequency and duration of its use would be highly dependent on system efficiency (Table 3.11). Finally, reports would have to be customizable, produced quickly, easily interpreted, and show comparative representations of rehab progress rather than raw EMG data. Of note, hospital regulations on data security could restrict wireless data transmission (Table 3.13).

Table 3.9: Summary of pros and cons of purely observational gait analysis.

Pros	Cons
An experienced PT can quickly assess gait with an acceptable degree of accuracy	Personal biases can affect PT opinions
	Circumstantial factors can affect patient performance
	Less objective without technology, even if accurate
	Can't necessarily correlate to other therapists opinions
	Takes a lot of experience to see many of the physical cues
No added cost or space required for equipment	
A well regarded clinician can be more motivating without technology	

3.3.2.4. Topic #3 – Biofeedback

The discussion of patient use of biofeedback indicated that a well-designed system could be used with most patients and that a true game based system could be important to the success of WEAR as a product. Of note, issues patient compliance, inaccessibility of clinics/unrestricted environment, and unsupervised biofeedback games providing more time for the PTs were introduced (Table 3.12). PTs expressed a need for simple and fast customization of biofeedback programs (Table 3.14).

Table 3.10: Summary of topic #2 calibration discussion.

Application	One size fits all	Three size options	Must stay on during motion/ sweating	Must be hygienic	One sleeve per patient
Interaction	Simple, basic display	If too much work, won't be used	Different pre-set options	Few buttons or touch screen	Scroll menu
Feedback	No guessing	Indication of success/ failure	View of input (raw or representative)		
Time	2-5 minutes	If too long, would quickly stop using	Same as current modalities	Must be unobtrusive in practice	

Table 3.11: Summary of topic #2 assessment discussion.

Interaction	Remote (i.e. with tablet PC/smart phone)	Single start/stop button	Could start and walk away, or have patient start
Feedback	Indicator of system activity	Patient should not see for assessment	Screen with muscle activity to ensure correct operation
Type of tests	Would originally be additional tests	Need evidence of system performance to replace old processes	Could add different tests, time permitting
Frequency of reassessment	Depends how long it takes to calibrate	Depends how long to get results	Frequency would depend on patient
Time	Depends on value of results (up to 15min)	5 minutes	

Table 3.13: Summary of topic #2 results analysis discussion.

Wireless vs. Physical	Memory card	Both	Data security issues with wireless transmission	
Real-time vs. Offline	Offline	Both good for marketability		
Images/Charts /Numbers	Comparative data	Scalable levels of detail	Representations of raw data (not raw data)	
Decision Support System	Would have to confirm until trust established	Good for teaching facility	Updated based on current research	
Reports	Views of progress, % change in a table or graph	Visuals to show where problems lie in gait	Customizable	Email and print
Time	Less than 5 minutes (1 minute ideal)	If similar to current gait assessment charts, would be faster to read	Based on patient complexity	

Table 3.12: Summary of topic #3 patient use of biofeedback discussion.

When	Right away	Within 1st year	Until no more progress	
Patient population	Any with attention span	Difficult for cognitive issues or brain injury	Language barriers	
Game based vs. functional	Game based	Scores are a good measure of improvement	Both important	
Standalone vs. GUI	Standalone could become boring	GUI based for use in clinic	Difficult to program standalone	Could have "app" to program and play
Take home vs. clinic	Take home good for those with mobility issues	Improved recovery with intensity and frequency	Can track compliance with take home	Cost could dictate
Time	If supervision not required, time not an issue	If effective, could replace current modalities	PTs can play against competitive patients	

Table 3.14: Summary of topic #3 PT use of biofeedback discussion.

Custom vs. Generic programs	Reusable and simple to program custom	Some generic programs	Menu based programming
Custom vs. Generic thresholds	Custom – varies between patients		
Decision Support System	Good for new users/students	Can be disabled	
Setup time	Under 1 minute	No time to pre-program	As fast as any current modality

3.3.2.5. Extras

In terms of appearance, the key point raised by the participants was that the system could not look "scary". Limitations of PVT cleaning facilities and some cost guidelines were also discussed (Table 3.15).

Table 3.15: Summary of focus group extras discussion.

Appearance	Cannot look "scary"	Compact with few exposed wires	Like EMS-TENS device
Cleaning	Strict requirements in hospital, lesser in PVT	PVT only have access to soap and water, alcohol, and towels	
Cost	Must be versatile to justify the cost	Starting at $200-$500, but ideal cost would be $99	Realistic pricing would be ~$1000, high for PVT

3.3.3. Discussion

Both focus group sessions uncovered new needs and limitations (section 3.3.2.1), as well as an expanded set of system requirements (Table 3.16). The new set of requirements in Table 3.16 is listed opposite the new needs and limitation that they address. Since there were common elements tying together certain requirements, these elements have been grouped together in the following subsections.

Table 3.16: New system requirements based focus group outcomes.

New requirement	Need/limitation
Game based option for biofeedback	• Patients not always motivated • Greatest gains achieved through frequency and intensity of exercise
Standalone indicator of achieved goals (i.e. sound/LED)	• Functional testing unrestricted by environment or activity level • Inability of patients to frequently access clinic • Greatest gains achieved through frequency and intensity of exercise
Setup "wizard", with generic use options and customizable goals/thresholds	• Lack of trust in new modalities/technologies
DSS to help interpret results/suggest appropriate treatments	• Lack of trust in new modalities/technologies
Real-time wireless data transmission and memory storage	• Lack of trust in new modalities/technologies • Functional testing unrestricted by environment or activity level • Inability of patients to frequently access clinic
Data security/information privacy	• Hospital privacy regulations
Remote start/stop recording	• Functional testing unrestricted by environment or activity level • Circumstantial/External factors affect performance of patients
Simple interface	• Certain populations afraid of unfamiliar technology
Setup can be performed on the system, or through wireless "app"	• Clinics have limited space • Functional testing unrestricted by environment or activity level
System activity indicator	• Lack of trust in new modalities/technologies
Obvious calibration results	• Lack of trust in new modalities
Unique mount per patient (cost dependent)	• People come in all shapes and sizes • Limited washing facilities
Non porous and easy to clean mount	• Limited washing facilities

3.3.3.1. Detailed Requirements for a Biofeedback Feature

A game-based option could increase the level of fun involved with rehabilitation and since game play releases endorphins in the brain, patients could benefit from pain and stress reduction, among other benefits. A game-based option could also provide a competitive aspect for goal oriented patients (i.e. passing levels, accomplishing more difficult tasks, or playing head-to-head against their therapist or other patients), which could help to ensure compliance with treatment programs. With one or more patients performing exercises self-monitored through biofeedback, the clinics could generate more income per PT.

Another requirement along the lines of biofeedback is a standalone indicator of achieved goals Sound or light feedback could allow patients to work away from the game-based biofeedback screen (i.e. flex a particular muscle until the indicator is activated). Standalone biofeedback could also help those who cannot attend a clinic regularly to proceed with their rehabilitation from their homes. For system use in different situations, a “wizard” could guide the PT through system options and configure customizable goals/thresholds for biofeedback. The setup wizard could increase clinician confidence that the system is correctly configured to accomplish the rehabilitation goals.

3.3.3.2. Requirements for System Output Handling

A flexible decision support system based on current research (updatable to reflect new findings) could aid in interpreting results and suggesting treatment options based on assessment data. Like the setup wizard, the decision support system, could alleviate trust issues, especially in experienced PTs by confirming some of their observational

suspicions in terms of patients' physical problems. Additionally, a decision support system would be quite beneficial in a teaching facility for trainees and new graduates.

Having sEMG data transmitted wirelessly in real-time and stored locally on a memory card enables the system to be used in a variety of environments. Within a clinic or location equipped with a computer (i.e. PC, laptop, Smartphone, etc.), real-time wireless transmission would facilitate biofeedback applications and give the PT a live visual representation of the output, thereby helping to eliminate trust issues by showing that the system is functioning properly. Since data would also be stored locally, on a memory card, remote testing could be performed in any environment with data analysis performed at a later date, which would also benefit those unable to frequently access a clinic. All data recording and transmission should be secure to ensure information privacy, especially in healthcare settings where privacy regulations are strict. Data security would also help to alleviate trust issues for PTs and patients worried about their information being stolen.

3.3.3.3. User Interface Requirements

An important aspect of any successfully implemented system is a well designed user interface. Remote operation was identified as a requirement for interfacing with WEAR. The PTs discussed how circumstantial or external factors can affect patient performance. With the ability to remotely control data capture, the patients would not know at which point the system is active, hopefully removing some performance anxiety. Additionally, this could provide opportunities for PTs to have their patients perform a number of

uninterrupted and varied activities in succession with only the important portions being recorded.

Implementing a simple control interface could reduce perceived complexity and help eliminate some of the fears certain populations face when dealing with new technologies (e.g., minimal buttons and an easily navigable menu rather than a keypad). An alternative method for set up, calibration and feedback while in use could be through a wireless application. Since clinics tend to have space limitations, clinic areas may not have computer workstations available. Wirelessly interfacing to a laptop computer, Smartphone, or tablet pc could also provide the PTs the opportunity to obtain real-time feedback in any location. While a wireless application could also provide an indication that the system has been properly calibrated, a visual or audio indicator on the system could increase user trust that the system is ready to collect data or in the process of data collection.

3.3.3.4. Hygienic Requirements

Two different ideas were suggested to aid in the cleanliness aspect of the mounting sleeve. The first is a unique sleeve for each patient, which would manage the PTs lack of washing facilities. If one sleeve per patient is not practical, the second idea was for a non-porous and easily cleanable material could be implemented to fight the spread of bacteria between patients. Hospital regulations for cleanliness could make the reusable sleeve approach difficult. Often, the only washing options are soap and water and alcohol swabs. A proper material must be chosen to satisfy the needs for effective cleaning.

3.4. User Research Outcomes

Results from the interviews (section 3.2) and focus groups (section 3.3) were analyzed to generate a final set of end-user needs and limitations. To address the needs and limitations a list of functional requirements (Table 3.17, Table 3.18) and a list of usability requirements (Table 3.19, Table 3.20) were generated. Functional requirements are those that focus on how the system operates to address needs and limitations [6]. Non-functional (usability) requirements focus on how the user interacts with the system and its ease of use [6].

Table 3.17: Functional requirements listed in order of priority.

Rank	Functional Requirement	Need/Limitation
1	Real-time wireless data transmission and memory storage	• Lack of trust in new modalities/technologies • Functional testing unrestricted by environment or activity level • Inability to frequently access clinic
2	Biofeedback feature which requires little to no PT supervision	• Lack of modalities that provide objective measures • Difficulty communicating with other healthcare providers, patients and insurance companies • Time restrictions • Functional testing unrestricted by environment or activity level • Patients not always motivated • Need means to generate extra income • Greatest gains achieved through frequency and intensity of exercise
3	Game based option for biofeedback	• Difficulty communicating with other healthcare providers, patients and insurance companies • Time restrictions • Patients not always motivated • Greatest gains achieved through frequency and intensity of exercise

Table 3.18: Functional requirements listed in order of priority (cont'd).

Rank	Functional Requirement	Need/Limitation
4	Standalone indicator of achieved goals (i.e. sound/LED)	• Functional testing unrestricted by environment or activity level • Inability of patients to frequently access clinic • Greatest gains achieved through frequency and intensity of exercise
5	Setup "wizard" with generic use options and customizable goals/thresholds	• Time restrictions • Lack of trust in new modalities/technologies • PTs possess little to no EMG knowledge
6	Remote start/stop recording	• Functional testing unrestricted by environment or activity level • Circumstantial/External factors affect performance of patients
7	Decision support system to help interpret results/suggest appropriate treatments	• Time restrictions • Lack of trust in new modalities/technologies • PTs possess little to no EMG knowledge
8	Data security/information privacy	• Hospital privacy regulations

Table 3.19: Usability requirements listed in order of priority.

Rank	Usability Requirement	Need/Limitation
1	Effective sEMG analysis system	• Lack of modalities that provide objective measures • Lack of trust in new modalities/technologies • Less experienced PTs have trouble recognizing visual cues • Personal biases can affect PTs' judgment • Circumstantial/External factors affect performance of patients • Need means to generate extra income
2	Efficient sEMG analysis system (5 minute guideline including setup/calibration and result reporting)	• Time restrictions

Table 3.20: Usability requirements listed in order of priority (cont'd).

Rank	Usability Requirement	Need/Limitation
3	Cost effective system	• Small operating budgets
4	Simple interface	• Time restrictions • Certain populations afraid of unfamiliar technology
5	Setup can be performed on the system, or through wireless "app"	• Time restrictions • Clinics have limited space • Functional testing unrestricted by environment or activity level
6	System activity indicator	• Lack of trust in new modalities/technologies
7	Obvious calibration results	• Time restrictions • Lack of trust in new modalities
8	Simple and easy to read output reports	• PTs possess little to no EMG knowledge • Difficulty communicating with other healthcare providers, patients and insurance companies • Time restrictions
9	System must be portable and wearable, with an innocuous appearance	• Clinics have limited space • Functional testing unrestricted by environment or activity level • Certain populations afraid of unfamiliar technology • Inability of patients to frequently access clinic • Greatest gains achieved through frequency/intensity of exercise
10	Mount must remain stationary during vigorous activity/sweating	• Functional testing unrestricted by environment or activity level • Lack of trust in new modalities/technologies
11	One size fits all, or three size options	• People come in all shapes and sizes
12	Unique mount per patient (cost dependent)	• People come in all shapes and sizes • Limited washing facilities • Time restrictions
13	Non porous and easy to clean mount	• Limited washing facilities • Time restrictions
14	Learnable	• PTs possess little to no EMG knowledge • Time restrictions

3.4.1. End-User Needs and Limitations

The amalgamated list of needs and limitations is ordered based on how much each was emphasized over the course of the user research (eight one-on-one interviews and two focus groups):

1. Lack of modalities that provide objective measures
2. PTs possess little to no EMG knowledge
3. Time restrictions
4. Difficulty communicating with other healthcare providers, patients and insurance companies
5. Lack of trust in new modalities/technologies
6. Less experienced PTs have trouble recognizing visual cues
7. Personal biases can affect PTs' judgment
8. Functional testing unrestricted by environment or activity level
9. Small operating budgets
10. Circumstantial/External factors affect performance of patients
11. Greatest gains achieved through frequency and intensity of exercise
12. Patients not always motivated
13. Inability of patients to frequently access clinic
14. People come in all shapes and sizes
15. Hospital privacy regulations
16. Limited washing facilities
17. Clinics have limited space

18. Certain populations afraid of unfamiliar technology

19. Need means to generate extra income

3.4.2. Functional Requirements

The eight functional requirements (FR) derived through information collected during the user research sessions satisfy 13 unique needs or limitations (Table 3.18, Table 3.18). Table 3.18 and Table 3.18 are in order of FR importance based on participant emphasis throughout the user research sessions.

The first four FRs deal with aspects of biofeedback, since it was heavily discussed throughout the user research. A biofeedback feature could address the need for objective measures of improvement for a variety of functional motions and a variety of patient ability levels. The PTs also stated that the extra motivation provided by an interactive biofeedback system and the ability for patients to take a system home with them to increase the frequency of rehab exercises would greatly decrease the overall rehab timeline. Time restrictions could also be addressed by aspects of a biofeedback feature, particularly if game based. A biofeedback feature could allow PTs to leave their patients unsupervised, providing time to treat multiple patients at once, or take care of other tasks, such as charting, or taking a break. Providing a setup wizard for biofeedback configuration could alleviate time issues since the PT would not have to spend a lot of time learning the system, or constantly searching menus for different options.

A decision support system could also help alleviate some time restrictions, since the PTs would not have to interpret all the results from a sEMG assessment themselves. PTs would also not have to figure out how to incorporate the information into a new rehab

programs or exercises, since that could be suggested by the decision support system. The decision support system would also be a benefit because PTs possess little EMG knowledge; they would not have to learn about EMG signals.

3.4.3. Usability Requirements

The 13 usability requirements (URs) listed in order of priority in Table 3.19 and Table 3.20 satisfy 16 unique needs or limitations. The URs are ordered based on participant emphasis throughout the user research sessions.

As previously discussed, effectiveness is an essential usability requirement. In addition to satisfying the need for modalities that provide objective measures, as discovered in the interviews (Table 3.6), effectiveness also satisfies a number of needs and limitations discovered in the focus groups. Trust of new technology was often emphasized as a limitation and an effective system could help to alleviate the lack of trust. Also, by providing reliable and timely objective results, human factors, such as PT bias or inexperience and patients' mental state could be removed from the assessment equation. Finally, a system that could reliably provide objective measures of rehabilitation progress could be offered as a service to patients and insurance companies at an additional cost, as mentioned in 3.4.2.

In addition to effectiveness, efficiency was also a theme that carried weight throughout the span of the user research. The results from the focus groups provided a more precise requirement measure for efficiency, with a maximum 5 minute guideline comprising system setup, calibration, and result reporting.

One of the initial requirements was that the system be wearable (Table 3.5). Needs and limitations and more detailed requirements for wearability were defined in the focus group sessions. Having a portable and wearable system with an innocuous appearance would help to address a number of needs and limitations. Since clinics tend to have limited space, a system with a small form factor would not add clutter. A wearable system could be used outside of the clinical setting, brought home for patients who cannot regularly access the clinic, and the innocuous appearance could help with patient populations who are fearful or nervous around unfamiliar or "scary" looking technology.

Patients come in multiple sizes, so the system must accommodate anyone. Having a one-size fits all, or three sizes to cover a range of people is an important UR. Regardless of the sizing design option, the mounting sleeve must remain stationary during vigorous activity and sweating. If the UR for a non-slipping sleeve is satisfied, PTs could have their patients perform a variety of activities in different locations and trust that the results will be consistent.

3.5. Conclusions

Employing a UCD process to capture design requirements for the WEAR system facilitated the definition of functional and non-functional (usability) requirements. While many of our initial assumptions were validated during the interview process, the in depth knowledge gained from the interviews allowed the discussion topics for the focus groups to be created. Coupling the outcomes of the interviews with those from the focus groups, enabled the development of comprehensive lists of functional and usability requirements along with the associated needs and limitations that they addressed.

The goal of the WEAR prototype (Chapter 4) was to produce results comparable to conventional sEMG systems in functional testing (Chapter 5), thus the prototype did not incorporate the requirements developed in this chapter. However, since UCD is an iterative process, a subsequent design session should implement many of the FRs and URs specified herein. It is expected that a more fully developed WEAR system incorporating these design requirements could result in a product with an advantage over conventionally designed sEMG systems in terms of ease of use, cost, efficiency, learnability, and wearability.

