Clinical Comparison of a Generic Electrode Grid with Targeted Electrodes in Lower Limb Prostheses: A Preliminary Investigation

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6/21/17

Abstract

Conventional prosthetic control strategies have utilized electromyography to provide function by targeting the prosthetic user's muscles with individual electrodes. With the development of new prosthetic technology, a grid of electrodes has recently been used in place of targeted electrodes as a prosthetic control system. However, current research has yet to compare targeted electrode systems with electrode grid systems for prosthetic control. This study compared the results of two individuals with unilateral transfemoral amputations using both a targeted and a grid EMG system. Both subjects performed walking trials for both conditions using an Ottobock C-leg, a dynamic response foot, and a novel gel-liner suspension system. The EMG data for each subject was visually analyzed for trends and the presence of motion artifact. The results of this study discovered a large amount of motion artifact with the novel EMG system that was used in the grid condition, motion artifact was found to be consistently correlated with particular phases of gait, and a number of clinical challenges were discussed regarding EMG implantation in the prosthetic setup. This study concludes that, while both systems are capable of detecting repeatable muscle signal patterns, each system presents its own set of challenges that impede viable clinical implementation.

Introduction & Background

Currently, the function of lower limb prosthetic components is controlled by the kinematics of the prosthetic user. While this control strategy does restore limited function to the prosthetic user, it fails to provide full function to the user in an intuitive and energy efficient manner. Electromyography (EMG), the process of gathering signals from an individual's muscle contractions, has previously been used in upper limb prosthetic components to provide the user with intuitive control of the prosthesis. As prosthetic technology continues to develop, EMG is being incorporated into the control of lower limb prosthetic devices, providing additional information about the prosthetic user's intent when ambulating.

The process of incorporating EMG into a prosthetic system is a challenging task. The conventional method has been to target specific muscles and then to assign each muscle's activity to a specific task, e.g. muscle contractions of bicep muscle yielding flexion of a prosthetic elbow. While this control method allows the user to perform discrete functions, it can become quite cumbersome and limiting as more joints are involved and simultaneous movement is required. Furthermore, targeting specific muscles requires extensive time and effort to fabricate a prosthetic socket with each individual's unique muscle sites. Additionally, the success of a targeted EMG system is highly dependent on the clinician's ability to accurately locate the appropriate muscles for proper control of the prosthesis. Because lower limb control requires synergistic knee and ankle function instead of discrete muscle functions for safe ambulation, the laborious and specific nature of targeting muscles is an impractical solution for clinical application as more lower limb prosthetic components begin to incorporate EMG as a control strategy.

One solution that is currently being used in an effort to reduce the clinical burden of locating and incorporating electrodes into prostheses is to use an electrode grid. The intent is that the grid will be able to detect overall patterns of muscle activation that each prosthetic user utilizes for different tasks, and the prosthesis will then be able to determine the appropriate function to initiate. Additionally, as a grid is not unique to any particular prosthetic user, it could be more easily implemented into prosthetic designs. However, in order for the electrode grid approach to be a viable solution, it must be able to provide real-time clinical performance that is equal to that of the conventional targeted electrode approach. Tkach et al. (2014) compared the performance of a generic electrode grid to the performance of targeted electrodes for upper limb subjects using a myoelectric prosthesis with pattern recognition software. Their conclusion was that the electrode grid pattern performed just as well or better than a targeted electrode pattern and that the electrode grid yields an approach that is both practical and cost-effective for clinical application. It is important to note that upper limb prosthetic functions are task-specific and goals are restoration of functionality, whereas the functional motion of lower limb prostheses is typically cyclical in nature and goals are stability, adaptation to various terrains, forward progression, and energy efficiency. Furthermore, lower residual limbs often differ from upper residual limbs in terms of anatomy, surgical techniques, and comorbidities. Consequently, it is important to study and compare the effectiveness of a generic electrode grid with that of targeted electrodes at meeting the goals of lower limb prostheses.

As more research has begun to investigate the use of EMG data in the function of lower limb prostheses, it is important to understand fully the influence of electrode placement on the quality of EMG data. The previous studies on EMG collection for lower limb prosthetic applications have yet to compare targeted electrodes and generic electrode grids. This study seeks to investigate the performance of a novel EMG system using a grid electrode pattern in comparison with a conventional EMG system using a targeted electrode pattern. The generic electrode grid system utilized in this study was the Mechanical Electrical Interface (MEI) system developed at the Center for Bionic Medicine (Reissman, Halsne, Lipschutz, Miller, & Kuiken, 2015). In this system, the electrodes were integrated into a gel liner during the fabrication of the gel liners and were linked to a custom attachment on the distal end of the gel liner. The distal attachment included magnets that coupled with magnets in the distal end of the socket, providing both suspension of the prosthesis and an interface for the internal electrical circuitry. The targeted electrode system used commercially available electrodes, MyoWare Muscle Sensor electrodes, to allow for comparison of muscle signal quality obtained by the two electrode systems. The targeted electrode system also utilized a gel liner and distal custom attachment. As the MyoWare electrodes included onboard circuitry, the distal attachments for the targeted liners did not contain any circuitry and were used primarily for consistency in the suspension method. The MyoWare electrodes were added to the gel liners based on the locations identified by palpation of each participant's residual limb. The purpose of this study is to provide a preliminary comparison of the clinical application and performance of a targeted electrode system and a generic electrode grid.

Materials & Methods

Subjects

Participants recruited for this study were individuals with unilateral transfemoral amputations who had prior experience walking with an Otto Bock C-leg. Individuals with bilateral amputations, K1 and K2 level ambulators, and those who did not currently use a gel liner for suspension in their personal prosthetic setup were excluded from this study. Participants were required to stand and walk for extended periods of time. In order to reduce any prosthetic fitting issues, individuals were selected who already used liners for suspension.

A total of two participants were recruited for this pilot study and provided informed consent. Northwestern University Internal Review Board approved the study. Subject A was a 68 year old male who has had a unilateral right transfemoral amputation for 41 years. Subject B was a 51 year old female who has had a unilateral right transfemoral amputation for 37 years.

Prosthetic Setup

Surface EMG was collected from the residual limb hip musculature since these muscles are active during ambulation and may produce valuable information for use in controlling powered prostheses. There were two different conditions utilized in this study: Targeted Electrode and Electrode Grid configurations. In both conditions, the suspension system comprised of a gel liner with the MEI distal end connector. In the Targeted Electrode condition,

the MEI distal end connector was only used for suspension purposes since the electronic components were contained within the MyoWare sensors. Each subject was fit with a separate gel liner for each condition. Both subjects utilized an Otto Bock C-leg for each condition, and the C-leg settings were tuned to each subject for optimal gait mechanics. A single prosthetic socket was fabricated per subject and used for both of the electrode conditions.

In the Targeted Electrode condition, surface EMG signals were collected for the following four muscle groups: hip flexion (rectus femoris), hip extension (semitendinosus and semimembranosus), hip adduction (adductor magnus), and hip abduction (tensor fascia latae). Electrode placement was determined utilizing conventional clinical techniques: each subject's residual limb musculature was palpated, and the locations for the Targeted electrodes were marked over the area of largest muscle width and strongest muscle contraction, as shown in Fig. 1. These locations were then transferred to a gel liner, and stainless steel electrode domes from Motion Control, Inc. were inserted into the liner at these locations. Depending on the thickness of the gel liner at the electrode location, the stem of each electrode dome was adjusted to an appropriate length such that the electrode dome was seated firmly in the gel liner and the electrode snap was seated firmly against the outside of the gel liner. A commercially available EMG acquisition system, MyoWare Muscle Sensor, was then attached on the outside of the gel liner at each of the four muscle group locations. As each MyoWare sensor required its own ground electrode, an additional electrode dome was added to the gel liner for each sensor. The total number of electrodes for the Targeted Electrode condition was 12 electrodes - 8 for all four muscle sites, and 4 for all four ground electrodes, resulting in 4 bipolar muscle signal recordings. EMG was pre-amplified and sampled at 1000 Hz.

Figure 1. Targeted electrode locations were palpated and marked on each subject's skin and were then transferred to the subject's gel liner.

In the Electrode Grid condition, a total of 13 electrodes (12 electrodes plus 1 ground electrode; Motion Control Inc.) were placed in an equidistant configuration around the circumference of the gel liner. The electrodes were also evenly divided into three rows (proximal, middle, and distal) which were positioned 70 mm apart, as shown in Fig 2. The

custom gel liner was fabricated with the electrodes and lead wires inside the gel of the liner creating 8 bipolar muscle signal recordings. This condition utilized the full MEI system. EMG data was amplified and recorded at 1000 Hz.

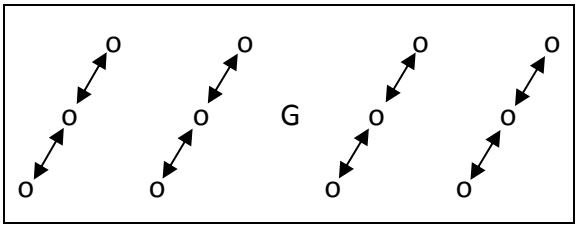


Figure 2. Configuration for Grid electrode placement in gel liner.

o = individual electrode, ↔ = bipolar muscle signal

Data Collection

Each subject was fit by a certified prosthetist for proper alignment and socket fit, and data was collected for both EMG systems. In order to reduce variability, the prosthetist donned each gel liner on each subject and assisted the subject in donning the prosthesis. The prosthesis was donned by sliding the residual limb into the socket, ensuring that the magnets in the liner connected successfully with the magnets in the socket, and then engaging a latch to lock the liner in place inside the socket. The subjects were instructed to perform isometric contractions so as to ensure each electrode pair was obtaining ample signal. Both subjects walked with the prostheses until they felt comfortable with the prosthetic fit and alignment. EMG data was collected for 5 trials of level-ground walking while the subjects walked at a self-selected speed, and this lasted approximately 20 minutes for each subject.

Signal Analysis

Due to the electronics used for each setup, the Targeted Electrode condition recorded from 4 EMG signals and the Electrode Grid condition had 8 channels that were processed and visually inspected for trends. The data was processed using a band-pass filter (30-350 Hz) and rectified using custom scripts in Matlab. For each subject, 5-second samples of each trial were then compared and analyzed for trends. Pronounced spikes in the data that occurred simultaneously across all channels were suspected to be caused by motion artifact, and any consistent patterns were analyzed in how they corresponded to the phase of gait. Any other pronounced irregularities in the data were noted and inspected for relevance.

Results

MEI system - Electrode Grid

For both participants, motion artifact peaks were present across all channels at Heel Contact (HC) and at Toe Off (TO) phases of gait (Figures 3 and 4). The largest motion artifact peaks were primarily seen consistently in Channels 1 and 2 as well as in Channels 5 and 6. This may be significant since these two channel pairs were located opposite each other on the liner and thus on the subject's residual limb. Additionally, Channels 1 & 2 contained a second motion artifact peak in the Foot Flat phase of gait directly after Heel Contact for both participants.

Important to note, Channel 8 for Subject B had to be removed from the data set due to excessive noise. This issue was found to be caused by the dome not being fully screwed into the liner, and the noise was later resolved by fully screwing in and loctiting the dome.

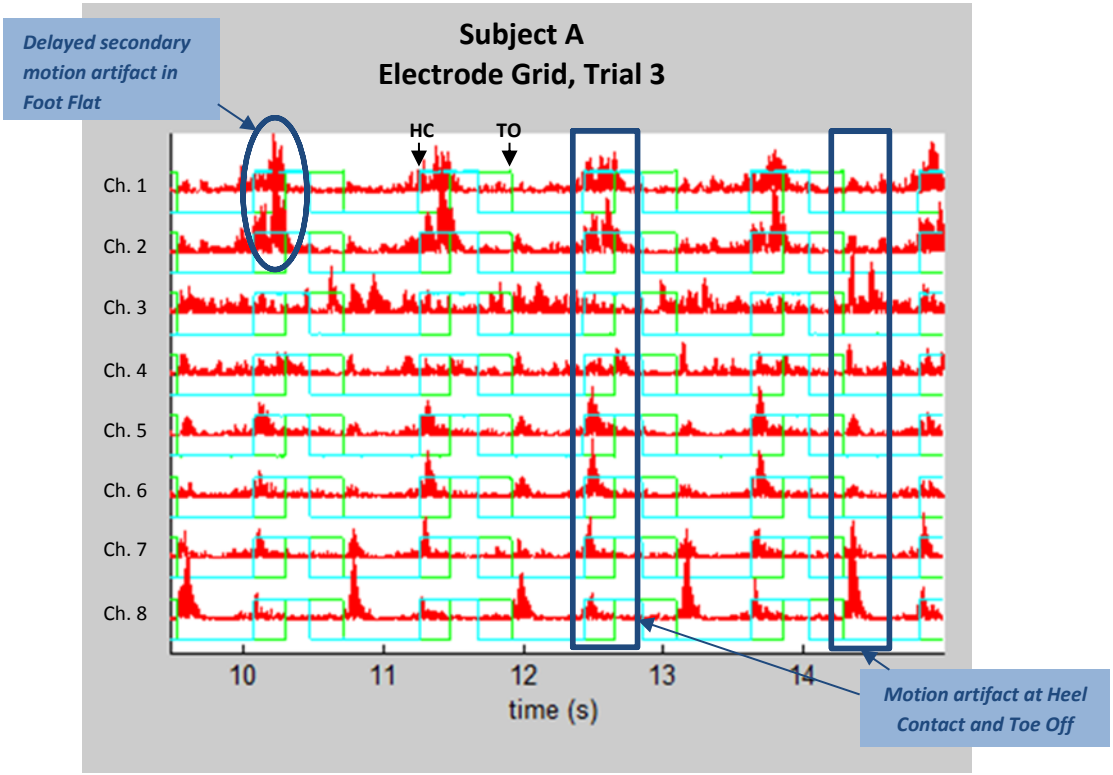


Figure 3. Trial #3 data for Subject A using the MEI Electrode Grid.