4. Design and Implementation

4.1. Introduction

A need for objective muscle function measures in a clinical setting has been identified through end-user research (Chapter 3). sEMG can non-invasively provide information on the timing and force of muscle contractions, co-contractions, and indicators of spasticity and muscle fatigue [14]. The time, equipment, and expertise requirements, traditionally associated with sEMG data acquisition, are the main barriers to wide-spread clinical use [5][49][50]. The WEAR system, introduced in this chapter, is a novel, wearable sEMG acquisition system that aims to overcome these barriers [50].

A functional WEAR prototype was implemented as a proof-of-concept using modified commercial off-the-shelf (COTS) components. To provide initial validation of the WEAR system, pilot tests were performed on one participant. Pilot validation consisted of comparisons between the WEAR and two conventional sEMG systems. In addition to comparing the performances of the three different systems, two types of electrodes were used to distinguish differences electronics (e.g., biopotential amplifiers) and electrodes.

4.2. System Design

Figure 4.1 shows a conceptual view of the WEAR system. The WEAR system is composed of three main sub-systems: 1) physical interface used to collect sEMG information through electrodes; 2) electronics for bioamplification, analog-to-digital

conversion, and data storage and transmission; and 3) signal processing to filter unwanted noise. Each of these sub-systems are discussed in the following sub-sections.

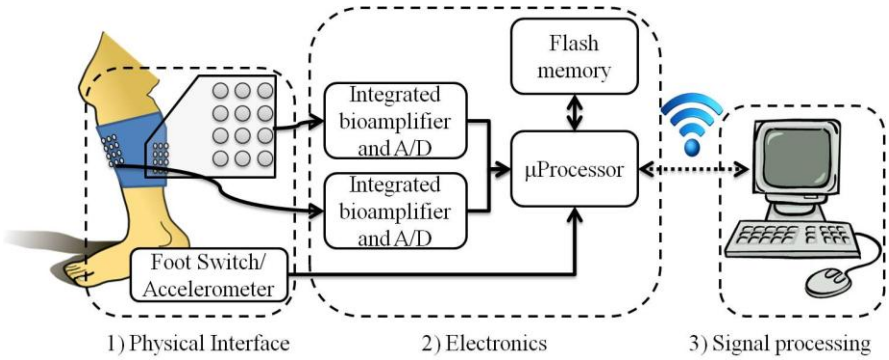

Figure 4.1: WEAR system architecture.

4.2.1. Physical Interface

4.2.1.1. Electrode Array and Mount

Conventional sEMG acquisition is performed by placing a single electrode pair above the muscle of interest, based on anatomical landmarks and physical measurements (e.g., SENIAM project guidelines [16]). Using anatomical landmarks for electrode placement is time consuming and can lead to inter- and intra-patient variability since the landmarks are not always obvious and different clinicians may place electrodes in slightly different locations [24][17]. Instead of a single electrode pair, the WEAR system would employ an electrode array that can be quickly positioned above the muscle of interest; a software algorithm can later select an appropriate electrode pair from the array. Electrodes could be integrated into a wearable sleeve to hasten the process of affixing the electrode array to the patient.

4.2.1.2. Foot Switches/Accelerometers

Discerning the various gait cycle phases from sEMG can be difficult since the signal lacks a specific pattern, such as the PQRST wave associated with the ECG signal. WEAR would employ either foot switches or accelerometers which have both been shown to provide adequate information to identify events in the gait cycle (e.g., foot strike, toe off, and swing) [51].

4.2.2. Electronics

Rather than using discrete components to perform bioamplification and analog-to-digital conversion, the WEAR system would employ one of the new integrated analog front end (AFE) solutions, such as the ADS1298 AFE (Texas Instruments, Dallas, TX, USA), or the ADAS1000 AFE (Analog Devices, Norwood, MA, USA). Advantages of an integrated front end solution include small package size (i.e. under 10 mm X 10 mm), light weight, and low power (i.e. under 22 mW). A general purpose microprocessor unit (MPU) would be used to initialize the system and control data flow. Data would pass through the MPU for storage and/or forwarding to a PC or central hub for processing.

Storage requirements for an eight channel AFE, with 24-bit resolution and 1000 Hz sampling recording sEMG data for an hour would require 86.4 MB. To handle memory requirements, small flash memory cards (i.e. microSD) are readily available with storage capacities up to 32 GB. As reported in chapter 3, visibility of real-time sEMG data is a usability requirement for the WEAR system. To provide capability for immediate data forwarding without the measurement interference inherent with being tethered to a stationary system, a wireless module (i.e. WiFi, Bluetooth, ZigBee) would be selected based on size, power requirements, and range.

4.2.3. Signal Conditioning

A common type of noise associated with sEMG is power line interference from nearby electrical sources [52]. This would appear as 60 Hz noise and potentially its harmonics (60 Hz is the power line frequency in North America; in some other parts of the world it is 50 Hz). Another type of noise is motion artifact, originating from impedance changes in electrode-skin interface and/or movement of electrode leads during locomotion [14]. An effect of motion artifact is caused by changes in the electrode-skin interface (e.g., half cell potential values) due to motion [14]. Noise can also come in the form of baseline drifts caused by slow shifting in the electrode-skin interface (e.g., channel gel concentrations) and electronics drift. Motion artifact and baseline drift are low frequency (< 20 Hz) components of the sEMG signal and can be suppressed by the application of a of a 15-20 Hz high-pass filter (HPF) [14]. The spectral content in such low frequency ranges includes information related to the firing rate of active motor units. While firing rate information is important to some applications, in the case of movement analysis, it is inconsequential [23].

4.3. Prototype Implementation

A WEAR prototype was designed to validate the physical interface and bioamplifiers; as such, wireless data transmission was not necessary for this stage of implementation.

4.3.1. Physical Interface

4.3.1.1. Electrode Array and Mount

An array of 8 electrodes was used for the WEAR prototype, comprised of 2 columns of 4 electrodes aligned in parallel with the muscle fibers. Electrodes were paired to form

6 channels of data, with channels 1 and 4 proximal to the body (Figure 4.2). sEMG signals were acquired using a bipolar electrode configuration, with an inter-electrode distance of 20 mm, in accordance with SENIAM [16]. The SENIAM guidelines recommend an electrode size of 10 mm in the direction of the muscle fiber; however, 14.2 mm diameter medium dome metal electrodes (Liberating Technologies, Holliston MA, USA) were used in the WEAR prototype. The finite size of an electrode has a low pass filtering effect on the measured sEMG, with a greater loss of higher frequencies with increased electrode size [53]; however, the slightly larger size was thought to have minimal impact on the frequency content of the measured sEMG. Previous work had also shown that sEMG signals acquired with a larger dry electrode (35 mm diameter) were comparable to a smaller Ag/AgCl electrode (5 mm diameter) in terms of signals strength and frequency content [54]. Also, electrode selectivity in an array is more influenced by inter-electrode spacing than electrode size [55]. Using a larger electrode has the advantage of a lower the electrode-skin impedance.

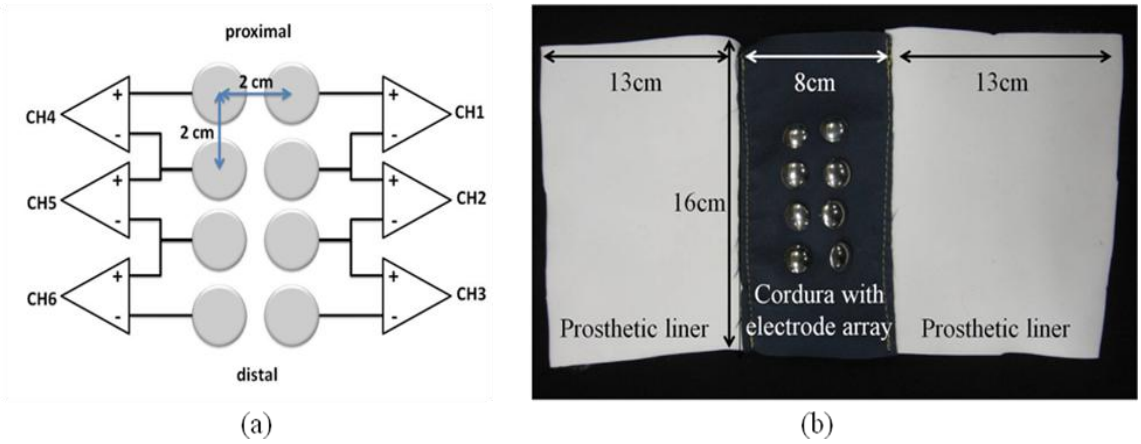

Figure 4.2: (a) Electrode channel configuration and (b) electrode mount.

The WEAR prototype utilized a modified silicone prosthetic liner to help reduce electrode shifting and mitigate the amount of motion artifact. An 8cm x 16cm piece of Cordura 1000 fabric (J. Ennis Fabrics, Edmonton, AB, Canada) was selected for its non-stretching properties to ensure consistent electrode spacing within the array and for its 100% polyurethane backing which has been shown to be non-irritating to the skin. A 13cm x 16cm piece of 3mm thick Össur Iceross prosthetic liner (Össur Americas, Foothill Ranch, CA, USA) was sewn onto the left and right hand sides of the Cordura. The liner was chosen for its elastic properties to ensure a custom and secure fit. The liner was secured at the back by two strips of hook-and-loop fabric. A view of the inside of the electrode mount can be seen in Figure 4.2.

4.3.1.2. Foot Switches

Foot switches were commonly employed in the TOHRC's Rehabilitation Technology Laboratory. This motivated the use of foot switches in the WEAR prototype, rather than the accelerometers; identical switches were used. Four switch pads were taped to the bottom of the shoe, three pads for the forefoot and one pad for the heel. Different voltage states were produced based on which pads were pressed (Table 4.1). The foot switches interfaced to the electronics via a 3-pin (i.e. signal, power, ground) male LEMO connector (LEMO Connectors, Morges, Switzerland).

Table 4.1: Foot switch voltage states.

Pad pressed	Voltage state
None	0
1 or more forefoot	1
Heel	2
1 or more forefoot & heel	3

4.3.2. Electronics

The prototype WEAR electronics included the ADS1298 (Texas Instruments, Dallas TX, USA), an 8-channel, 24-bit analog front end designed specifically for biopotential measurements; the PIC24FJ128GA010 (PIC24; Microchip, Chandler AZ, USA), a general-purpose 16-bit flash microcontroller, and a SD flash memory card. To simplify prototyping, the ADS1298ECG-FE demonstration board (Texas Instruments, Dallas TX, USA), Explorer 16 development board, and Microchip PICtail daughter board for SD and MMC (Microchip, Chandler AZ, USA) were used. These boards integrated the ADS1298, PIC24, and SD card interface module, respectively. The system was powered by six AA batteries. Figure 4.3 shows the WEAR prototype, highlighting the main hardware components.

To provide a wearable system, the ADS1298FE was mounted to a molded plastic bracket that could be strapped to the lower leg, just above the electrode mount. The proximity of the ADS1298 to the electrodes allowed for minimal lead lengths between the sensors, bioamplification, and analog-to-digital (A/D) conversion, thereby helping to reduce noise. The Explorer 16 and power supply were worn in a pouch strapped around the waist (Figure 4.3). Since all communications between the Explorer 16 and ADS1298FE were digital, distance was not a concern.

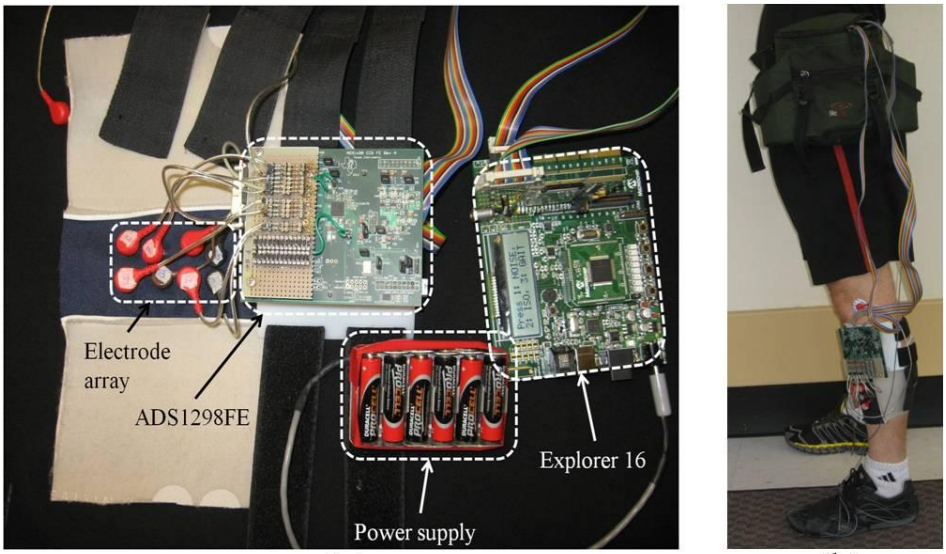

Figure 4.3: (a) WEAR prototype hardware and (b) WEAR prototype as worn by participant.

4.3.2.1. ADS1298

The ADS1298 accepted analog sEMG signals, amplified the signals, performed A/D conversion, and multiplexed the multiple data channels into a single bit-stream for transmission along a serial port interface (SPI). The ADS1298 was aimed towards electrocardiography and electroencephalography, but is suitable for sEMG with the eight integrated programmable gain amplifiers, eight high-resolution A/D converters, and small package size (8mm x 8mm). In terms of bandwidth, 500 Hz is often used for sEMG applications [14]. Even at the highest programmable gain setting (12), the ADS1298 nominal bandwidth would be 32 kHz; well above the sEMG requirements. The ADS1298 was configured with the programmable gain amplifiers (PGAs) set to a gain of 6 (the default value). The sampling rate was set to 1000 Hz per channel with six operational channels

The ADS1298 used for the prototype was part of the ADS1298ECG-FE demonstration board, designed to interface with the Texas Instruments MMB0 mother board. Since the ADS1298ECG-FE was expecting three different power supplies (1.8V, 3.3V, and 5V) from the MMB0, the Explorer 16 development board was modified to supply these voltages. Additionally, the differential channel inputs to the ADS1298 were not directly accessible since the ADS1298ECG-FE was originally designed to demonstrate ECG operation in a limited configuration. To bypass the ADS1298ECG-FE on-board circuitry prior to the ADS1298 differential inputs, surge protecting circuitry was added.

4.3.2.2. PIC24

The PIC24 is a 16-bit RISC microcontroller with an on-chip oscillator and low operational power requirements that makes it suitable for portable and weight restricted applications. The PIC24 interfaced with the ADS1298 through an SPI interface. A separate SPI was used to interface the PIC24 to a SD flash memory card on the PICtail board, where digitized sEMG signals were stored. Foot switch information was acquired by the PIC24 through one of its analog-to-digital converters via an added 3-pin female LEMO connector. System operation was controlled by a series of pushbuttons on the Explorer 16 with the operation mode indicated on a LCD screen also located on the Explorer 16.

4.3.2.3. Embedded Software

Embedded software was implemented on the PIC24 to program and command the ADS1298, and manage data flow throughout the WEAR prototype. On power-up, the

PIC24 sent commands to the AD1298 to initialize its programmable registers so that it could operate with the required settings. Once the ADS1298 was initialized, it automatically began amplifying analog sEMG data and converting them to digital format. Since the specific PIC24 used lacked direct memory access (DMA), custom flow control had to be implemented.

The user initialized data recording by pressing one of the buttons on the Explorer 16. Once the PIC24 had been commanded to begin recording data, the PIC24 waited for the interrupt signal from the ADS1298 prior enabling data transfer. The interrupt signal generated by the ADS1298 was used to indicate when it had amplified and A/D converted a single 216 bit sEMG data packet (24 status bits, followed by 24-bits per channel: six active channels and two inactive channels for the WEAR prototype). sEMG data packets transmitted from the ADS1298 via the SPI interface, were temporarily stored in a circular, or ring, buffer in the PIC24. Once a complete data packet was received, the PIC24 wrote the sEMG data from the circular buffer to the SD flash memory card. Concurrently, analog data from the footswitches were converted to digital format by a PIC24 internal A/D converter, temporarily stored in the ring buffer, and then written to the SD card with the sEMG data. Lack of DMA combined with slow write speeds of the SD card resulted in the ADS1298 being configured for operation on six channels, with 1000 Hz sampling rate. Attempts to use all eight channels and/or a higher sampling frequency resulted in lost data since the PIC24 could not write packets to the SD card fast enough to keep up with the input rate.

4.3.3. Signal Conditioning

WEAR data files on the SD memory card were manually transferred to a computer for offline signal processing performed in MatLab (The Mathworks, Natick, MA, USA). Data were digitally high-pass filtered using a 3rd order Butterworth filter, with a frequency cutoff of 30 Hz to eliminate motion artifact and any baseline drift. Next, notch filtering was performed on the data using a second-order digital filter, with a center frequency of 60 Hz and a Q-factor of 35. No harmonics were observed and thus only 60 Hz filtering was used. Comb filtering could have easily been implemented if necessary. Filtering was performed in the forward and reverse direction for zero-phase filtering.

4.4. Methodology for Pilot Validation

4.4.1. sEMG Acquisition Systems

To validate the WEAR prototype we compared it to two conventional sEMG systems. Data was collected for all three systems with a dry electrode array, a wet electrode array to separate out the effects of the acquisition system and the electrodes. The same reference electrode placement was used for each set-up, a single wet electrode on left fibular head.

4.4.1.1. WEAR Prototype

The WEAR prototype used in pilot validation was as described in section 4.3.

4.4.1.2. The Ottawa Hospital Rehabilitation Centre System

The first conventional sEMG acquisition system, was located in the TOHRC's Rehabilitation Technology Laboratory (TRC system). The TRC acquisition system was a custom built amplifier system comprised of four AD524 instrumentation amplifiers (Analog Devices, Norwood MA, USA) each connected to a pair of electrodes, each with

a gain of 100, connected to a junction box. The junction box was then connected to a OP27 precision operational amplifier (Analog Devices, Norwood, MA, USA) with an adjustable gain set to 20 (total gain of 2000), followed by an electrical isolation circuit, and then a high-pass, 3rd order Butterworth filter, with a frequency cutoff of 30 Hz. Data were sampled at 2000 Hz using a Vicon MX Ultranet HD console with a 16-bit A/D converter (Figure 4.4). Data were resampled in Matlab to 1000 Hz to be consistent with the WEAR prototype's sampling rate.

Electrodes were located 10 cm from the AD524 amplifiers to help minimize the noise. 130 cm leads connected the AD524 to the junction box, which was connected to the OP27 through a heavily shielded ~57 m long cable. The OP27, isolation circuit and 3rd order Butterworth filter were housed in a custom made unit in a shelving rack. The Vicon MX Ultranet HD and A/D were also located in the shelving rack (Figure 4.4).

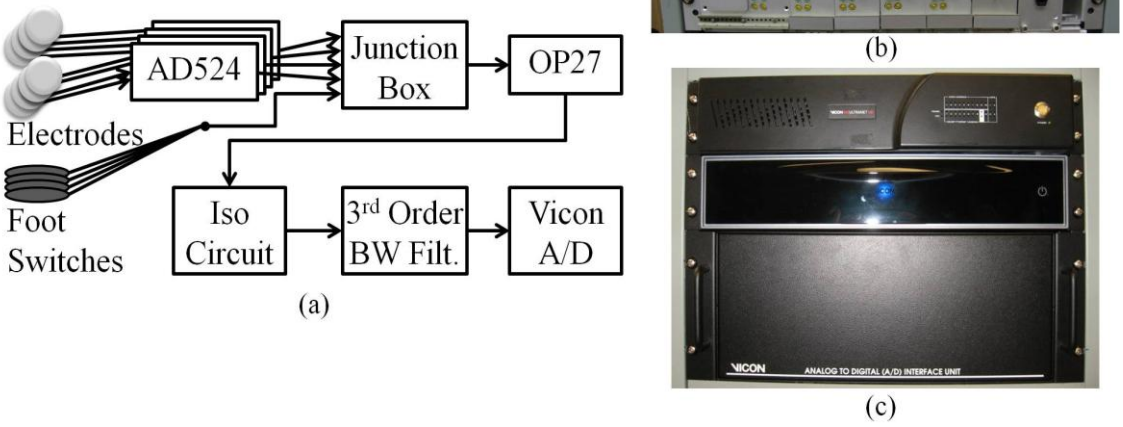

Figure 4.4: (a) TRC system block diagram, (b) custom EMG unit, and (c) Vicon A/D.

4.4.1.3. Modified TRC System

The second conventional sEMG acquisition system, the Modified TRC (MTRC) system (Figure 4.5), had four electrode pairs connected via 150 cm leads to a junction box (F-15EB/B1 16-channel electrode board, Grass Technologies, West Warwick, RI, USA), which was connected by a 4.2m cable to the biopotential amplifiers (M15LT system using a M15A54 quad amplifier, Grass Technologies). The M15LT system was connected via a 4.5m cable to the same junction box used by the TRC system to align the sEMG signals with the foot switches. The remaining parts of the system were the same as the TRC system. The variable gain on the M15 amplifier was set to 100 and the OP27 adjustable gain was set to 10 (total gain of 1000). As with the TRC system, MTRC system data were sampled at 2000 Hz using a Vicon MX Ultranet HD console with a 16-bit A/D converter. Data were resampled in Matlab to 1000 Hz for consistency with the WEAR prototype.

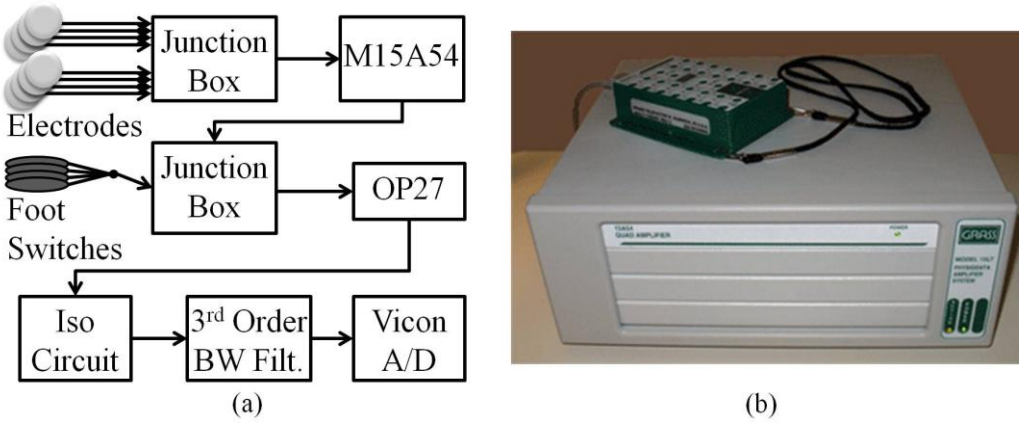

Figure 4.5: (a) MTRC system block diagram and (b) M15LT system with one M15A54 quad amplifier and a F-15EB/B1 electrode board.

4.4.2. Electrodes

Dry and wet electrodes were used in the pilot validation to observe the effects of electrode type on system performance. The dry electrodes, described in section 4.2.1.1, were the LTI medium dome electrodes, housed in the electrode mount. The wet electrodes were self adhesive 5 mm diameter pre-gelled Ag/AgCl electrodes (Meditrace 130, Kendall, Mansfield MA, USA). Since the wet electrodes were self adhesive, the wet electrode array did not require the electrode mount. Both arrays used eight electrodes aligned as seen in Figure 4.2.

4.4.3. Pilot Data Collection

Data were collected from the TA muscle of the left leg of one male participant (age 35, weight 74.8kg, calf diameter 39 cm), with no known neuromuscular disorders. Six trials were performed in succession: the first three with the dry electrode array and the last three using the wet electrode array (Table 4.2). Three tasks were performed in each trial: 1) resting, 2) isometric and isotonic contractions, and 3) walking. The resting task was performed to collect noise data. The isometric and isotonic contractions were performed to compare inter- and intra-system signal quality. The walking task was conducted to compare how the systems performed on a moving participant, since the intent of the WEAR was for gait/motion analysis.

Prior to each trial, the skin's surface above the TA was cleaned with an alcohol wipe. The appropriate electrode array was placed on the participant, positioning the center of the array at the position recommended by SENIAM. Positioning for trial #1 was done visually; that is, no measurements were made to guide the placement, enabling rapid

Table 4.2: Validation test order.

Trial #	System	Electrodes
1	WEAR	Dry
2	TRC	Dry
3	MTRC	Dry
4	WEAR	Wet
5	TRC	Wet
6	MTRC	Wet

positioning of the electrode mount (< 20 s). Since the dry electrodes left a temporary physical depression on the skin surface, the appropriate electrode array could be positioned in the same location for each trial.

4.4.3.1. Task #1: Resting

The participant began seated on a bench with their legs extended and 10 s of data were acquired while the participant's leg was relaxed. These data should be representative of the noise associated with the acquisition system (i.e. no sEMG present).

4.4.3.2. Task #2: Isometric and Isotonic Contractions

While seated on a bench, a 5 lb weight was tethered via a pulley to the top of the left foot (Figure 4.6). The weight rested on a support block while the participant's muscle was relaxed. Ankle dorsiflexion raised the weight, which provided a counter force of approximately 22 N. The participant performed 10 repetitions of dorsiflexions, holding an isometric contraction for 3 seconds, plantarflexion to the starting position, and 3 seconds with the muscle relaxed before the next repetition.

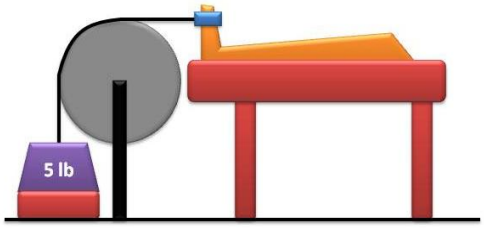

Figure 4.6: Experimental setup for TA muscle activation.

4.4.3.3. Task #3: Walking

The participant began seated on a stool, stood up, walked straight for 5m at a self selected pace, turned around, walked 5m back to the starting point, turned and sat back down. The participant performed five repetitions of the walking task.

4.4.4. Data Processing

The mean of each data recording was subtracted to remove any offsets. To enable direct comparisons of the amplitudes between the WEAR and conventional systems, recorded amplitudes were converted to voltages and were divided by the total gain of their respective acquisition systems. Since significant power line interference noise at 60 Hz was observed in both the WEAR and MTRC, the 60 Hz notch filter (as described in section 4.2.3) was applied to all data. Significant noise was also observed at 300 Hz in the MTRC trials, thus a second-order digital notch filter, with a center frequency of 300 Hz and a Q-factor of 35 was applied only to MTRC trial data. All data processing was performed in Matlab.

4.5. Results

4.5.1. Task #1: Resting

Ten seconds of data were captured for each system, with eight seconds extracted, one second after the start to avoid any effects from the digital filtering. There were no notable differences between electrode types within each system, however, the noise amplitudes varied between systems (Figure 4.7).

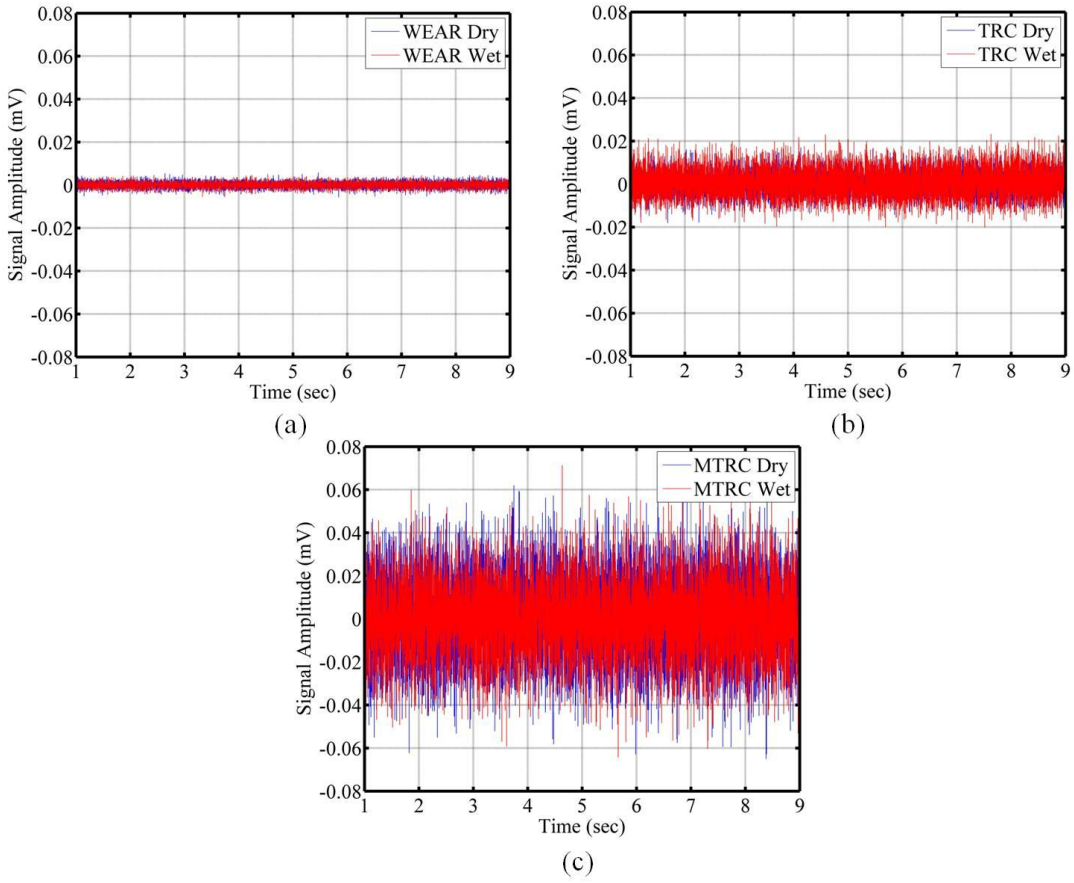

Figure 4.7: Resting noise from channel 3 for all trials. (a) WEAR system, (b) TRC system, and c) MTRC system.

4.5.1.1. Noise Root Mean Square Comparison

. There was very little difference in root mean square (RMS) voltages between electrode types for any of the systems, with mean differences of 8.42% +/- 8.60%, 12.06% +/- 10.98%, and 4.75% +/- 3.45% across the six channels for the WEAR

prototype, TRC, and MTRC systems, respectively (Figure 4.8). The low variability between electrode types showed that the larger electrode sizes of the dry electrodes did not seem to have an impact on system performance. WEAR had the lowest noise RMS values for every channel. The TRC system had the second highest RMS noise. The MTRC system's RMS noise was much higher than either the TRC system or WEAR noise RMS levels (103.13% and 166.01% difference, respectively, for the means across all channels and trials).

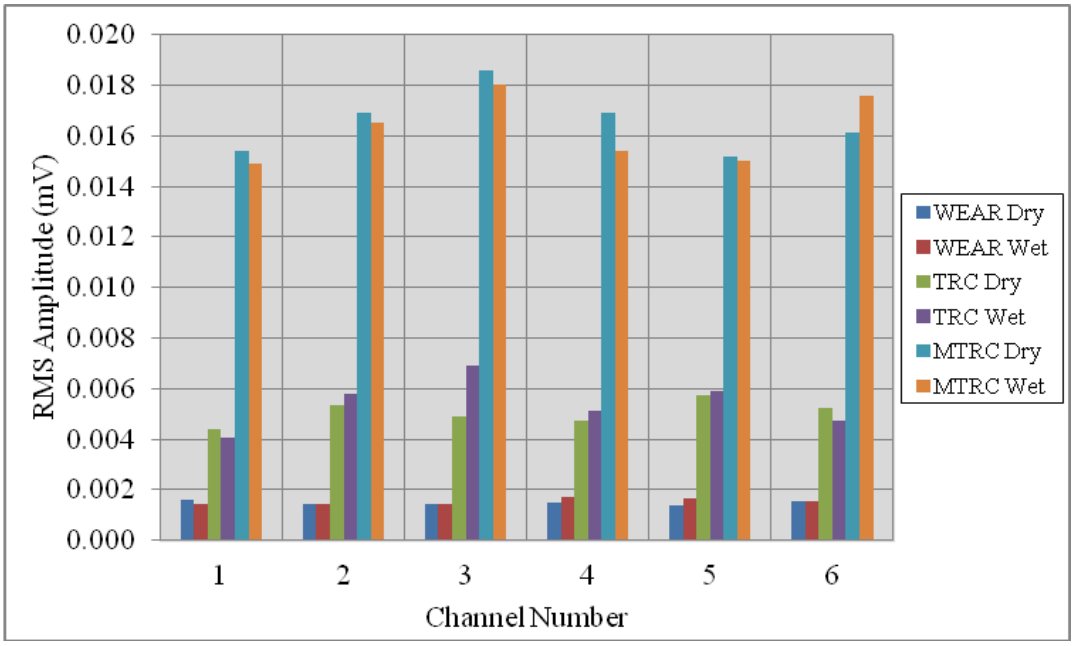

Figure 4.8: Noise RMS amplitude, for all 6 channels of sEMG.

4.5.2. Task #2: Isometric and Isotonic Contractions

For each isometric, isotonic contraction, 2048 ms segments of data were extracted, 512 ms after the start of the contraction; the starting time of each contraction was identified manually through visual inspection of the recorded sEMG signals. This segmentation avoided the transient portions of each contraction (i.e., segments

correspond to isometric, isotonic contractions). An example of the WEAR with dry electrodes output from the channel 3 isometric and isotonic contractions post-processing can be seen in Figure 4.9.

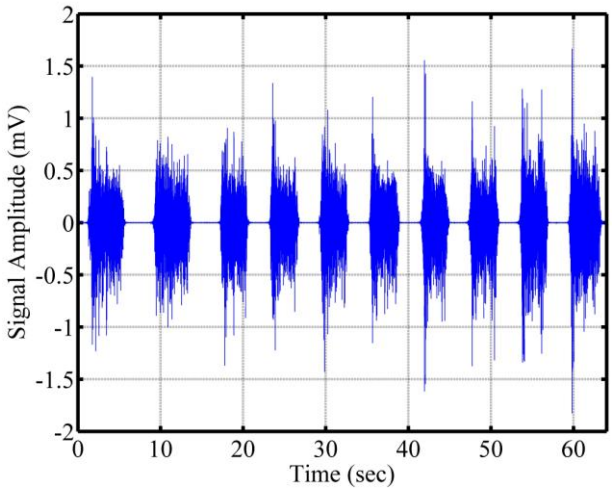

Figure 4.9: Isometric and isotonic contractions from channel 3 of WEAR with dry electrodes.

4.5.2.1. Signal RMS Comparison

The RMS value of each sEMG segment was computed. Figure 4.10 is a bar chart of the RMS values, averaged over the 10 contractions, for each channel and trial. The WEAR prototype using the wet electrodes had the highest overall RMS values (0.25mV +/- 0.04), while, except for the TRC system channel 6, the MTRC system using the wet electrodes had the overall lowest RMS values (0.14mV +/- 0.003). Channel 3 had the highest RMS values for each trial (0.24 mV +/- 0.05) and channel 5 had the lowest (0.15 mV +/-). As channel 3 had the highest mean RMS value, it was deemed the most reasonable electrode pair for further analysis.

Although relative RMS values were consistent across the different systems and electrodes, the TRC system did not always perform well with the dry electrodes. An outlier can be seen in Figure 4.10, where channel 6 on the TRC dry trial had a RMS value close to zero for all contractions. As can be seen in Figure 4.11, it appeared as though channel 6 was not functioning (i.e. no contractions visible). The non-functioning channel behavior of the TRC with dry electrodes was visible in previous tests (on different and/or multiple channels) not reported here.

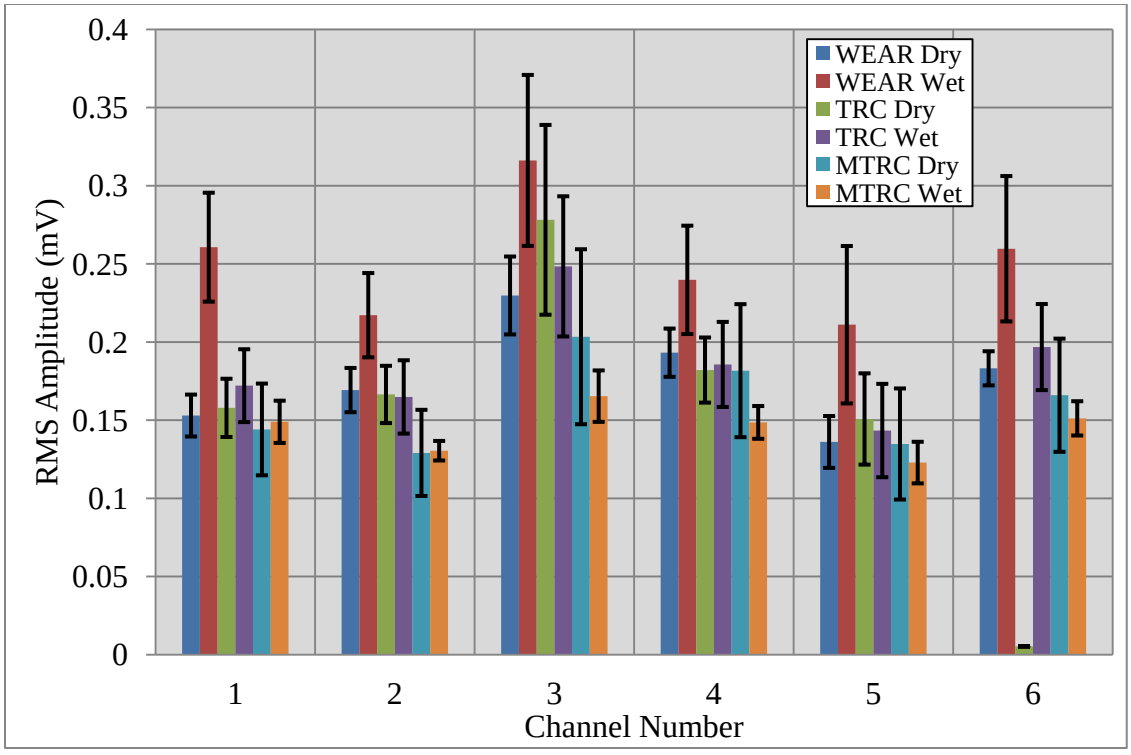

Figure 4.10: Signal mean RMS amplitude, averaged across 10 contractions (1 standard deviation error bars), for all 6 channels of sEMG.