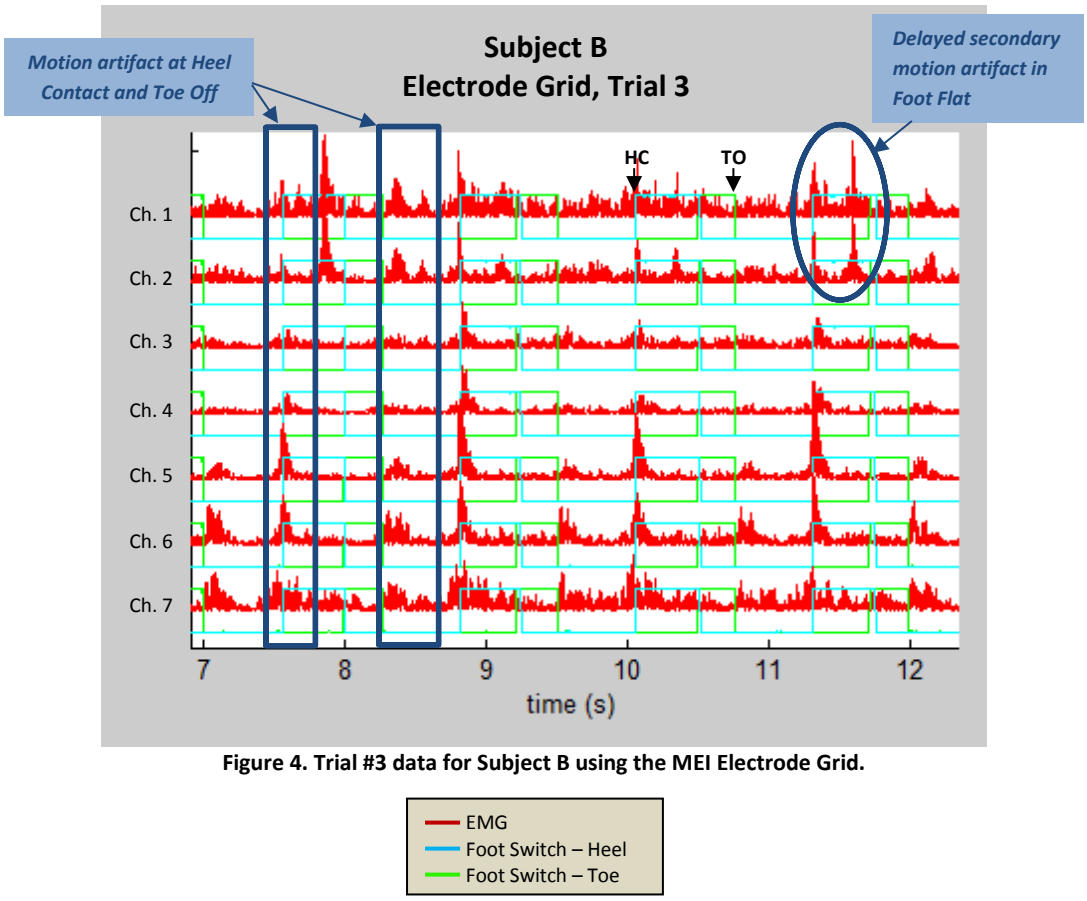


Figure 4. Trial #3 data for Subject B using the MEI Electrode Grid.

MyoWare system - Targeted Electrode

For both participants, motion artifact peaks were much less pronounced overall in the MyoWare Targeted Electrode system than in the MEI Electrode Grid system. Any motion artifact peaks that were present in the MyoWare Targeted Electrode system were located primarily at Heel Contact (HC) and Toe Off (TO) phases of gait, similar to results of the MEI Electrode Grid system.

Both subjects appeared to have fairly similar muscle activation patterns across all 4 channels with only a couple of minor differences. As shown in Fig. 5, Subject A exhibited similar signal patterns across all channels with the highest activity occurring right before and after Heel Contact and moderate activity occurring around Toe Off. For Subject B, the hamstring channel (ST) appeared to have large motion artifact peaks at Heel Contact, as shown in Fig. 6. However, these large, consistent peaks coincide with the expected timing for the hamstring muscles to contract at Heel Contact for stability of the prosthetic knee joint at this phase of gait. Additionally, Subject B consistently exhibited significant muscle activity in the rectus femoris (RF) channel during Toe Off, as demonstrated in Fig. 6. This muscle activity is expected as the hip is actively flexed to initiate swing phase. It was noted that the hip abductor (TFL) channel for Subject A had more baseline noise than the other three channels during all trials. This was possibly due to an electrical issue with the MyoWare sensors or the placement of the electrodes.

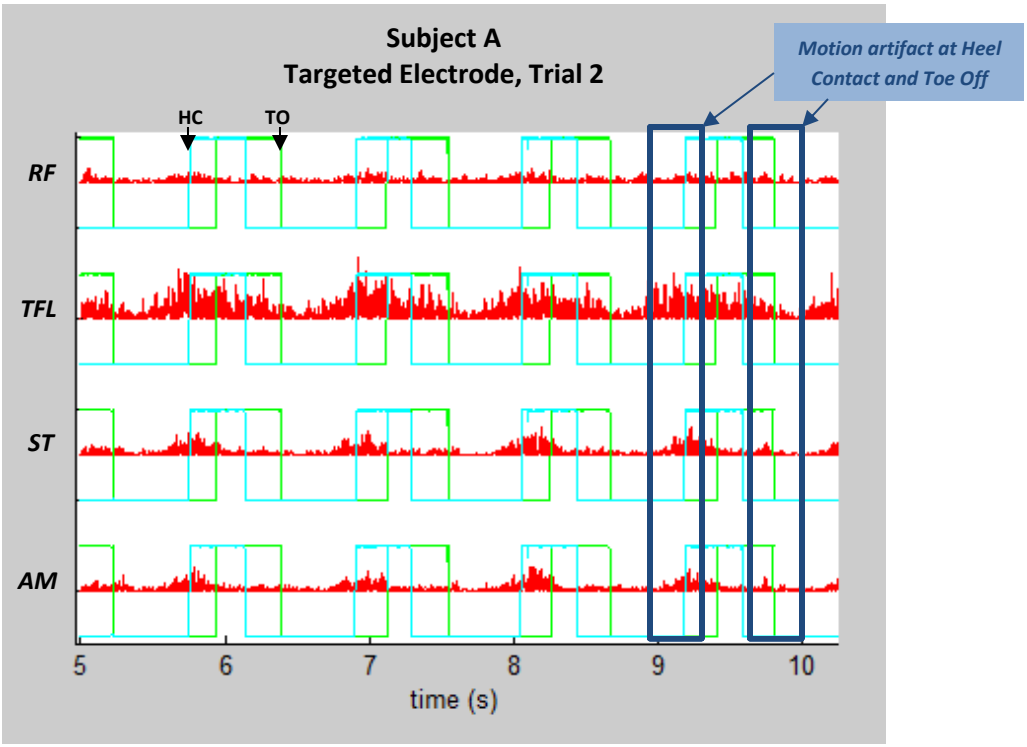


Figure 5. Trial #2 data for Subject A using the MyoWare Targeted Electrodes.