4.5.2.2. Signal-to-Noise Ratio Comparison

An estimate of the noise was established in task #1 (section 4.5.1). A signal-to-noise ratio (SNR) can be derived by taking the ratio of the mean RMS value, averaged across

the 10 contractions, and the RMS value of the noise. Figure 4.12 is a bar chart of the mean SNR over the 10 contractions for channel 3 of each trial. Based on the high RMS and low noise associated with the WEAR prototype with wet electrodes, it was expected that WEAR with wet electrodes would have the highest SNR, which proved to be the case (46.7 dB +/- 1.4). The SNR of the WEAR with dry electrodes (43.9 dB +/- 0.9) surpassed the SNR of the TRC system with either electrode type (22.77% difference and 34.45% difference for dry and wet electrodes, respectively). Based on showing the lowest RMS and highest noise values, the MTRC system trials had the lowest SNR values. The mean SNR across both MTRC system trials was 78.02% different than WEAR SNR (mean across both electrode types) and 49.54% different than the TRC system's SNR (mean across both electrode types).

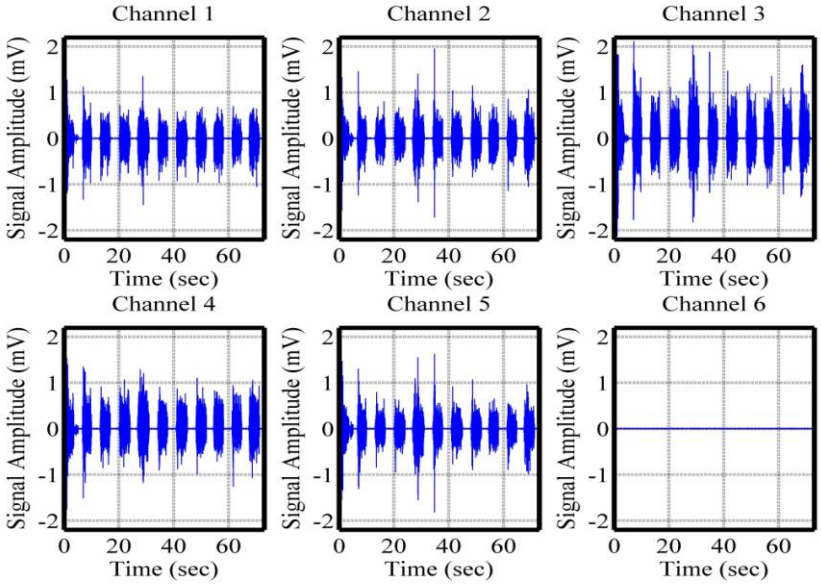

Figure 4.11: Isometric and isotonic contractions from all channels of TRC with dry electrodes.

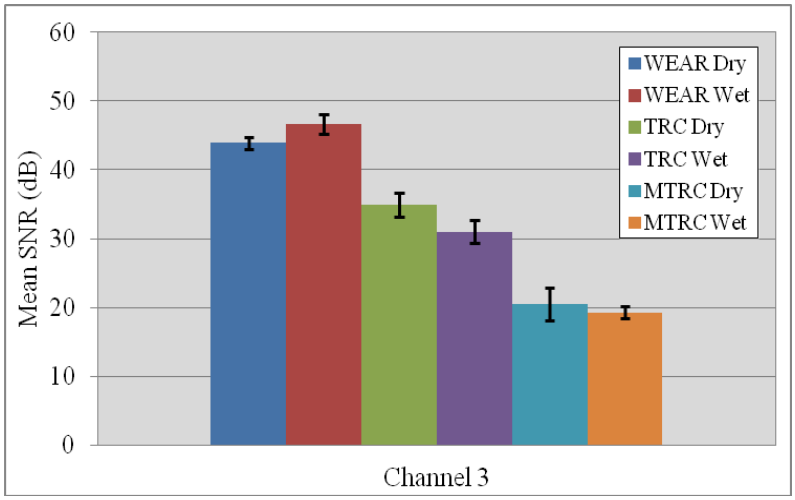

Figure 4.12: Mean SNR, averaged across 10 contractions for channel 3 for all trials.

4.5.2.3. Power Spectral Density Comparison

Power spectral densities (PSD) for each 2048ms data segment of the isometric and isotonic contractions were calculated using Welch's method [56], using Hamming windows of 512 samples, with 50% window overlap. A PSD plot (power vs. frequency) for each trial type with the PSD values averaged over all 10 isometric and isotonic contractions from channel 3 can be seen in Figure 4.13.

Based on correlation coefficients calculated for all six PSD curves, which ranged from 0.95 to 0.99 (where 1.00 is an exact match), the spectral content was consistent. The maximum power of the curves followed the same patterns seen in the RMS results, with WEAR with wet electrodes showing the highest maximum power (-87.18 dB), followed by the two TRC system maximum powers (-88.92 dB and -89.79 dB for dry and wet electrodes, respectively), then the WEAR with dry electrodes (-90.00 dB), and finally the two MTRC system maximum powers (-91.26 dB and -93.67 dB for dry and wet electrodes, respectively).

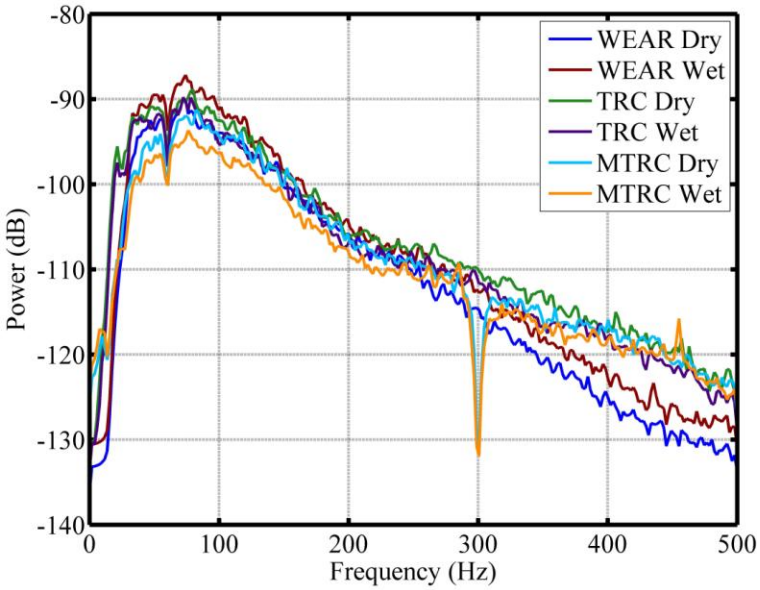

Figure 4.13: PSD averaged across 10 contractions for channel 3 for all trials.

The effects of the 60 Hz notch filters can be seen in each curve and the effects of the 300 Hz notch filter can be seen in the MTRC system curves (Figure 4.13).

4.5.3. Task #3: Walking

4.5.3.1. Data Segmentation

To analyze the walking trials, a linear envelope was computed for the sEMG data. Based on the method developed by Barrett, Donnelly, and Olaighin in [57], raw sEMG data were rectified and digitally low-pass filtered using a fifth-order Butterworth filter, with a cutoff frequency of 5 Hz. By aligning the filtered and rectified sEMG data with the foot switch data, different actions from the walking trials were segmented. Four actions from each trial were used for analysis: sit-to-stand, stand-to-sit, loading response of every step (i.e. the loading response of the TA from the beginning to the end of its contraction),

and swing phase of every step (i.e. TA activity beginning from push off and ending during terminal swing) (Figure 4.14). The loading response and swing phase were selected for analysis since they represent the periods with the most TA activity in the gait cycle [58]. Sit-to-stand and stand-to-sit were selected since they are distinct actions in the sequence; however, since the actions themselves varied between trials, they were analyzed as a whole rather than segmented.

4.5.3.2. Signal Strength Comparison

To calculate the signal strength (SS) of the portion being analyzed, the normalized integral of the sEMG signal was calculated. The area under the linear envelope curve was estimated using trapezoidal numerical integration and then normalized by dividing the relevant area under a curve by the number of samples in the area [44]. To compare intra- and inter-system performance, boxplots for each action were created in Matlab (Figure 4.15).

Boxplots show variability and median SS relative to each movement action within each trial. The top of box represented the upper 75^{th} percentile (q_3) of the values and the bottom of the box represented 25^{th} percentile (q_1). Interquartile ranges (q_3-q_1, IQR) are a measure of variability within a set of data. The median value is indicated by the red line inside the box. The "whiskers" show minimum and maximum values (i.e. the vertical lines coming off the top and bottom of the boxes ending in horizontal lines) [59].

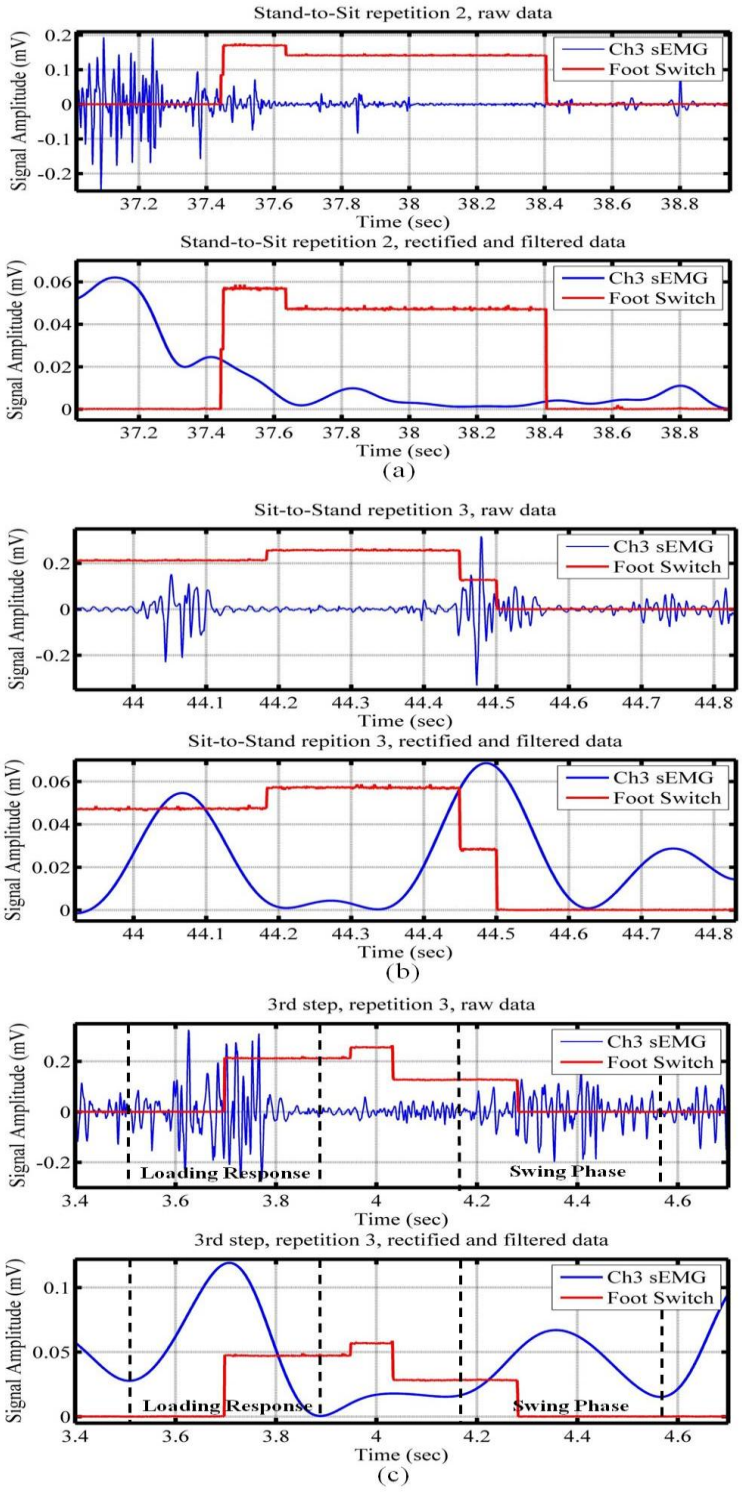

Figure 4.14: Data segmentation, WEAR channel 3 with dry electrodes: (a) stand-to-sit, (b) sit-to-stand, (c) loading response and swing phase.

To determine the limit of the upper whisker, Matlab found the nearest data point below $q_3 + w(IQR)$. To determine the limit of the lower whisker, Matlab found the nearest point above $q_1 - w(IQR)$. In both cases, w was set to the default value of 1.5 which corresponded to an approximate standard deviation of +/- 2.7 and coverage of 99.3% for normally distributed data. Outliers (data points beyond the whiskers) are represented by red plus symbols. [59].

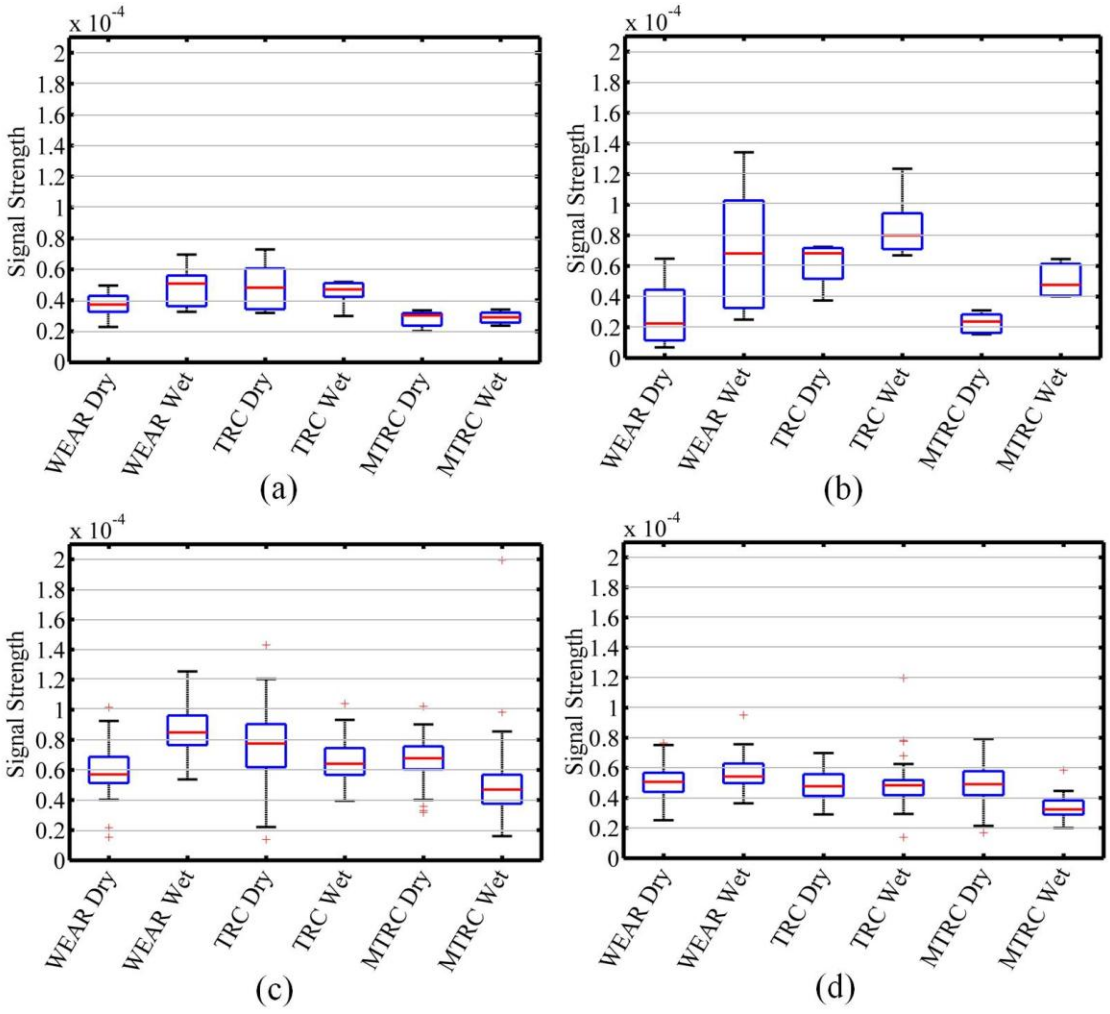

Figure 4.15: Mean SS boxplots across all five repetitions of each trial for (a) sit-to-stand, (b) stand-to-sit, (c) loading response, and (d) swing phase.

. Intra-system variability for the WEAR prototype was comparable to those seen in both the TRC system and MTRC system (Figure 4.15). Values from the boxplots shown in Table 4.3 reveal that except for the WEAR with wet electrodes IQR for the stand-to-sit action (0.70×10^{-4}), WEAR IQRs ranged from 0.10×10^{-4} to 0.33×10^{-4}. TRC system IQRs had a slightly lower range than WEAR IQRs, going from 0.09×10^{-4} to 0.29×10^{-4}. The MTRC system showed the lowest variability of the three systems, with IQRs ranging from 0.06×10^{-4} to 0.21×10^{-4}. No outliers were present in the sit-to-stand or stand-to-sit actions. Except for WEAR with wet electrodes during the loading response action and the TRC system with dry electrodes during swing phase, all systems had from one to five outliers in the loading response and swing phase actions.