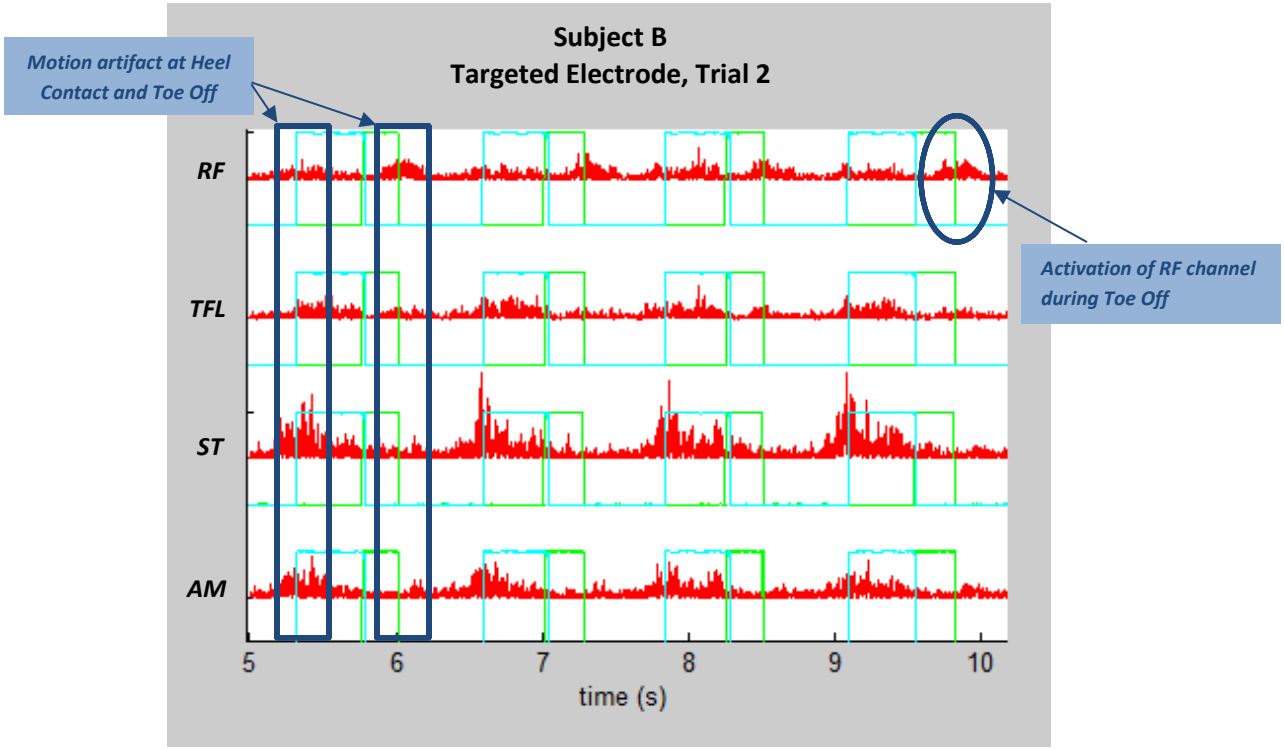
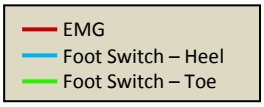


Figure 6. Trial #2 data for Subject B using the MyoWare Targeted Electrodes.



Discussion

EMG Issues

It is a difficult task to eliminate motion artifact from the EMG signals of a transfemoral limb while the subject is walking. Both the MEI and MyoWare EMG systems recorded various amounts of motion artifact during walking with a passive leg. For both systems, the motion artifact peaks seen in Figures 3-6 at Heel Contact and Toe Off were most likely created by the subjects pistoning inside the prosthetic socket as they walked. However, what is unknown is whether the motion artifact was occurring between the liner and the subject's skin or between the socket and the outside surface of the liner. It was noted that the data for the MyoWare system did not contain the same prominent motion artifact peaks as did the data for the MEI system. For the MEI system, it was discovered that touching the outside of the liner at each electrode generated noise in the EMG signals. While both systems utilized the same electrode domes inside the gel liner and both systems were fit with the same prosthetic socket, the MEI system did not have the same external covering that the MyoWare system had that protected the external component of each electrode. The apparent insufficiency of insulation for the MEI system may therefore indicate that the motion artifact was coming from motion between the socket and the outside surface of the liner. Furthermore, while the MyoWare system contains all of the electronics at each electrode location for EMG data processing, the MEI system is designed with all of its electronics located below the distal end of the residual limb. This design may possibly add more noise into the EMG data. Additionally, the use of conductive fabric between the electrodes and the distal electronics in the MEI system may introduce more noise than would shielded wires.

During experimentation, issues were encountered regarding securing the electrode domes into the liners without creating any signal interference. Channel 8 for Subject B's MEI data had to be removed entirely from the data set due to excessive noise. It was later discovered that this excessive noise was caused by the dome becoming loose and no longer making full, continuous contact with the fabric lead wire. In order to achieve a secure connection throughout the entire gait cycle, the domes required adding Loctite before being fully screwed into the gel liner. Resolving this issue led to another observation when analyzing the data. When analyzing Subject A's MEI system data, the secondary motion artifact spike at Foot Flat on Channels 1 and 2 (Figures 3 & 4) was initially suspected to be caused by an issue with the electrode dome since both Channels 1 and 2 share an electrode dome as part of their pairings. However, it was noted that this spike was also present in Subject B's MEI system liner – a separate liner – indicating that the cause was not necessarily an issue with the electrode domes. It is possible that this secondary peak is evidence that the MEI electrode grid system is capturing specific muscle activation patterns of the subjects, particularly since this secondary peak was observed in Channels 1 and 2 and in Channels 5 and 6 which are situated on opposing muscles on the subject's limbs. Alternatively, it is possible that these channels were more susceptible to motion artifact due to their position in the socket.