Comparing inter-system results for the sit-to-stand action revealed inconsistency in both IQR and median value comparisons. For the sit-to-stand action, WEAR with wet electrodes and the TRC system with dry electrodes showed the highest percent IQR differences with the other trials (ranging from 24.42% to 121.56% differences). Between the other four trials, IQRs for the sit-to-stand action only showed a range of 8.92% to 45.43% difference. Sit-to-stand median SS values for the MTRC system with wet electrodes and MTRC system with dry electrodes were very close (4.33% difference), but both MTRC system trial medians differed more from all other trials (from 20.73% to 50.70% difference). Outside of the MTRC system trials, sit-to-stand median SS differences ranged from 5.22% to 30.78%.

Table 4.3: SS data for all actions and all trials.

	WEAR Dry	WEAR Wet	TRC Dry	TRC Wet	MTRC Dry	MTRC Wet
Sit-to-stand						
IQR (x 10^{-4})	0.10	0.20	0.26	0.09	0.08	0.06
Median (x 10^{-4})	0.37	0.51	0.48	0.47	0.30	0.29
# of outliers	0	0	0	0	0	0
Stand-to-sit						
IQR (x 10^{-4})	0.33	0.70	0.20	0.23	0.12	0.21
Median (x 10^{-4})	0.22	0.68	0.68	0.80	0.24	0.48
# of outliers	0	0	0	0	0	0
Loading response						
IQR (x 10^{-4})	0.17	0.20	0.29	0.18	0.15	0.19
Median (x 10^{-4})	0.57	0.85	0.78	0.64	0.68	0.47
# of outliers	3	0	2	1	4	2
Swing phase						
IQR (x 10^{-4})	0.13	0.13	0.15	0.10	0.16	0.09
Median (x 10^{-4})	0.51	0.54	0.48	0.48	0.49	0.32
# of outliers	1	1	0	5	1	1

Comparing inter-system results for the stand-to-sit action also revealed inconsistency in both IQR and median value comparisons. For the stand-to-sit action, WEAR with wet electrodes and the MTRC system with dry electrodes showed the highest percent IQR differences with the other trials (ranging from 49.69% to 141.19% differences). Between the other four trials, IQRs for the stand-to-sit action showed a range of 3.90% to 48.59% difference. Stand-to-sit median SS values for WEAR with dry electrodes and the MTRC system with wet electrodes were very close (5.25% difference), but medians compared to all other trials differed to a higher degree (from 67.25% to 112.30% difference). Outside

of the WEAR with dry electrodes and MTRC system with wet electrodes trials, stand-to-sit median SS differences ranged from 0.06% to 50.65%.

For the loading response action inter-system comparisons, only the TRC system with dry electrodes showed IQR differences higher than other trials. IQR differences for the TRC system with dry electrodes compared to all other trials ranged from 37.12% to 60.95%. Between the five other trials, IQR differences ranged from 2.05% to 25.62%. Median SS differences for the loading response actions in the MTRC system with wet electrodes trial showed the highest differences versus other trials (ranging from 19.36% to 57.65%). Between all other trials, median SS differences ranged from 5.58% to 39.38%.

In terms of the swing phase action inter-system comparisons, the TRC system with wet electrodes and MTRC system with wet electrodes showed IQR differences higher than other trials. Although the IQR of the TRC system with wet electrodes and MTRC system with wet electrodes only differed by 7.78% from each other, compared with all other trials, differences ranged from 23.67% to 53.13%. Between the other four trials, IQR differences ranged from 2.56% to 22.80%. Median SS differences for the swing phase actions in the MTRC system with wet electrodes trial showed the highest differences with other trials (ranging from 38.43% to 50.48%). Between all other trials, median SS differences ranged from 1.44% to 12.66%.

4.6. Discussion

4.6.1. Task #1: Resting

4.6.1.1. Noise RMS Comparison

The noise RMS voltage levels while the participant was at rest showed differences between trials (Figure 4.8). Inaccurate gain settings in one or all three systems was a likely explanation for some of the differences (i.e., the amplifier gain was not exactly what it was programmed or designed to be). Elevated noise in the TRC system could also be explained in part by the fact that the TRC system had the highest input impedance of all three systems (TRC input impedance was 1GΩ, WEAR was 500MΩ, and MTRC was 20MΩ). High amplifier input impedance has been associated with increased motion artifact due to movement of electrode leads and power line interference [52]. The MTRC system showed the highest noise RMS of all three systems. MTRC system noise may have been due to the 5.5 m between electrodes and the M15 amplifier. Pre-amplification is generally placed close to the electrode to reduce noise [52].

4.6.2. Task #2: Isometric and Isotonic Contractions

4.6.2.1. Signal RMS Comparison

Since electrode positioning was maintained for both dry and wet electrode arrays for all three systems, it was expected that the channel with the highest RMS amplitudes would be the same. This is precisely what was observed (Figure 4.10). This result showed good intra-system repeatability for the WEAR prototype. With the same channel resulting in the highest mean RMS value for each trial, WEAR showed similar sEMG acquisition capabilities to the two conventional systems. Since the same electrode array was used, differences in RMS between systems were attributed to inaccurate gain settings in one or all three systems as described in section 4.6.1.1.

The RMS amplitude for the WEAR prototype with the dry electrode array was notably lower than the RMS amplitude of the WEAR prototype using wet electrodes (37.60% difference).Dry electrodes are polarizable and tend to have much larger electrode-skin impedances than wet electrodes, which are non-polarizable [22]. The higher electrode-skin impedance could account for the decrease in RMS amplitude, since signal strength loss is associated with higher impedance. However, the same behavior was not seen in the TRC or MTRC systems, where the RMS values varied by channel, with certain channels showing higher RMS amplitude for the dry electrodes. This may have been attributed to individual anomalies from a single-case study.

In the TRC trial with dry electrodes, no signal was recorded on channel 6 (Figure 4.11). The non-functioning channel occurred over 75% of the time in preliminary prototype testing. The non-functioning channel varied position in the array and sometimes occurred on multiple channels. Dry electrodes are known for having higher electrode-skin impedance than wet electrodes, which could result in a large impedance mismatch between the two electrodes; this in turn could result in a large differential voltage at the AD524 amplifier causing it to saturate. A non-functioning channel was never on TRC seen with wet electrodes, or on either the WEAR or MTRC systems. Since the non-functioning electrode pair behavior was never seen in MTRC results, the AD524, which is the difference between the TRC and MTRC systems, in combination with the dry electrodes was a likely enabler the problem. An investigation into the root cause of the intermittent, nonfunctioning channels, when using the TRC system with dry electrodes, is outside the scope of this thesis.

4.6.2.2. SNR Comparison

The SNR bar chart (Figure 4.12) showed similar patterns to channel 3 in the signal RMS bar chart (Figure 4.10) except for the WEAR with wet electrodes trial. The WEAR prototype exhibited less noise, resulting in the highest SNR. Similar to the noise and signal RMS values, the differences in SNR may be explained by the differences in gain settings, amplifier input impedances, and distance between electrodes and pre-amplification.

Despite not suffering from the TRC system amplifier saturation issues with dry electrodes, the MTRC system's results were not as high quality as expected. The SNR values for the MTRC system trials were lower than the other two systems. Since the main difference between the TRC and MTRC systems was the proven, COTS bioamplifier, one would have expected performance to be similar. The lower MTRC system SNR may be explained by the added distance between the electrodes and the amplifier allowing more noise into the signal.

4.6.2.3. PSD Comparison

Spectral content was similar for all trials with minor differences attributable to differences in configured versus actual amplifications.

4.6.3. Task #3: Walking

4.6.3.1. Data Segmentation

Gait sEMG output was rectified and filtered, producing linear envelope curves, before segmentation. Since sit-to-stand and stand-to-sit linear envelopes did not show consistent patterns between repetitions and trials, it was difficult to segment them into specific

portions, thus they were analyzed as a whole. The other two actions analyzed, the loading response and the swing phase had more distinct patters in the linear envelope curves and were thus simpler to segment from each step. The foot switch data enabled segmentation to be more obvious, although the linear envelopes showed some variation from step to step and system to system.

4.6.3.2. SS Comparison

Comparing the WEAR prototype's performance to the TRC and MTRC systems for IQR across the four actions did not reveal any glaring differences. For each action, there were one to two trials that showed much higher or much lower IQR values than the other trials. WEAR with wet electrodes had IQR values that were substantially different in two actions (sit-to-stand and stand-to-sit), while the TRC system had three such actions (two with dry electrodes, one with wet) and the MTRC system had two such actions (one with dry electrodes, one with wet). Median values across all trials and actions had lower percent differences than with the IQR values. WEAR with dry electrodes stood out only in the stand-to-sit action, while the MTRC system had substantially different medians five times (twice with dry electrodes, three times with wet). WEAR also had slight less outliers combined across all trials and actions (five for WEAR and eight each for the TRC and MTRC systems).

4.7. Conclusion

In response to a proven need for objective measures of muscle function in clinical rehabilitation, a functional prototype of the WEAR sEMG acquisition system was designed and implemented. Pilot tests validated the functionality of the WEAR prototype

and suggest that its performance is comparable to two conventional sEMG acquisition systems. Additional testing was conducted to provide a more thorough comparison (Chapter 5).

5. Participant Testing

5.1. Introduction

Following successful validation of the WEAR prototype (section 4.4), further testing with was needed to gather comparative information across multiple participants. This chapter describes the methodology and reports results from participant testing carried out at the TOHRC Rehabilitation Technology Laboratory.

5.2. Methodology

5.2.1. Participant Demographics

Ten able-bodied individuals were recruited from TOHRC and Carleton University. Exclusion criteria included presence of neurological, orthopaedic, or cardio respiratory issues that affected gait. After reading and signing information and consent forms, the testing procedure was explained and participants were given the opportunity to ask questions. Prior to testing, participant height, weight, and calf circumference were recorded (Table 5.1).

5.2.2. sEMG Acquisition Systems

For participant testing, two sEMG acquisition systems were compared: 1) the WEAR prototype system (section 4.3), which uses a dry LTI electrode array (section 4.3.1.1) and 2) the conventional TRC system (section 4.4.1.2) using one wet Ag/AgCl electrode pair (section 4.4.2). A MTRC system (section 4.4.1.3) evaluation was not required for this testing phase since only wet electrodes outcomes were used as a comparator (i.e., MTRC testing was required in due to issues with dry electrode use with the TRC system

Table 5.1: Participant demographics.

Participant #	Gender	Ht (cm)	Wt (kg)	Calf diameter (cm)
1	M	180.0	65.0	35.0
2	M	167.6	64.4	35.0
3	F	162.5	58.9	33.0
4	F	160.0	49.9	34.5
5	F	175.2	58.9	35.5
6	F	167.6	74.8	43.0
7	M	185.4	74.8	38.5
8	M	175.2	90.7	40.0
9	F	167.6	63.5	36.5
10	M	185.4	99.8	42.0

described in section 4.5.2.1). The WEAR prototype was described in section 4.3 and the TRC system was described in section 4.4.1.2.

5.2.3. Electrodes

Wet electrode placement with the TRC system followed the process outlined in the SENIAM project for TA: the first electrode was placed "at 1/3 on the line between the tip of the fibula and the tip of the medial malleolus" [60]. The second electrode was placed two centimeters down the same line from the first electrode. Figure 5.1 shows the electrode placement method with the blue dot representing the tip of the fibula and the orange 'x' representing the first electrode location.

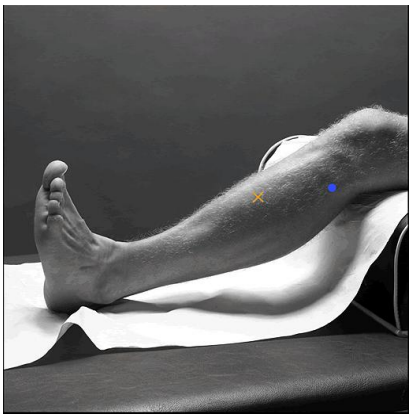

Figure 5.1: SENIAM electrode placement for TA [60].

5.2.4. Data Collection

Data collection was as described in section 4.4.3, except that the TRC trials were performed using a single, SENIAM placed, wet electrode pair and WEAR trials were performed with the dry electrode array. Array positioning for each WEAR trial was done visually (i.e., no measurements were made to guide array placement). Unlike the dry electrode placement method described in section 4.4.3, there was no effort made to place the electrode mount in the same position for each WEAR trial.

Each participant underwent a total of six trials, three for each sEMG acquisition system. Participant 1 was tested with the TRC system for the first three trials and the WEAR system for the last three trials. The starting system was alternated for subsequent participants (Table 5.2).

Table 5.2: Validation test order.

	Participants 1, 3, 5, 7, 9	Participants 2, 4, 6, 8, 10
Trial #	**System**	**System**
1	TRC	WEAR
2	TRC	WEAR
3	TRC	WEAR
4	WEAR	TRC
5	WEAR	TRC
6	WEAR	TRC

As with the experimental methods described in section 4.4.3, three tasks were performed in each trial: 1) resting, 2) isometric and isotonic contractions, and 3) walking. The resting task was performed as described in section 4.4.3.1 and isometric and isotonic contractions were performed as section in chapter 4.4.3.2. The walking task was performed as described in section 4.4.3.3. Data processing was performed as described in section 4.4.4.

5.2.5. Statistical Analysis

The null hypothesis was that signal RMS and SNR means from task #2, and mean SS IQR, median value, and number of outliers from task #3 for both the WEAR and TRC systems were the same. Two tailed t-tests were used to disprove the null hypothesis and calculate the statistical significance of the difference between the two systems ($\alpha = 0.05$), since it was unknown which system would have the higher mean values prior to data collection. Paired t-tests were used since the same participants were tested with each system [59]. Statistical power, which provides a measure of the likelihood that the null hypothesis would be rejected given that another outcome is true, was also measured for

all five data sets [59]. Finally, ideal sample sizes for achieving good statistical power in the testing of the five data sets were calculated [59].

5.3. Results

5.3.1. Task #1: Resting

The mean noise RMS across the three trials per system was lower with the WEAR than the TRC system for each participant (Figure 5.2). Mean noise RMS across all 10 participants was 88.80% different between WEAR trials (2.16×10^{-3} mV +/- 6.57×10^{-4}) and TRC system trials (5.16×10^{-3} mV +/- 1.83×10^{-3}). Figure 5.2 displays noise data for the channels as selected in section 5.3.2.1. Output from five WEAR resting trials (participant 1, trial 1; participant 6, trial 1; participant 4, trials 2 and 3; and participant 5, trial 1) showed anomalies and were thus discounted from further analysis (Figure 5.3). Since only one WEAR noise trial was used for participant 4, there was no standard deviation, thus no error bars on the corresponding bar in Figure 5.2. The standard deviation for the two WEAR noise trials used for participant 5 (+/- 1.27×10^{-6}) was too small to be viewable on the corresponding bar in Figure 5.2.

5.3.2. Task #2: Isometric and Isotonic Contractions

2048 ms data segments were extracted per contraction, as described in section 4.5.2.

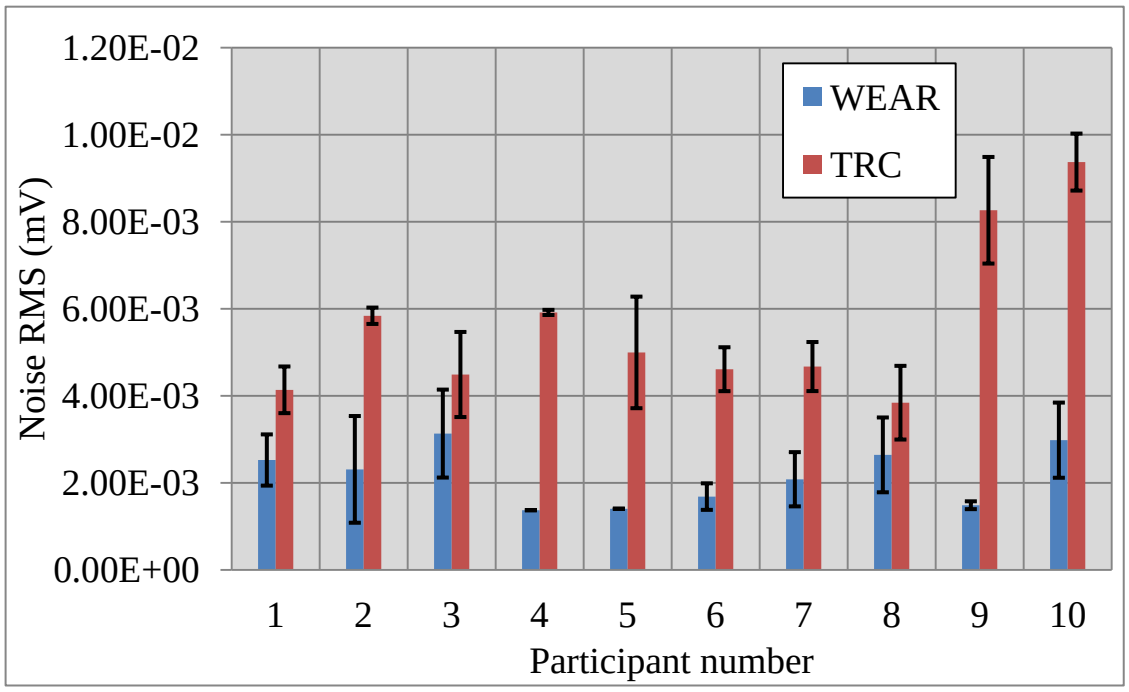

Figure 5.2: Mean noise RMS, averaged across 3 trials (1 standard deviation error bars), from selected channel for all 10 subjects.

5.3.2.1. RMS Comparison

For each trial, the RMS value of each sEMG segment was computed and averaged across all 10 contractions per channel (Figure 5.4). The channel with the highest RMS value (selected channel) for each WEAR trial was used in analysis for comparison to the single TRC system electrode pair (Table 5.3).

The WEAR system had a higher mean RMS voltage for every participant except participant 10. WEAR mean signal RMS across all participants (0.274 mV +/- 0.126) and TRC system mean signal RMS (0.159 mV +/- 0.077) differed by 52.95%. T-test results revealed a significant difference between mean RMS values for the WEAR and TRC systems ($p = 0.0114$).

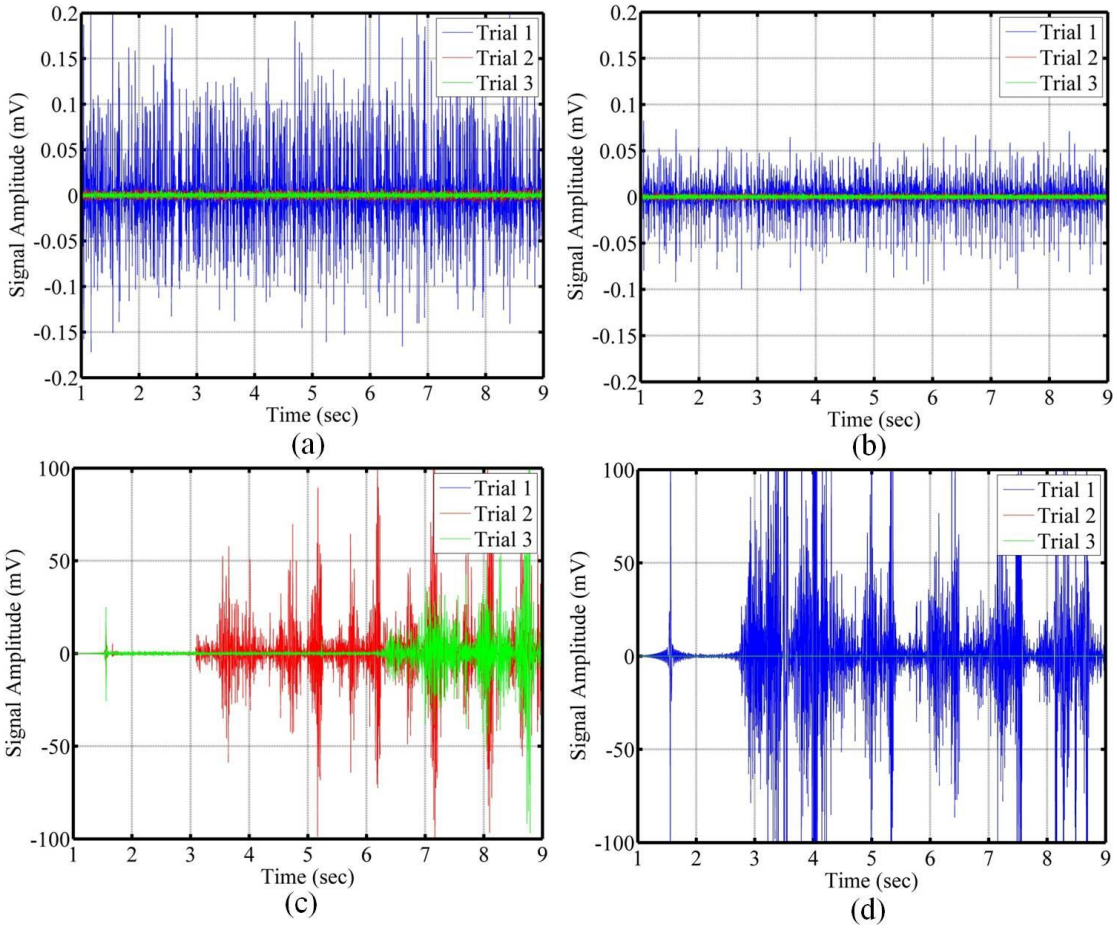

Figure 5.3: Abnormal noise signals from (a) participant 1, (b) participant 6, (c) participant 4, and (d) participant 5.

5.3.2.2. SNR Comparison

SNR was calculated as in section 4.5.2.2. Based on the generally higher RMS (nine out of ten participants) and lower noise associated with the WEAR system, the higher WEAR SNR was as expected for all participants (Figure 5.5). WEAR mean SNR across all participants (41.697 dB +/- 3.073) and TRC system mean SNR (28.299 mV +/- 4.224) differed by 38.28%. T-test results revealed a significant difference between mean SNR values for the WEAR and TRC systems ($p < 0.0001$).

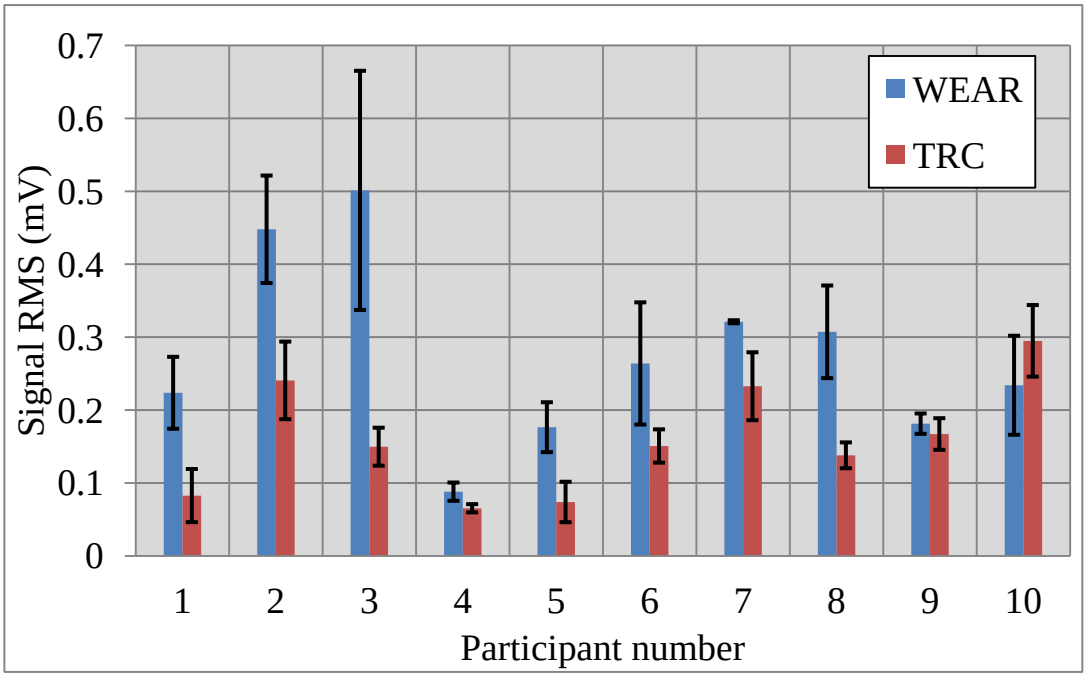

Figure 5.4: Mean RMS, averaged across 10 contractions and 3 trials (1 standard deviation error bars) per system, for all 10 participants.

Table 5.3: Electrode channel with highest mean RMS per trial for each participant.

Participant #	Trial 1 selected pair	Trial 2 selected pair	Trial 3 selected pair
1	5	6	5
2	6	6	6
3	3	6	6
4	5	6	4
5	4	4	4
6	5	5	4
7	5	3	6
8	6	6	6
9	6	6	6
10	4	4	6

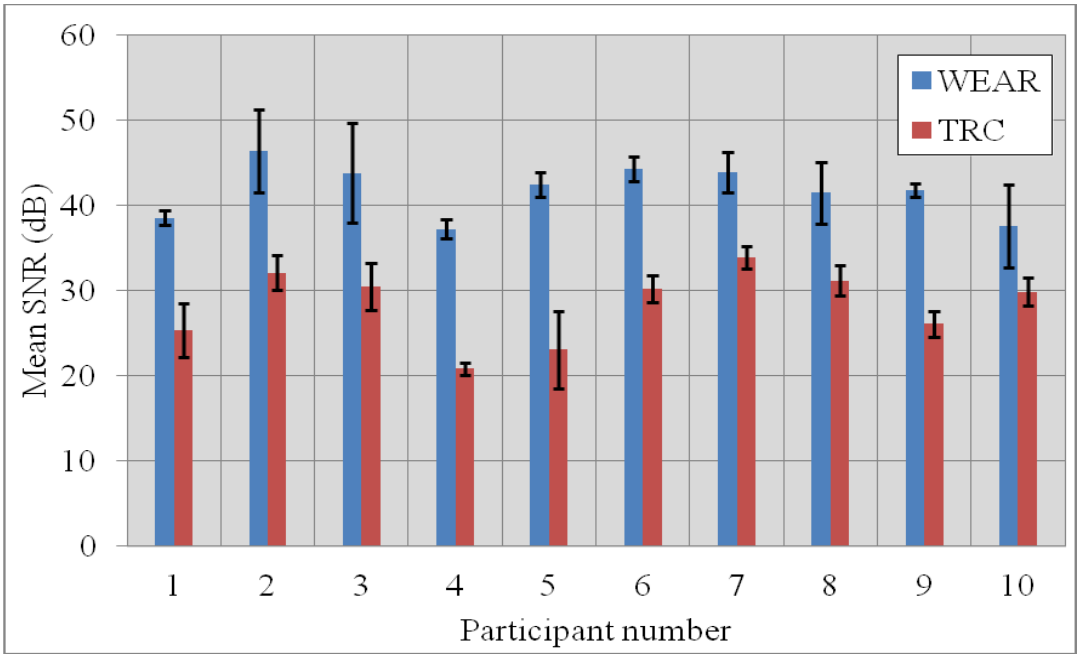

Figure 5.5: Mean SNR, averaged across 10 contractions and 3 trials (1 standard deviation error bars) per system, for all 10 participants.

5.3.2.3. PSD Comparison

PSDs were calculated and plotted as in section 4.5.2.3 (Figure 5.6). Correlation coefficients were calculated for each participant to derive intra-system variability within the three WEAR trials and within the three TRC system trials. Correlation coefficients were also calculated for each participant to compare the outcomes on an inter-system basis (i.e., comparing the variability between WEAR and TRC system trials). The WEAR prototype mean correlation coefficient across all 10 participants was 0.987 +/- 0.008 (where 1.00 is an exact match), indicating that the spectral content was consistent. The mean correlation coefficient across all 10 participants with the TRC system (0.985 +/- 0.005) showed that spectral content was almost as consistent as the WEAR prototype.

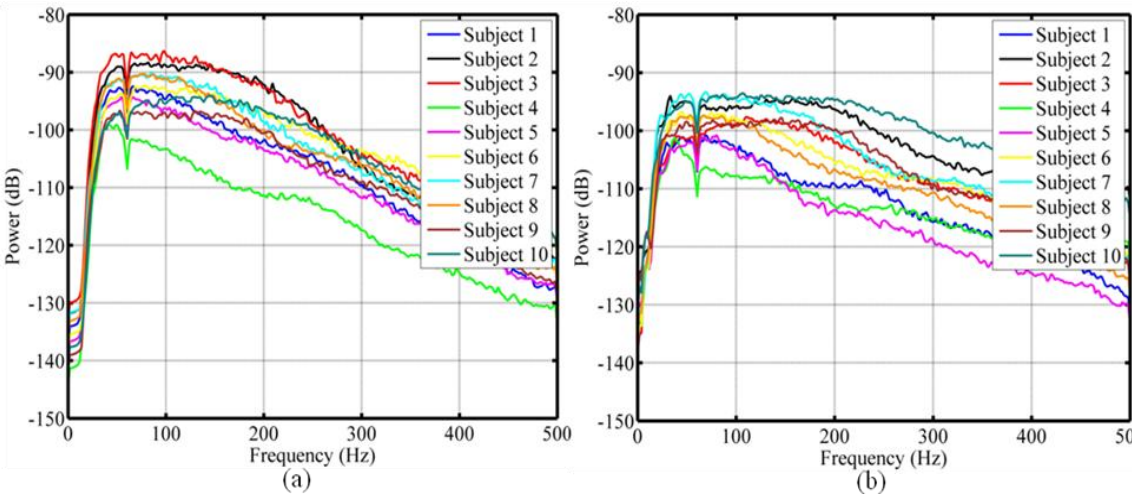

Figure 5.6: (a) WEAR and (b) TRC system PSD averaged across 10 contractions and 3 trials per system for all 10 participants.

Comparing PSD curves from WEAR trials to those from TRC system trials showed more variability (0.949 +/- 0.018) than in the intra-system comparisons.

The maximum power of the PSD curves followed the same patterns seen in the RMS results (every subject had a higher maximum PSD power with WEAR except for participant 10), with WEAR showing higher mean maximum power across the 10 participants (-92.32 dB +/- 3.83) than the TRC system (-97.30 dB +/- 3.02). The effects of the 60 Hz notch filters can be seen in each curve (Figure 5.6).

5.3.3. Task #3: Walking

For walking trials, data segmentation was performed as in section 4.5.3.1.

5.3.3.1. SS Comparison

The SS for each action was calculated as in section 4.5.3.2. Analysis of the sit-to-stand action boxplots (Figure 5.7) showed only small differences in SS IQR and median values between systems (12.51% and 11.52%, respectively averaged across all

participants, Table 5.4). There were only five total outliers per system across all participants. T-tests for SS IQR, median value, and number of outliers showed no statistically significant differences ($p = 0.598$, $p = 0.43$, and $p = 1.00$, respectively, Table 5.5).

Data extracted from stand-to-sit boxplots (Figure 5.7, Table 5.4) once again showed similar mean SS IQR values (10.92% difference), although the medians differed more that with the sit-to-stand action (23.66% difference). There were only three total outliers for the WEAR prototype and one outlier for the TRC system. As with the sit-to-stand action, stand-to-sit comparisons did not show statistical significance SS IQR, median value, and number of outliers ($p = 0.554$, $p = 0.174$, and $p = 0.168$, respectively, Table 5.5).

Boxplots for the loading response action (Figure 5.8) showed higher differences in SS IQR and median values between systems than the sit-to-stand and stand-to-sit actions (28.43% and 33.18%, respectively averaged across all participants, Table 5.4). The loading response action also saw a large increase in outliers, with 42 and 51 for the WEAR prototype and TRC system, respectively, although t-tests showed that comparison of number of outliers was not statistically significant ($p = 0.575$). Loading response SS IQR and median comparisons were statistically significant ($p = 0.045$ and $p = 0.003$, respectively).

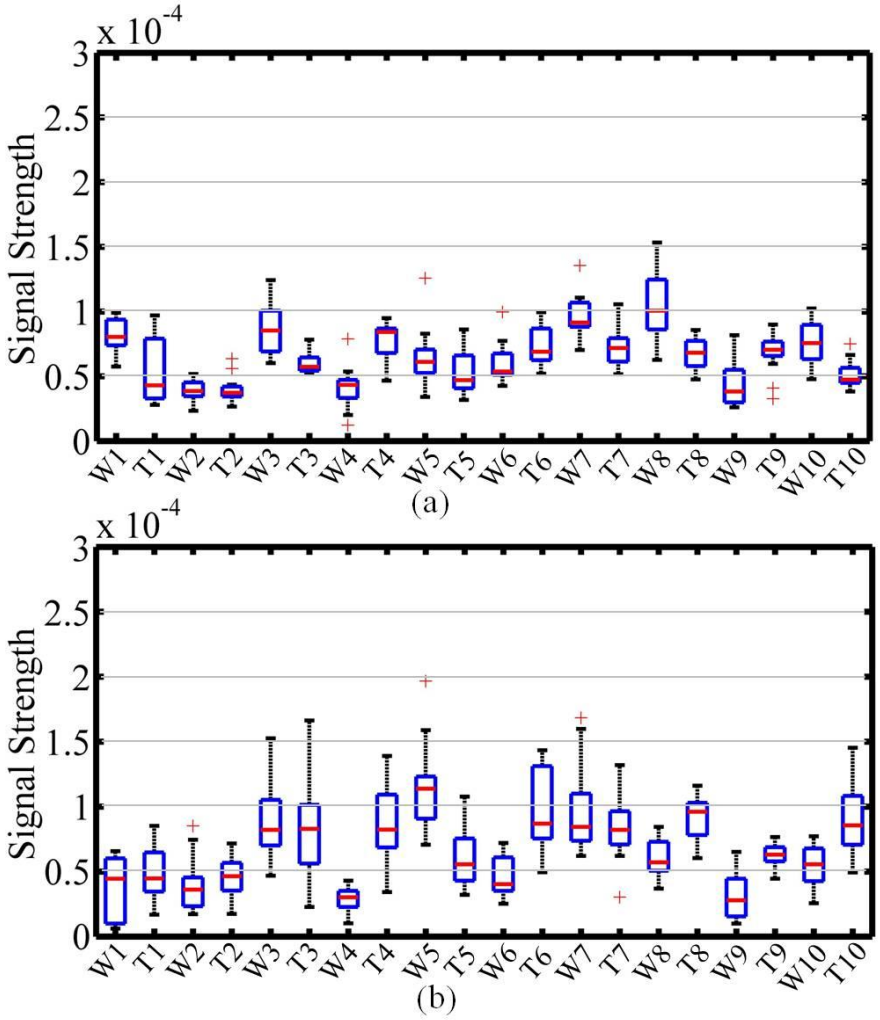

Figure 5.7: (a) Sit-to-stand and (b) stand-to-sit signal strength comparisons of both systems for all 10 subjects.

Swing phase boxplots (Figure 5.8) averaged across all the participants provided similar SS IQR values between systems, but the highest difference in means than previous actions (9.86% and 40.24%, Table 5.4). The swing phase action had the most total outliers of all actions (77 and 86 for the WEAR prototype and TRC system, respectively). While t-tests for SS IQR and number of outliers showed that the

comparisons were not statistically significant (p = 0.381 and p = 0.384, respectively), median comparison was statistically significant (p = 0.002, Table 5.5).

Table 5.4: Walking SS for all four actions and both systems across all participants**.**

	WEAR	**TRC**
Sit-to-stand		
IQR (x 10-4)	0.219 +/- 0.084	0.193 +/- 0.112
Median (x 10-4)	0.667 +/- 0.229	0.595 +/- 0.154
# of outliers	0.500 +/- 0.710	0.500 +/- 0.850
Stand-to-sit		
IQR (x 10-4)	0.291 +/- 0.102	0.325 +/- 0.129
Median (x 10-4)	0.571 +/- 0.280	0.724 +/- 0.185
# of outliers	0.300 +/- 0.480	0.100 +/- 0.320
Loading response		
IQR (x 10-4)	0.322 +/- 0.148	0.242 +/- 0.104
Median (x 10-4)	1.035 +/- 0.278	0.740 +/- 0.210
# of outliers	4.20 +/- 2.530	5.100 +/- 3.900
Swing phase		
IQR (x 10-4)	0.149 +/- 0.049	0.135 +/- 0.059
Median (x 10-4)	0.632 +/- 0.176	0.420 +/- 0.098
# of outliers	7.700 +/- 5.060	8.600 +/- 5.340

5.4. Discussion

5.4.1. Task #1: Resting

As reported in section 4.6.1.1, differences in noise RMS (section 5.3.1) between systems could be attributed to inaccurate gain settings and higher input impedance in the

TRC system. Based on results from pilot validation and participant testing, the WEAR prototype seems to have a generally lower RMS noise level than the TRC system.