While it did not exhibit as many motion artifact peaks as did the MEI electrode grid, the MyoWare targeted electrode system did appear to detect differences in the timing of muscle activation patterns of the two subjects. It was noted that Subject A's MyoWare data displayed simultaneous activation across all four channels while Subject B's data revealed asynchronous

activation for all four channels. Whereas Subject A appeared to contract all of his muscles simultaneously at Heel Contact, Subject B displayed distinct activation of the semitendinosus muscle at Heel Contact (the semitendinosus is responsible for hip extension at Heel Contact for stability) and activation of the rectus femoris muscle at Toe Off (the rectus femoris is responsible for hip flexion at Toe Off for swing initiation). The perceived difference in muscle activation timing between the two subjects may have been due either to actual differences in their muscle activation patterns or to differences in the level of accuracy in targeting the muscles. In other words, both subjects may have been contracting their muscles in the same pattern, but it is possible that Subject B's MyoWare setup more accurately captured this pattern than did Subject A's setup. Conversely, it is also possible that both subjects had truly different muscle activation patterns as a result of differences in physical therapy training, surgical methods or muscle attachments, or acquired habits when learning to adapt to different prosthetic components or environmental variables.

Of note, a comparison should not be made between the signal amplitude values between subjects as the relative amplitude values are not to scale.

Clinical applications

In addition to the EMG data results, there were a number of clinical factors that require discussion, including skin issues, donning techniques, MyoWare system setup challenges, and MEI system manufacturing issues. It is the author's hope that these findings will be useful for future research on EMG interfaces with prosthetic components.

Skin issues: For the MyoWare system, an initial concern was that MEI-compatible sockets would have to be fabricated that could accommodate the MyoWare sensors since the housings for these electrodes were applied to the outside of the liners. Each sensor was approximately 55 mm long, 23 mm wide, and 9 mm tall. However, it was found that the subjects in this study were able to tolerate wearing the MyoWare sensors in the socket for the short duration of testing required as neither subject wore the MyoWare liner and socket for more than 30 minutes. This is likely due to each subject having a large residual limb with sufficient compressible tissue. The MyoWare sensors left obvious impressions on each subject's skin, but these impressions cleared up within 20 minutes of doffing the prosthesis. Though additional sockets were not required in this study for use with the MyoWare system, future studies with longer data collection appointments may require MyoWare-specific prosthetic sockets to be fabricated, thus increasing the amount of effort to incorporate this electrode system.

Donning issues: The MEI electrode grid configuration sometimes resulted in domes being placed over invaginations or scar tissue on the subjects' limbs, thus affecting the signal quality. Donning the liner in such a way as to completely avoid these areas proved to be challenging. This study did not seek to study the effect of invaginations on EMG signal quality. However, as it is not uncommon for persons with transfemoral amputations to have scar tissue or invaginations on their residual limb, it may be useful to study the effect of having electrodes in a grid configuration over compromised skin.

For subjects with particularly mobile tissue, it was difficult to consistently don the liner in the same orientation each time. This appeared to affect the reliability of consistent electrode dome placement and thus potentially added variability to the EMG data that was collected. Additionally, it was noted that the liners stretched differently depending on who was donning the liner and in which direction the liner was donned (i.e. whether the subject rolled the liner onto their residual limb as opposed to having the researcher roll the liner onto the subject while facing the subject). Despite attempting to accurately place the targeted electrodes on the indicated muscle sites, this amount of variability in donning very likely reduced the accuracy of the targeted locations in matching the originally marked locations. It is possible that the targeted electrode data was more affected by the inconsistency in electrode dome location than was the electrode grid. However, this outcome was not measured in this study. A potentially useful area for future research could be to investigate the effects of donning variability and various donning techniques on the consistency of EMG data collection and EMG signal quality, and whether or not donning variability significantly affects EMG signals in prosthetic applications.

MyoWare targeted electrode system setup: Determining the appropriate location for the targeted electrodes was a lengthy process. The first step was to palpate each subjects' musculature. The researchers in this study found this process to be more difficult on some individuals than on others. Additionally, the author notes that palpation alone does not afford clinicians the ability to know exactly where the optimum targeted electrode location is based on recommended standards (Hermens, 2000). Furthermore, the appropriate inter-electrode distance between the two electrodes of the MyoWare sensors had to be determined with the gel liner donned on the patient. This is due to the variability of the stretch placed on the gel liner when donning. If the electrodes were not marked on the liner while the liner was donned on the patient, the electrode placements would not have matched the MyoWare sensors. This was also somewhat of an issue for the ground electrode dome locations due to the short lead wires for these electrode domes. Though the issue of inter-electrode distance may not necessarily be an issue for all electrode systems, the variability in the amount of stretch a liner possesses may create other challenges.

One of the difficulties encountered during this study was in the setup of the electrodes in each liner. The electrode domes needed to have stems long enough to extend through the gel in order to attach to the electrode snap. If the stem of the electrode dome was too short, tightening the electrode too much would cause the dome to sink into the gel and lose contact with the skin. Thus, longer-stemmed domes had to be ground to custom lengths that were dependent on their location in the gel liner and how thick the gel was at that particular location. This requirement of unique electrode dome stem length is an additional consideration that may need to be accounted for in future prosthetic componentry designs.

MEI electrode grid system manufacturing issues: One important difference between the MEI system and the MyoWare system is that all electronic components were contained within the MEI system liners. The complex fabrication process required to make the MEI gel liners presented several unique challenges:

- T-nut application: When tightening electrode domes into the gel liners, it was found that the domes would poke into the gel liner and pull gel out of the liner around the dome, thus breaking down the integrity of the gel liner. In order to prevent this, t-nuts were added to the gel liners to act as a backing for the electrode domes. However, if the t-nuts were not placed exactly perpendicular to the surface of the gel liner during the fabrication process, the electrode domes would be seated at an angle with respect to the surface of the gel liner. This resulted in gapping between the surface of the domes and the gel liner which created the possibility of pinching the subjects' skin between the gel liner and the electrode domes. Similar to the MyoWare setup, the electrode domes required additional shortening in order to be connected to the t-nuts and not extend above the surface of the gel liner. Another issue with the use of the t-nuts was that the gel liners had insufficient thickness with which to insulate the t-nuts, resulting in additional signal noise.
- Gel degradation: As domes were tightened into each t-nut, the gel was degraded and t-nuts easily became loose inside the gel. Loosening of the t-nut within the gel resulted in unreliable signals as the lead to each t-nut was strained during tightening of the electrode domes into the liner. Once the t-nut had become loose inside the gel of the liner, the researchers had no ability to re-secure the t-nuts to prevent damage to the electrode leads.
- Electrode location: As noted above, some of the most distal electrodes were located over invaginations or distal scar tissue on the subjects' residual limbs. Due to the fact that these electrodes were fabricated into the gel liner in the MEI system, the clinicians did not have any capability to adjust the electrode location during the fitting process in order to avoid the compromised tissue. This issue was not present in the MyoWare system due to the nature of targeting the electrode locations and the inherent ability to avoid any scar tissue or invaginations.

Limitations

This study was preliminary and has several limitations that should be considered. The sample size was small, consisting of only 2 subjects with similarly-sized limbs. Only two subjects were able to be included in this study due to the amount of time and effort required to create MEI socks as well as other unavoidable circumstances. As mentioned earlier, the technique of targeting muscles using palpation is a subjective method and relies on the expertise of the clinician to accurately locate the correct electrode placement. In this study, the same clinician was responsible for determining the targeted electrode placement for both subjects. However, this does not necessarily mean that the optimal electrode locations were used for data collection, nor was there any verification that crosstalk from adjacent muscles was eliminated. Furthermore, the amount of variability in donning was not measured in this study, and thus it is not possible to determine how accurate the positioning of the targeted electrodes was in relation to the intended locations. Finally, the EMG data results were created from visual analysis of the data and did not utilize any objective measures.

Conclusions & Significance

The goal of this research study was primarily to perform an initial comparison between the performance of an electrode grid system and a targeted electrode system in a prosthetic setup. This study showed that both electrode systems were capable of detecting repeatable muscle patterns but that there is still improvement required to reduce the amount of motion artifact captured during EMG data collection. Additionally, this study revealed that there are various clinical challenges associated with incorporating either a novel electrode grid system or a conventional targeted electrode system into gel liners. These clinical challenges make it difficult to reliably and efficiently obtain useful EMG data for use with prosthetic devices. While the findings of this study cannot be used to determine which electrode system is superior to the other, they will hopefully provide direction for future research in the development of prosthetic technology.

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Design and Evaluation of a Cable-Driven, Body-Powered Orthosis for Individuals with Spinal Cord Injury

A Prosthetic Resident Research Project

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Introduction

Spinal cord injuries occur when any damage has been done to the spinal cord.[1] Spinal cord injuries may be classified as complete or incomplete and temporary or permanent.[2] Thirty one percent of spinal cord injuries are at the cervical level; further broken down to 14.8% at C5, 11% at C6, and 5.4% at C7, as reported by King.[3] A spinal cord injury at the cervical level will result in a certain degree of loss of function of the upper extremity, requiring an assistive device to help improve grasping techniques for functional independence.

Typically, a person with a SCI at C6 or C7 level has the ability to operate a wrist driven flexor hinge orthosis (WDFHO) to complete various activities of daily living (ADL). This is due to the ability to actively extend their wrist to create a tenodesis grasp. To successfully use a tenodesis orthosis, like the WDFHO, wrist extensor must score 3 or higher on the manual muscle testing scale.[4] If a patient presents with little to no wrist extension, there are limited options available in current clinical practice to create prehension.

Previous literature has briefly described modifying the WDFHO with a Bowden cable system to substitute the wrist muscle activation with more proximal joint motion that causes three-point prehension. [4] However, there is no further evidence on the use or effectiveness of the orthosis. The lack of research on cable-driven orthoses led to the development of this study; there is a need to design a cable-driven, body-powered orthosis and assess its effect on a person's ability to complete tasks such as independent grooming, feeding, and object manipulation.

Design of Body-Powered Orthosis

The orthosis was designed using an iterative process to optimize the device

1. Casting Technique and Socket Design

The design process started with creating a casting protocol. Initially the hand and forearm were wrapped in plaster in one part cast; however, this was found to be unsuccessful, as the hand was compressed at the metacarpal phalangeal joints and the contour of the palmar surface was inconsistent. Hence, casting was adapted to a two part procedure. A hand splint was used to allow the palmar panel to take shape. Then a wedge was placed between the thumb and hand to prevent excessive compression, as well as to provide time to ensure the proper extension and deviation were captured. The optimal degree of concavity is still to be determined, and the thumb design needs to be improved to truly assess the socket design. Over time, a wrist was found to be necessary, and a prepositional wrist joint was added. The palmar surface of the hand was covered with a textured material to create friction and assist in grasping an object. The socket design modifications are shown in Figure 1.

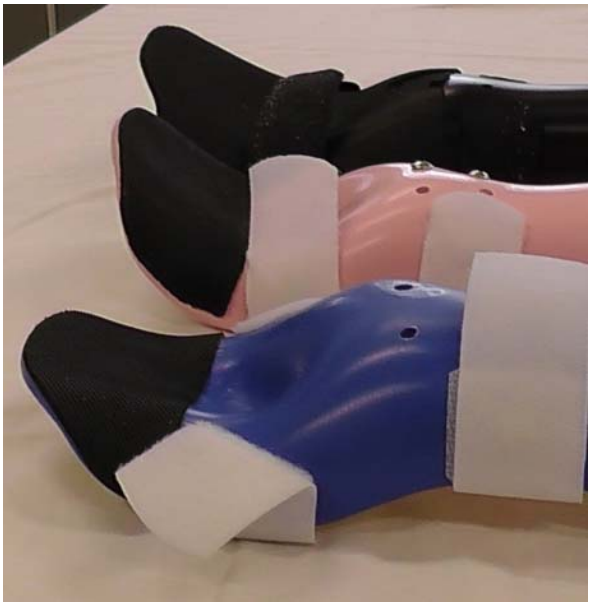

Figure 1: Iterative socket designs

2. Thumb design

During design development, box and blocks tests were performed with the thumb in two positions. Prior to performing outcomes measures on able bodied subjects, the thumb design was modified.

The initial thumb design was influenced by a patient with a partial hand amputation who operated the thumb via a Bowden cable system. The thumb was positioned against his fingers. Based on that design, the design engineer was able to make the thumb able to rotate in the transverse plane with an anteroposterior slide. Unfortunately, these modifications were too finite and did not provide enough adjustability to assess function and proper placement. A block was used as a starting point for design. The thumb was shaped with multiple contours to allow for ease of gripping of various objects. A cross point was added, creating a "T" thumb, to allow for easier grasp of long objects, like pens or silverware. Finally, padding was added to increase the gripping capabilities. The various thumb design iterations are shown in Figure 2.

3. Harness

As previously mentioned, the harness design uses features of a standard transradial Bowden cabling system and also went through a few variations (Figure 3). Due to limited range of motion for persons with a spinal cord injury, there was concern that a Figure of 8 harness would be too difficult to don. A figure of 9 harness was trialed with a TRS Elf Strap. Unfortunately, the Elf strap did not provide enough support for the cabling system, so a figure of 8 harness was required. Initially, a northwestern ring was used but the straps slid around the ring too much. So, a TRS Baha buckle was used, which was more successful than a northwestern ring.

Figure 2: Design iterations of thumb from initial block design (left) to final design with added cross point (right).

A functional prototype is pictured in Figure 4a; however, this version has no wrist joint. Figure 11b shows subject SCI 2 wearing this device and opening the thumb. The final device design used by subjects in the study had a wrist joint and a Baha buckle.