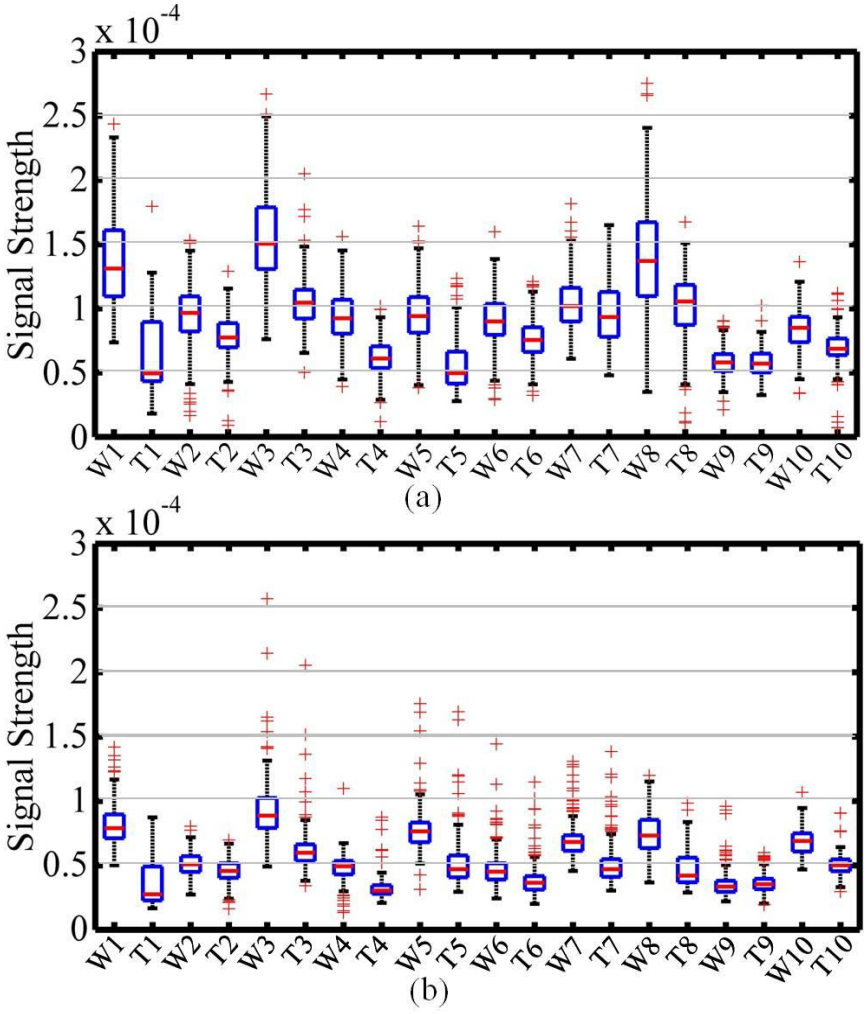

Figure 5.8: (a) Loading response and (b) swing phase signal strength comparisons of both systems for all 10 subjects.

Table 5.5: Walking SS statistics for all four actions and both systems across all participants.

	% Difference	p-value	Statistical power	Ideal sample size
Sit-to-stand				
IQR	12.51%	0.598	9%	343
Median	11.52%	0.433	13.10%	106
# of outliers	0.00%	1.000	5%	1.33×10^{19}
Stand-to-sit				
IQR	10.92%	0.554	10%	200
Median	23.66%	0.174	30.20%	23
# of outliers	100.00%	0.168	19.50%	51
Loading response				
IQR	28.43%	0.045	28.80%	24
Median	33.18%	0.003	76.40%	1
# of outliers	19.35%	0.575	9.40%	228
Swing phase				
IQR	9.86%	0.381	8.90%	257
Median	40.24%	0.002	91.40%	0
# of outliers	11.04%	0.384	6.70%	636

As mentioned in section 5.3.1, five resting trials produced abnormal data, which could be classified in two distinct types. The first abnormal data type was seen with participant 1, trial 1 and participant 6, trial 1. The second abnormal data type was seen with participant 4, trials 2 and 3 and participant 5, trial 1 (Figure 5.3).

The abnormal data seen with participants 1 and 6 could have resulted from the participants maintaining a small, but constant TA activation. The signals showed patterns consistent with isometric contractions, but with much lower RMS voltages (0.042 mV and 0.018 mV for participant 1, trial 1 and participant 6, trial1, respectively). The abnormalities were not recognized in post-trial data evaluation and were only discovered

at a later date. To handle such issues in the future, a wireless connection which could enable real-time viewing of recorded sEMG data would allow users to see whether participants (or patients) are performing tasks as instructed.

Abnormal resting data from participants 4 and 5 were very different than those from participants 1 and 6. Abnormal data from participants 4 and 5 were corruptions due to low battery power. The low battery power was discovered prior to the start of the walking task during trial 1 of participant 5. There was no designated battery power indicator on the prototype WEAR system, but text on the LCD screen (visible on the Explorer 16 in Figure 4.3a) was dim and the recording process was ending prior to the stop button being pressed. A fresh set of batteries fixed the LCD screen and data recording issues. Data recorded during the other tasks for participants 4 (trial 2 and 3) and 5 (trial 1) did not show any corruption. Once again, the abnormalities were not recognized in post-trial data evaluation and were only discovered at a later date. In order to avoid losing data files due to low batteries, a battery power indicator could be added in future design iterations.

5.4.2. Task #2: Isometric and Isotonic Contractions

5.4.2.1. RMS Comparison

As expected, RMS values were generally higher in the WEAR trials than in the TRC trials. Only participant 10 had a higher mean RMS for TRC trials with a difference of 23.02%. As previously discussed, these differences can be attributed to the inaccurate gain settings and differences in amplifier input impedances between the WEAR prototype and TRC system. The low p-value from the t-test ($p = 0.0114$) showed statistical

significance to disprove the null hypothesis that the RMS mean was the same for both systems.

5.4.2.2. SNR Comparison

The WEAR prototype exhibited less noise and higher signal RMS values, resulting in higher SNR values than the TRC system. Similar to the RMS values, the differences in SNR may be explained by inaccurate gain settings and differences in amplifier input impedances. The low p-value from the t-test ($p < 0.0001$) showed a statistical significance to disprove the null hypothesis that the SNR mean was the same for both systems. Since SNR has been shown to be highly indicative of sEMG signal fidelity [61], the outcomes indicate that the WEAR prototype was highly proficient in acquiring good quality sEMG signals relative to the TRC system, which is a proven and accepted conventional sEMG acquisition system.

5.4.2.3. PSD Comparison

Differences in intra-system mean correlation coefficients across the 10 participants between the WEAR prototype and TRC system were nominal. Although slightly larger than the intra-system variabilities, the inter-system variability still showed a high degree of correlation between the two systems. PSD comparisons showed that the WEAR prototype produced comparable results to the TRC system in terms of spectral content of the sEMG signals. Differences in maximum powers could have been due to inaccurate gain settings and differences in amplifier input impedances.

5.4.3. Task #3: Walking

5.4.3.1. SS Comparison

Except for loading response and swing phase median tests, which had low p-values and high statistical power, all the other tests had low statistical power, showing a low probability of rejecting the null hypothesis (WEAR and TRC system values are the same) when a specific alternative was true (e.g., WEAR IQR for sit-to-stand is lower than TRC system IQR for sit-to-stand) (Table 5.4). Given that neither system had consistent IQR values nor lower mean IQRs compared to the other system across all actions, it is likely that variability of results had as much to do inter-participant locomotive variations as it did with inter-system technical differences. As such, it would probably not be worth the time required to obtain data from the calculated ideal sample sizes for each action listed in Table 5.5. What can be derived from this analysis in practical terms, is that the WEAR prototype is as likely to provide acceptable representations of muscle contractions throughout motion as the TRC system.

5.4.4. Secondary Outcomes

Through regular use of the WEAR prototype operational observations were discovered which either validated user requirements (Chapter 3), or revealed new design requirements:

1. Remote operation is required since system control located on the device results in time consuming and awkward delays.
2. A battery power indicator is required to ensure that the system is recharged in a timely manner, thus avoiding losing power during use.

3. A real-time view of sEMG activity (i.e., representative information rather than raw data) is required to ensure that system is functioning correctly to avoid having to repeat full data collection procedures.
4. The electrode mount, as designed is effective, in that it does not allow the electrode array to shift during operation, even when perspiration is present.
5. Despite the advantages of the chosen materials, the mount does induce perspiration in a short period, thus a breathable material could be investigated.
6. The approximate maximum calf circumference of the electrode mount was reached at 43cm, thus a longer mount and/or multiple size options for the hook-and-loop straps are required to satisfy larger calf sizes.

5.5. Conclusion

Comparative analysis of the WEAR prototype and TRC system across 10 participants showed statistically significant higher levels of SNR in the WEAR prototype, suggesting higher signal fidelity. Statistical analysis of the walking task data proved inconclusive, except to say that neither system showed higher degrees of consistency. Average mean IQRs across all four walking actions differed by only 9.16%. Based on the statistical analysis of the isometric and isotonic contractions and walking actions, the WEAR prototype is a viable alternative to the TRC system for clinical sEMG signal acquisition.

6. Conclusions and Future Work

6.1. Conclusions

Following a UCD process to conduct user research with a group of PTs yielded a comprehensive list of design requirements (functional and usability) for a wearable sEMG acquisition system (Chapter 3). Additionally, the user research validated the inclusion of the electrode array as an initial design concept. The array was originally motivated by two assumptions, both of which were validated: 1) PTs did not have a lot of time to accommodate for conventional electrode placement and 2) PTs did not have detailed training or education in sEMG methods. Implementing the design requirements into WEAR development could result in high levels of acceptance by physiotherapists and other professionals whose rolls routinely involve measuring human performance (i.e., occupational therapists, high-performance athletic trainers, human kinetics researchers).

The WEAR functional prototype performed well in validation and participant testing. The electrode mount with an array of dry electrodes proved to be a viable alternative to conventionally used wet electrodes placed by anatomical measurements. The compact, low power, integrated AFE (ADS1298) also performed favorably compared to two conventional sEMG acquisition systems using discreet components. As a proof-of-concept, the WEAR prototype successfully confirmed that a fully developed WEAR system could perform high-quality sEMG acquisition.

The WEAR prototype, while wearable, was bulky due to the use of development boards. As a guideline, a realistic size for the WEAR system electronics would be a unit smaller than current Smartphones (i.e., less than 120mm high x 65mm wide x 15mm

deep). Since system operation should be handled through a wireless application, only a small display would be required to provide system awareness (i.e., battery power indication, mode of operation, error state, etc.). A desired price range for the WEAR system, as indicated by the PTs (section 3.3.2.5) including the physical system and operational software tool suite would be $200-$500. Despite PT expectations of a higher initial price (~$1000), the $200-$500 range should be attainable given the low cost of the COTS components. To achieve these goals, further research and development activities should be based on design requirements captured in user-research and experience using the WEAR prototype in participant testing.

6.2. Recommendations for Future Work

Recommendations for future work can be grouped into four categories: design process, physical system design, automation of signal analysis/interpretation, and user experience/interface design. Although as many of the requirements from chapter 3 should be incorporated as possible, the following are recommendations for the next iteration of WEAR system development.

6.2.1. Design Process

Chapter 3 described user research performed following a UCD process. PTs participating in the user research were cooperative and enthusiastic not only with the idea of the WEAR system, but also of the participatory process. As described in section 2.5, UCD is not exclusively employed at the beginning of system design, but is a process used throughout the design lifecycle. We highly recommend continuing with the UCD process as system design proceeds. Specifically, furthering the user research by incorporating

end-users into system testing of the next design iteration (i.e., usability testing) could prove highly beneficial.

6.2.2. Physical System Design

Two major steps for the next design iteration are to develop a custom printed circuit board and to select a DMA enabled MPU. Incorporating the ADS1298, microprocessor, and other electronic components into a single, compact unit would be more physically robust, portable, and wearable than the current WEAR prototype. A DMA enabled MPU would allow for full 8-channel operation of the ADS1298 with a sampling rate of 2000 samples per second and thus a bandwidth of 1000Hz.

A lighter, rechargeable power supply would also need to be incorporated with the electronics in a custom shell. A battery power indicator would also be needed to help mitigate data corruption issues (section 5.3.1). To satisfy PT needs and provide better insight into system function, an indicator of operating status (i.e., a flashing LED when acquiring data and/or small display) and a wireless transmitter, so that data could be viewed in real-time, should also be implemented into the next design iteration.

Research into alternative materials for the electrode mount should be conducted to find a breathable material. Although the prototype mount performed well in reducing motion artifact by holding the electrode array stationary during motion and was easy to clean, profuse sweating under the mount was common even in short-term use. Sizing options for the mount should also be investigated. Size options could be implemented through different mounts or different strap lengths to hold the mount on the leg.

6.2.3. Automation of Signal Analysis/Interpretation

In its current state, the WEAR prototype uses a manual, multi-step process to take raw data from a memory card and perform signal conditioning operations in Matlab. Since the intent is for the system to display output in real-time based on an optimal electrode pair, research is required to determine whether or not signal RMS is the best indicator of electrode performance. Algorithms must also be developed to perform signal conditioning (i.e., scaling to volts, mean removal, noise/motion filtering) either on the MPU, or in the wireless application.

Another venue for further research would be in the implementation of a multi-array electrode mount for analysis of multiple muscles (i.e., TA, soleus, and gastrocnemius). The challenges involved in such a development not only include the physical spacing of the arrays on the mount and incorporating multiple ADS1298 AFEs, but in analyzing the data retrieved from the electrodes. Research would be required to discover methods of ensuring that crosstalk from neighboring muscles would not affect array operation, especially when dealing with closely spaced muscles.

6.2.4. User Experience/Interface Design

Based on PT feedback, real-time results display and biofeedback applications should be developed. Given PTs' lack of EMG knowledge, WEAR results must be presented in a manner that is understandable to physiotherapists, either real-time or post-assessment. User research revealed that moving bars, color meters, or numerical indicators could be implemented as representations of muscle activity for assessment purposes. In addition to patient assessment, a game-based biofeedback application should be developed to give the WEAR system more breadth of applicability in the rehabilitation process.

In terms of system control, remote operation is also an important step. In participant testing walking to the participant to start and stop operation was time consuming and awkward. PTs indicated that a wireless application (i.e., for Smartphone and/or tablet PC) for system operation and feedback would be desirable. Since the WEAR system is not confined to a clinic or lab, a wireless app could provide physiotherapists with real-time results in any setting.

It is important that user experience/interface development be concurrent with physical system development so that they can undergo usability testing as a package. Developing WEAR as a complete system can result in a cohesive unit that can offer the physiotherapy industry an all-in-on, simple to use, wearable, portable muscle function analysis solution.

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Appendix A

User Research Background Questionnaire

Participant #: _____

Background Questionnaire

EMG Technology Study

Name		Date (mm/dd/yy)	
Job title		Place of work	
Years in current role		Years in healthcare industry	
Current patient populations			

Please rate your comfort with using new technology

1	2	3	4	5
Uncomfortable				Very comfortable

Do you use EMG in your practice? **Yes** **No**

If yes:

How many years? _____

Which patient populations? _____

Appendix B

User Research Interview Questions

1. Please describe your role at work.
2. Give me an overview of a typical work day.
    a. How much time per client on average?
    b. Time outside of direct patient contact?
    c. How many clients in a typical day?
    d. Describe your general client populations.
3. What is the process when a new client comes in complaining of leg problems related to mobility? Please use as much detail as possible from beginning to end, including how long it takes.
4. What tools/methods do you find best help you with leg-related diagnoses?
5. How do the tools and methods change throughout the rehab process as you attempt to assess client improvement?
6. What would you say is the most frustrating part of assessing a client's condition?
7. Do you prefer tests that provide qualitative outcomes, quantitative outcomes, or a mix of the two and why?
8. Is there any other information you would like to be able to get about your clients when dealing with leg or gait issues?

9. Do you know of any additional tools or techniques that might help in assessment and rehab of leg problems?
10. Have you ever received training in surface electromyography (sEMG) testing?
11. What do you know about surface electromyography, or EMG?
12. If you had access to the relative strength and timing of your client's muscle contractions, how do you think it would affect your assessment process and rehab plan creation?
13. What is the maximum amount of time that you would spend on measuring muscle function during a patient encounter?
14. What proportion of your practice would benefit from muscle activity analysis? What client groups does this include?

Appendix C

Responses to Interview Questions

Common responses to question 1:

TOHRC/NG Response	Frequency	PVT Response	Frequency
"I am a physiotherapist"	4	"I am a physiotherapist"	2
Patient population: Out patient	4	Patient population: Orthopedic/MSK	4
Patient population: Neuro	3	Patient population: Post-op	2
Patient population: Complex orthopedic	2	Patient population: Athletic/active	2
Patient Population: Chronic pain	2	Patient population: Age range	2
Modality: Technology	2	Modality: Questionnaires/patient feedback	2
		Modality: Functional motion assessment	2

Common responses to question 2: See Table 3.2.

Common responses to question 3:

Response	TOHRC/NG Frequency	PVT Frequency	Overall Frequency
Conduct subjective interview/patient history	3	4	7
Strength tests	3	4	7
Range of motion	3	4	7
observational gait analysis/functional motion	3	3	6
Set functional goals	3	2	5
Balance	3	1	4
Create general overview/treatment plan	3	1	4
Special tests (ligament stability, neurodynamic, etc.)	1	3	4
Observe posture	1	2	3

1 to 1.5 hours long	1	2	3
Get patient to locate the pain	1	1	2
Reflexes	1	1	2
Observational cues (how patient sits, talks, other flags)	1	1	2

Common responses to question 4:

Response	**TOHRC/NG Frequency**	**PVT Frequency**	**Overall Frequency**
Manual muscle tests	3	3	6
ROM	1	3	4
Goniometer	2	2	4
Dynamometer/force measurement	3	1	4
Pain provocation	1	1	2
Gait/motor patterning	1	1	2
Subjective history	1	1	2

Common responses to question 5:

Tools and methods don't necessarily change, but their implementations are adapted to patients' improvements (i.e., more weight, more complex motions, more self administered/unsupervised exercise, etc.).

Common responses to question 6:

Response	**TOHRC/NG Frequency**	**PVT Frequency**	**Overall Frequency**
Lack of precision/objective measures	2	3	5
Communication (w/patient, w/caregivers)	2	1	3
Time constraints	2	1	3
External/psychological factors	1	2	3

Common responses to question 7:

Response	TOHRC/NG Frequency	PVT Frequency	Overall Frequency
Mix	4	2	6
Quantitative for measure of improvements	1	2	3
Patients can see hard #s with quantitative	2	2	3
Qualitative for quality of life/patient judge of improvement (participation)	1	1	2
Psychological aspects of rehab (#'s can also hurt motivation)	1	1	2

Common responses to question 8:

Response	TOHRC/NG Frequency	PVT Frequency	Overall Frequency
Objective muscle activation	3	4	7
Bilateral measures	0	2	2
Compare film to EMG output	0	2	2

Common responses to question 9:

Response	TOHRC/NG Frequency	PVT Frequency	Overall Frequency
EMG	2	2	4
Motion capture/analysis (Vicon, Dartfish)	0	3	3
Biofeedback	1	1	2
Virtual reality	1	1	2
Force plates/mats	1	1	2
Advanced manual therapy	0	2	2

Common responses to question 10:

Response	TOHRC/NG Frequency	PVT Frequency	Overall Frequency
No	2	3	5
Small amount in school	1	1	2
Employment at NG	1	1	2

Common responses to question 11:

Response	TOHRC/NG Frequency	PVT Frequency	Overall Frequency
None to very little	1	2	3
Observe muscle activation	2	1	3
Used more for research than clinical applications	0	2	2

Common responses to question 12:

Response	TOHRC/NG Frequency	PVT Frequency	Overall Frequency
Would change rehab plan	4	3	7
Teaching tool	2	2	4
Corrections in functional motion (balance/strength/weight shifting/bearing/timing)	3	0	3
Plan based on quantitative goals	0	2	2
Would have to research implications	1	1	2

Common responses to question 13: See Table 3.2.

Common responses to question 14: See Table 3.4.

Appendix D

Focus Group Spreadsheets

Focus group discussion topic #1 spreadsheet:

TECHNOLOGICAL		VS	OBSERVATIONAL	
Pros	Cons		Pros	Cons

Focus group discussion topic #2 spreadsheet:

Calibration:				
Application				
Interaction				
Feedback				
Time				
Assessment:				
Interaction				
Feedback				
Type of Tests				
Frequency of Reassessment				
Time				
Results:				
Wireless vs Physical				
Realtime vs Offline				
Images/Charts/Numbers				
Decision Support System				
Reports				
Time				

Focus group discussion topic #3 spreadsheet:

Patient use:				
When				
Patient population				
Game based vs functional				
Standalone vs GUI				
Take home vs clinic				
Time				

Physiotherapist use:				
Custom vs Generic programs				
Custom vs Generic thresholds				
Decision Support System				
Setup time				

Focus group extras spreadsheet:

Appearance:			
Cleaning:			
Cost:			

Appendix E

Focus Group Raw Data

Discussion topic #1: Pros and cons of technological gait analysis.

Pros	Cons
Use with performance athletes	Not enough info
Under 10 minutes ok	Can feel muscle being activated
Can compare with video	Too long, time consuming
Can see improvements over time (small improvements)	Referral needed
Neuro patients (longer term patients)	3 weeks
Can average out circumstantial issues	Billing setup time, treatment time, equipment costs
Could pick up on neurogenic fatigue better	Can't charge more to WSIB for extra information
Could generate income	Very difficult to get normalization of results (mechanics vary from person to person)
Private insurers could pay more	Variability between patients
Can prove incremental improvement to insurers	Neuro - hypertenisity/spasm could be picked up (noise/co-contractions)
Better idea of sequencing/amplitude	Learning curve/time - new therapists need pre-learning
Get a real measure when analyzed, objectivity	Touchiness of equipment (i.e. electrode placement, equipment failure)
Feedback potential to client unparalleled	Get through the white coat syndrome (difficult to get them to produce a normal gait when hooked up - psychological)
Biofeedback - communications tool (they can see what they're doing/learning/motivation)	Older clients might be more "freaked out"
Motivation - Concrete way to show Improvement (obvious)	If there is no improvement, objective Measure can be de-motivating (still have to give some positive feedback)
Younger people being raised on technology	

Discussion topic #1: Pros and cons of observational gait analysis.

Pros	Cons
Can see things observationally	Personal biases, Fluctuates - After taking a course everyone has that issue (bias)
Free, less expensive	Circumstantial -patient may be having a bad day
Simple	Less objective - even if accurate
Quick	Can't necessarily correlate to other therapists
Less clutter	Takes a lot of experience
A well known clinician can be more motivating without technology	

Discussion topic #2: sEMG calibration.

Application	Interaction	Feedback	Time
One size fits all if it works	Simple	No guessing	5 min or under
Stay on when sweating, running	Adjustment based on muscle	Obvious signal (green vs red light)	If 10 minutes, would use for a while, but then drop it
Infection control issues (disposable, or easily cleaned)	1-2 button	Beep	Under 5 minutes
Rules for cleanliness change between sites (hospitals more strict)	If too much work, won't be used	Green light/red light (working/not working)	2 minutes
Retractable positional electrodes for one unit	Potentially different calibration options	Tech support #	Weighing whether to do things observationally or use the machine
Three sizes could work as well, based on limb size	One button	Wants to see raw data/charts - trust of system an issue	Would not use a slow machine
If it could be accurate for a small size and use the same for all limbs	Flow through touch screen		If it takes a long time, can eat into time needed to explain homecare exercises
Hygiene - hard to	Should not have		5 minutes for MVA

clean a sleeve	to write in parameters		for objective data for insurance companies - worth it
Not porous (easy to swab with alcohol	Scroll menu (mode button, set button)		Every 2 weeks or every session
Little skin contact as possible	Simple/basic display		Biofeedback could be used a lot more - has to be shorter
Hospital regulations			Should be the same time as any other system they currently use - unobtrusive in practice
Dedicated sleeve per client (must be LOW cost)			

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Discussion topic #2: sEMG assessment.

Interaction	**Feedback**	**Type of Tests**	**Frequency of Reassessment**	**Time**
Remote (could record a specific segment, patient would not know if they're being recorded, people change if they're being monitored)	What is going on at the time (light go as the muscle under test is firing)	At the beginning would be something additional	Depends if it's 5 minute cal	Depends on how much detail you need (patient parking, commitments , etc)
Data recording needs to be recorded and then analyzed	As treatment (beep when it fires enough to lift foot: biofeedback)	Still could miss something	how long to interpret results (would only use on initial and final if too long)	15 minutes, or longer if really difficult and WEAR can show the way
single start/stop button	No indicators - could change patient behavior	At the beginning would do both (adding	once/week	5 minutes

		proprioceptive input)		
patients in outpatient clinic could press it themselves	See a waveform	If after time, they're identical, then would do one	every three sessions	
not a problem to start and move away	simple data capture signal might save bad data	Would do both (see how the move first and then apply the system)	based on physiology	
perfect world, wireless to iPad	graph/bars for motor recruitment	tests in addition: endurance testing (i.e. pain after 5km - dorsiflexion, can measure to see fatigue point compensations	slow progressing patients - every couple of weeks	
raw data could be stored unidentified to ensure privacy	maybe a light flashing as muscle contracts	could experiment if not too busy	could use it more frequently to see difference between facilitation/gain	

Discussion topic #2: sEMG assessment results.

Wireless vs. Physical	**Real-time vs. Offline**	**Images/Charts/ Numbers**	**Decision Support System**	**Reports**	**Time**
Memory card	Offline	Would be nice to have comparison	If confident that it works (double check, then would rely more)	Yes - where you were, where you are, % change - table/graph	should be fairly obvious, less than 5 minutes
Hospital	If can do both	Easily	In teaching	gait pattern	raw EMG

would not allow wireless transmission with patient information	would be good (marketability)	understandable to show patient, more detailed for PT	centre would be very useful	to show where problem lies (good for neurological patients)	tough - should be processed
Saving and wireless (direct to laptop)	Real-time could be a light (good data), but could look at all data offline (more detail)	#'s better than raw	no	Both email and printout	similar to gait assessment charts (people familiar, so it would be faster to analyze)
independent/ freestanding		Clear numbers (scaled width/height - correlate data to something)	flexible - programmable based on current research	customizable	1 minute
		superimposed progressive results	trust would be an issue		depends what you're looking for
		waves are fine for saved results, but hard to put different signals on one graph if they are not normalized			options for basic or more advanced results

Discussion topic #3: Patient use of biofeedback.

When	Patient population	Game based vs. functional	Standalone vs. GUI	Take home vs. clinic	Time
when there's recovery (arm starts moving, flaccid to tone, within first year - standard for stroke)	brachialplexus, lumbarplexus, sacralplexus	Game - endorphin release	Depends on patient, but some could be good with beeps, others would get bored	Wheelchair bound, cannot get to rehab often	If they don't have to be supervised, no problem for time
would not use after 1 year (discharge in hospital)	no restriction for age	score	myotrack has light and beep and patients hate it - annoying for therapist and patient	need intensity and frequent practice (nerve injuries)	can play against them for competitive
would not put energy into it if no change after a year	would be hard with TBI	game sounds	Screen needed for game based (within the clinic)	good for patients who are rigid (reactions cause muscular contractions - upper traps for example under stress)	can walk away if data printout
Earlier before start to compensate with other muscles	As long as they have attention span	competitive people like scores/seeing improvements	standalone for at home practice (beep every time	awareness of involuntary co-contractions	if effective, could replace some of what we're

			they hit target)		doing
start right Away if effective	No good if cognitive problems	Function based activities very important	difficult to program a standalone - less effective without display	biggest gains made at home by patients who are truly self aware	going to change education
early rehab - mobilizations	brain injuries/language barriers	Both would be best (options)	App - interface	Compliance - evidence that they did their exercise	
	can replace other activities depending on client	Zone in for some patients/specific muscle then shift to functional		Helps for PTs to understand how long/frequent certain exercises required	
	some not appropriate	All features important		Cost	
		once skill is acquired, nothing drives it like a game		simplicity of control for take home	

Discussion topic #3: PT use of biofeedback.

Custom vs. Generic programs	**Custom vs. Generic thresholds**	**Decision Support System**	**Setup time**
A few generic good programs	Custom - varies between patients	Yes for ease of use, students, new people, but can turn it off	5 minutes max for whole scenario, not just EMG
Record custom and then reuse	Need to set custom thresholds	important to have a guide through programming depending on complexity of system (If straightforward,	10 too much

		need less help)	
diagnosis based (certain could use generic)	monitored by data/numbers		1 minute if patient waiting
Generic more			30 seconds during appointment
Custom with simplicity			Wouldn't be able to be the day before very often (work late enough as it is)
Generic programs would be hard to get proper functions			Recall their schedule in the morning and only focus on one patient at a time
menu based programming (i.e. function: up/down stairs, up from chair)			as fast as any other modality
			too many features not good
			Must be very simple
			App based could make it easier
			Not currently using a lot of PC/App based applications

Extras:

Appearance	**Cleaning**	**Cost**
nothing scary	problem in hospital setting, easier in clinic	must be versatile and sell the features to justify cost
looks like EMS/TENS	soap and water	$200-$500
little box, some wires	Alcohol	$99
big boxes are scary	drying towel	realistically, would be $1000, but less chance of them buying in private

Appendix F

User Research Information and Consent Form

Information Sheet and Consent Form for Physiotherapists

Surface EMG Device Study

Principal Investigator: Adam Freed 613-737-7350 ext. 75958
Site Investigator: Ed Lemaire 613-737-8899 ext. 75592

Sponsor: NSERC

Introduction

You are being asked to participate in a research project to assess the needs of physiotherapists for assessing and treating leg muscular deficiencies. This research will help us better target and design a new surface EMG device to best suit physiotherapists (our target end-users). We will use the results of this research to ensure that the new device will be easy to use and readily accepted. The device is being developed by the project research team from The Ottawa Hospital Rehab Centre and Carleton University.

Please read this Information Sheet and Consent Form carefully and ask as many questions as you like before choosing whether to participate in this research study. You can discuss this decision with your family, friends and health providers.

Background, Purpose and Design of the Study

User centred-design (UCD) has been proven to improve productivity, reduce operator errors, reduce the amount of training and support required and improve acceptance of a product or system by the users. Our project team has developed an idea for improving muscle activity analysis. Having identified physiotherapists as our primary end-users of this system, it is important to include knowledge from actively practicing physiotherapists into the design team. At this stage, we will be conducting interviews and group-brainstorming sessions to identify the needs for leg assessments and potential technology-based solutions.

Study Procedures

Interviews will be split into two sections: a one hour, one-on-one exploratory interview at your workplace and a one hour interactive discussion forum with all participants, held at The Ottawa Hospital Rehabilitation Centre.

These sessions will be scheduled to suit your availability.

Audio and video of the interview and forum will be recorded to ensure accuracy. We will ask your permission to use the audio and video recordings in future presentations or for publication purposes.

Possible Risks

There are no possible risks to you during these sessions.

Benefits of the Study

Although there is no direct benefit to you as a participant of this study, your participation may help us develop new technology better suited to meet the needs of physiotherapists.

Withdrawal from the Study

Since participation is on a volunteer basis, you are not obligated to participate. If you decide to participate, you will be free to withdraw from the study at any time without suffering any negative consequences and without it affecting any of your present or future relationships with Carleton University, The Ottawa Hospital, or TOHRC. If you decide to withdraw, you may also choose to withdraw the data and information from the study which relates to you.

You also have the right to check your study records and request changes if the information is not correct.

Study Costs

You will not be paid to participate in this research study. However, you will be reimbursed in cash for parking costs at TOHRC.

Confidentiality

Your confidentiality will be maintained at all times, and only the research team will keep a record of your name. Your data will be stored on a password protected computer. Your information will be accessed only by the research team (investigators and research assistants from TOHRC and Carleton University). The research team will not disclose the contents of your study records to any party.

The results of the study may be used for medical and scientific publications. The Ottawa Hospital Research Ethics Board, the Ottawa Hospital Research Institute and the Carleton University Research Office may audit the study and study materials at any time to ensure

compliance with approved research processes. At no time will your identity be disclosed. All study data will be identified with a study number.

The link between your name and the independent study number will only be accessible by research team. The link and study files will be stored separately and securely. Both files will be kept for a period of 15 years after the study has been completed. All paper records will be stored in a locked file and/or office. All electronic records will be stored on a hospital server and protected by a user password, again only accessible by the research team. At the end of the retention period, all paper records will be disposed of in confidential waste or shredded, and all electronic records will be deleted.

Voluntary Participation

Your participation in this study is voluntary. If you choose not to participate, your decision will not affect the care you receive at TOHRC or any relationship with Carleton University at this time, or in the future. You will not have any penalty or loss of benefits to which you are otherwise entitled to.

New Information About the Study

You will be told of any new findings during the study that may affect your willingness to continue to participate in this study. You may be asked to sign a new consent form.

Questions about the Study

If you have any questions about this study, or if you feel that you have experienced a research-related injury, please contact Adam Freed at 613-737-7350 ext. 75958, Dr. Edward Lemaire at 613-737-8899 ext.75592, Dr. Adrian Chan at 613-520-2600 ext 1535, or Dr. Avi Parush at 613-520-2600 ext 6062.

The Ottawa Hospital Research Ethics Board (OHREB) and the Carleton University Research Office (CURO) have reviewed and approved this protocol. The OHREB considers the ethical aspects of all research studies involving human subjects at The Ottawa Hospital. If you have any questions about your rights as a research participant, you may contact the Chairperson of the OHREB at 613-798-5555, extension 14902, and the Carleton University Research Office at 613-520-2517.

Appendix G

Participant Testing Information and Consent Form

Information Sheet and Consent Form for Volunteers

Surface EMG Device Study

Principal Investigator: Adam Freed 613-737-7350 ext. 75958
Site Investigator: Ed Lemaire 613-737-8899 ext. 75592

Sponsor: NSERC

Introduction

You are being asked to participate in this research project to test a new reusable device that provides detailed information about muscle activity during motion (sEMG). This wearable device will help healthcare providers identify muscle related problems, thereby improving decision-making for rehabilitation. This study will determine if the new sEMG device is faster and easier to setup. As well, we will compare muscle signals between the new device and the typical sEMG method. The new device has been developed by this project's research team from The Ottawa Hospital Rehabilitation Centre and Carleton University.

Please read this Information Sheet and Consent Form carefully and ask as many questions as you like before choosing whether to participate in this research study. You can discuss this decision with your family, friends and health providers.

Background, Purpose and Design of the Study

Surface electromyography (sEMG) is often used in a motion analysis laboratory to identify which muscles are active, and how much activity is present, during walking or other movements. The current sEMG setup process is long, complicated, and requires specialized training. A user-friendly, wearable device could allow many more people to receive detailed muscle testing.

To address this need, a device has been designed to record sEMG in the healthcare clinic or in the home. The new device wraps around the lower leg and records muscle signals from groups of dry electrodes. The conventional EMG system requires the taping of disposable electrodes, with gel between the electrode and the skin, to precise locations on

the lower leg. These electrodes are then connected to a computer to measure your muscle contractions.

Study Procedures

The testing session will take roughly two hours to complete.

You will be asked to wear shorts for the testing. We will record your height, weight, gender as well as some measurements of your lower leg. Your lower leg will then be cleaned with alcohol wipes and either the conventional sEMG electrodes or the new sEMG system will be fitted on your leg. You will be asked to perform a series of foot and leg motions to setup the system. After setup is complete, we will record your leg muscle activity while you stand up from a chair, walk 10m, return, and sit down. You will be asked to repeat these tasks 5 times. After 5 good trials are completed, the sEMG system will be removed, your leg will be cleaned again, and the other system will be fitted to your leg. The testing procedure will be repeated until each system has been tested three times. This will bring the total number of trials to 30 (15 for conventional and 15 for the new sEMG system). Breaks can be taken as needed.

Possible Risks

We will ask your permission to take video or photographs of the test session for future presentation or publication purposes.

All testing will take place at The Ottawa Hospital Rehabilitation Centre (TOHRC), Rehab Technology Lab. Testing will be completed in one visit, to be scheduled to suit your availability.

Benefits of the Study

Although there is no direct benefit to you as a participant of this study, your participation may help us develop a new device that could make muscle activity analysis available in any healthcare clinic or for homecare.

Withdrawal from the Study

Since participation is on a volunteer basis, you are not obligated to participate. If you decide to participate, you will be free to withdraw from the study at any time without suffering any negative consequences and without it affecting any of your present or future relationships with Carleton University, The Ottawa Hospital, or TOHRC. If you decide to withdraw, you may also choose to withdraw data and information that relates to you.

You also have the right to check your study records and request changes if the information is incorrect.

Study Costs

You will not be paid to participate in this research study. However, you will be reimbursed in cash for parking costs at TOHRC.

Confidentiality

Your confidentiality will be maintained at all times, and only the research team will keep a record of your name. Your data will be stored on a password protected computer. Your information will be accessed only by the research team (investigators and research assistants from TOHRC and Carleton University). The research team will not disclose the contents of your study records to any party.

The results of the study may be used for medical and scientific publications. The Ottawa Hospital Research Ethics Board, the Ottawa Hospital Research Institute and the Carleton University Research Office may audit the study and study materials at any time to ensure compliance with approved research processes. At no time will your identity be disclosed. All study data will be identified with a study number.

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Voluntary Participation

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