Functional Evaluation of Orthosis

Methods

The plan was to recruit up to 5 able-bodied subjects for design development—taking outcomes to help establish "normative data." Then the plan was recruit 2 subjects with SCI to continue with design development. Finally, up to 5 more SCI subjects were to be recruited for outcomes measures. Two outcomes measured were decided upon, by a process of elimination, based on the goals of the study: the Box and Blocks test and the Jebsen-Taylor Hand Function test were selected to best assess device function. Both measures have been tested on the spinal cord injury population and both have normative data associated with them. Box and Blocks is recommended for use for the spinal cord injury population[5]. Jebsen-Taylor is reasonable to use in research for a person 3+ months post injury.[6] As the orthosis was being tested in the lab at RIC, quality of life outcomes were disregarded; however, these issues can be evaluated in further trials.

Results

Unfortunately, recruitment was very low. Three able-bodied subjects were consented and data were gathered from these individuals. Two SCI patients were recruited; however, one patient withdrew consent due to medical issues and then left the country. Therefore, one SCI patient took part in the study.

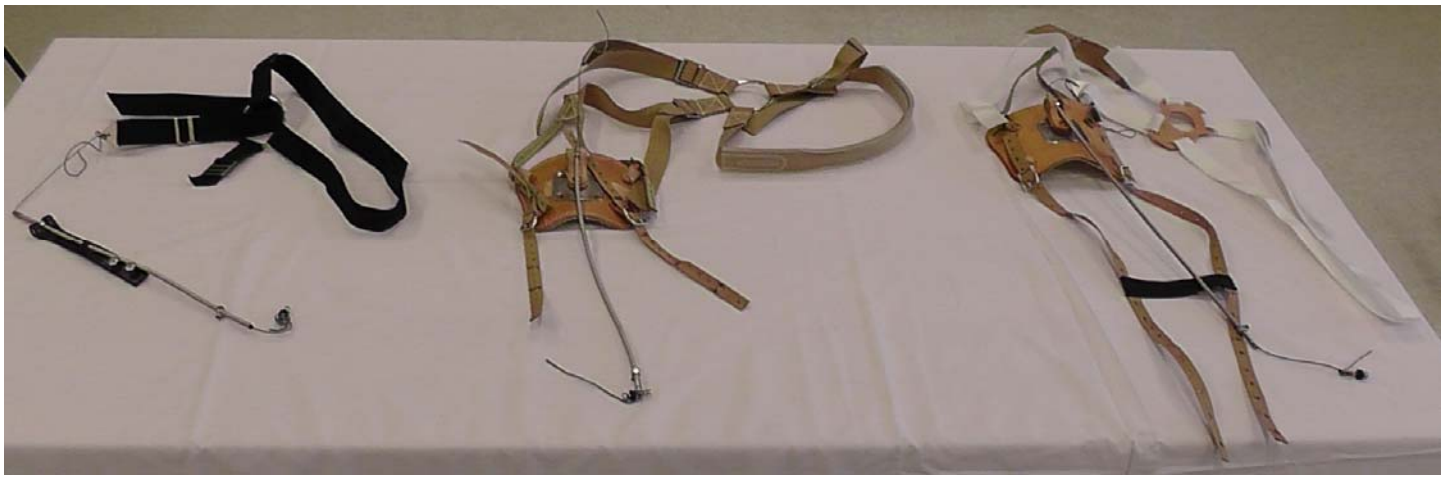

Figure 3: Design iterations of harness

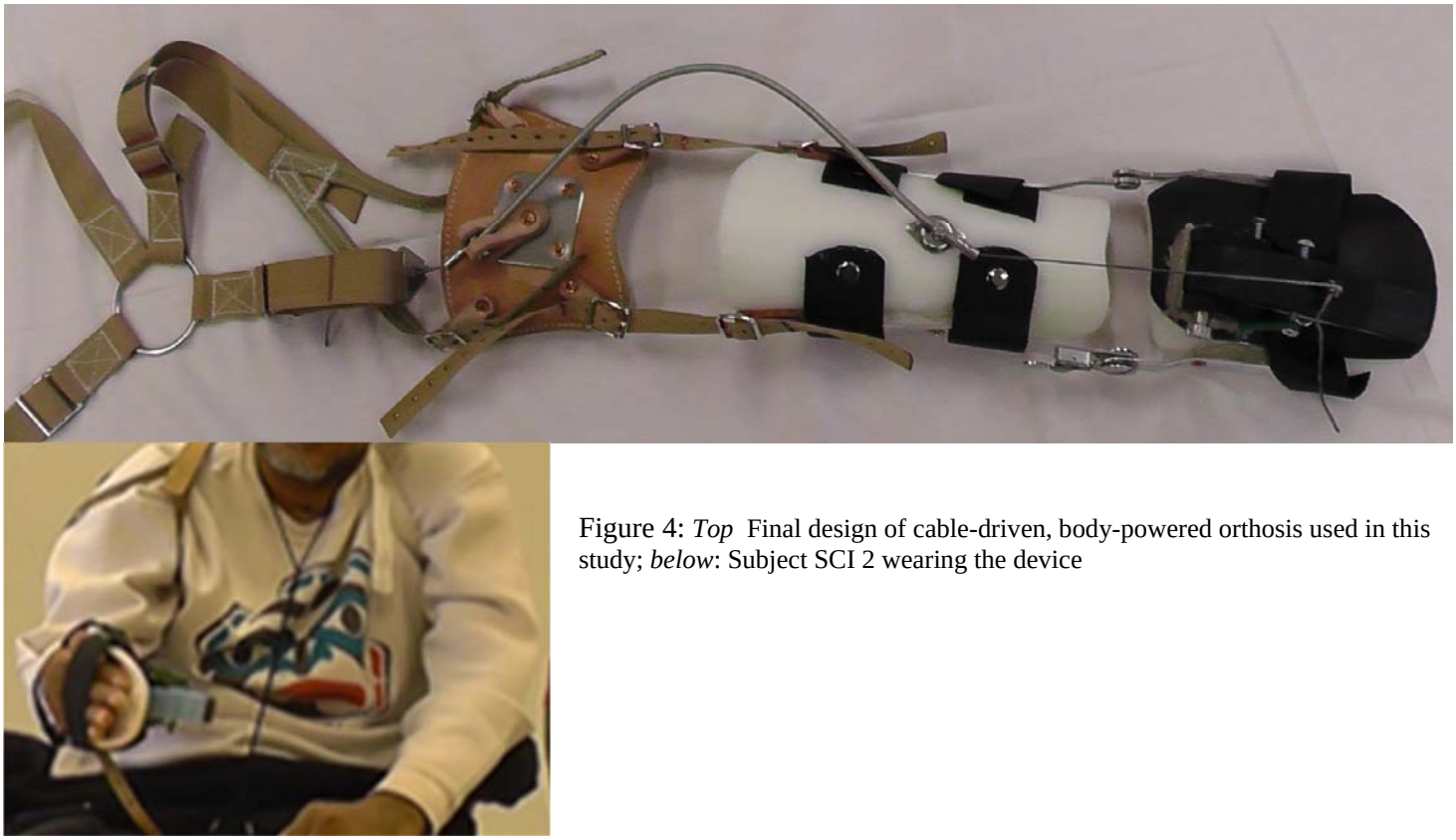

Figure 4: *Top* Final design of cable-driven, body-powered orthosis used in this study; *below*: Subject SCI 2 wearing the device

To determine where the optimal thumb positioning should be, the Box and Blocks task was performed with the orthosis in two positions, thumb to pointer and thumb to pinky (Table 1). Most of the able-bodied subjects preferred the thumb to pointer position. Their feedback provides future design considerations and will be discussed in the next section. Subject SCI 2 was actually able to gather more blocks without wearing the assistive device (Table 2). This was due to the thumb shape and indicates that further device modifications are necessary. The Jebsen-Taylor task could not be performed due to the poor thumb design.

Table 1: Number of blocks moved in 1 minute by able-bodied subjects using each orthosis option

Subject	Thumb to Pinky	Thumb to Pointer
AB 1	8	9
AB 2	13	16
AB 3	N/A	17

Table 2: Number of blocks moved in 1 minute by subject with SCI

Subject	Without Orthosis	With Orthosis
SCI 2	6	1

Future Work

All though the design requires further development, recruitment for this study was significantly difficult, which begs the question, is there a population to use this orthosis? The size of the prototype thumb needs to be shrunk down to a more anatomic size. The main future design considerations are making the thumb stationary yet prepositional and having the pivot point be at the MCP. The thumb must reflect an anatomical size thumb otherwise, grasping objects is too challenging for the patient. Since every person is different, it would be ideal to have the anchor of the thumb adjustable. Having adjustability in the coronal and sagittal planes would be ideal for proper function. The adjustability would allow for more productive fitting appointments prior to making a definitive orthosis.

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Localization of residual limb muscles of individuals with a transfemoral amputation and intact limbs

A Prosthetic Research Resident Project

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Background

Most current commercially available transfemoral prostheses utilize passive knee and ankle components. While passive components are more common, there are some powered lower limb prosthetic components that are commercially available including the Ossur Power Knee and the BionX BiOM ankle. These components utilize mechanical sensors (i.e. load cells, inclinometers, inertial motion units, etc.) to determine when powered assistance should be provided. Using powered components can enable people to walk with increased gait efficiency by providing net positive work similar to muscles in intact limbs. Powered components can perform the majority of the work while ascending stairs step over step and ascending ramps. These benefits may translate into reduced joint damage over time. Research is currently being done to develop new powered knee and ankle components as well as improve the control of these components. One method of improved control may be the addition of inherent muscle signals from the residual limb. The addition of electromyography (EMG) data to mechanical sensor data when used in the control of a transfemoral powered leg prosthesis has been found to be beneficial in controller accuracy.[1-3] Improved control can allow for more seamless transitions between ambulation modes, such as switching from level ground walking to stairs, without the need for a key fob or unnatural movement.

Current methods of EMG collection used on people with transfemoral amputations involve targeting specific muscles in the patient's residual limb. The process of establishing these EMG locations can be difficult and time consuming given the movement of muscles following surgery and decreased signal due to disuse. There is also the potential of donning variability to effect the placement of electrodes when electrodes are integrated into either a liner or the socket. This variation could lead to changes in signal quality and potential errors in mode prediction based on changes in muscle contraction patterns. To our knowledge, there are no previous studies investigating donning variability and its effect on the control of a lower limb prosthesis.

In 2000, the Surface ElectroMyoGraphy for the Non-Invasive Assessment of Muscles (SENIAM) project published recommendations for EMG data collection locations in skeletally intact individuals.[4] While recommended EMG locations for able-bodied individuals are available from the work of SENIAM, several of the boney prominences used for these recommendations are no longer present in individuals with a transfemoral amputation. Additionally, some of the recommended muscle locations may be distal to the level of amputation. To our knowledge, no such recommendations have been made for people with transfemoral amputations.

Surgical technique for the amputation is likely to effect the muscle belly location. In the conventional transfemoral amputation approach, the surgeon would suture the residual adductors and the other muscles around the femur forming a myoplasty while the residual femur in a flexed and adducted position. This approach can change the muscle tensions affecting their ability to control the residual limb.[5] A more common amputation technique for transfemoral amputations

currently involves dissecting the major nerves two to four centimeters proximal to the cut end of the bone. The quadriceps muscles are detached just proximal to the patella to retain some of the tendinous portion. The medial hamstrings are cut two to two and a half cm distal to the cut end of the femur, while the biceps femoris is transected at the level of the bone cut. The adductor magnus is first sutured to the lateral aspect of the residual femur via drill holes. The quadriceps are then sutured to the posterior aspect of the femur via posterior drill holes. The hamstring muscles are anchored to the posterior aspect of the adductor magnus or quadriceps.[6] In the Dundee technique, all muscles are sectioned at the level of the skin cut (~8cm distal to the bone cut). The adductors and medial hamstrings are anchored to anterior medial drills holes. Vastus lateralis and lateral hamstrings are sutured anterior lateral. The quadriceps are then brought over the end of the femur and attached to the hamstrings.[5] Surgical technique may vary for several reasons including surgical training, time of amputation and cause of amputation. In the case of a traumatic amputation, the surgeon may have less time to plan, less experience with amputations and/or damage to other structures within the residual limb. Based on the amputation method followed, muscle contraction strength, location and direction of pull may vary.

In addition to surgical technique effecting muscle belly location, thigh composition has been found to change in people with amputations with muscle decreasing and fat increasing following amputation.[7-10] Without hamstring fixation, the hamstrings experience 70% atrophy.[10-11] There is decreased muscle atrophy in people with longer residual limbs.

The goal of this study was to determine if there are generalizable muscle belly locations in the residual limbs of people with a unilateral transfemoral amputation based on residual limb characteristics. The study also examined differences between measurements taken while wearing a liner to locations without a liner. Donning variability was investigated. Muscle belly locations of subjects with transfemoral amputations were compared to those of people with intact limbs.

Methods

Subjects provided written informed consent for participation in this study that was approved by the Northwestern University institutional review board. The study was conducted between February 2017 and July 2017 at the Rehabilitation Institute of Chicago and the Shirley Ryan AbilityLab. A convenience sample was recruited from patients who met the following eligibility criteria: (1) a unilateral transfemoral amputation (2) ability to independently stand on his/her intact limb with upper extremity support. Nine subjects were recruited for this study. Nine able-bodied individuals were recruited as controls.

For individuals with a transfemoral amputation, the area of greatest contraction was determined for six muscles on each subject's residual limb using palpation while the subject was seated. This location was denoted using a sticky electrode placed on the skin. The muscles identified were vastus medialis (VM), rectus femoris (RF), vastus lateralis (VL), an adductor muscle (AM), semitendinosus (ST), and biceps femoris (BF). Subjects were asked to visualize the different contractions as they completed them. If the subjects had difficulty achieving the contractions, they were asked to complete the contractions simultaneously with their intact limb. In order to determine the location of RF, subjects were asked to flex their hip as they visualized extending their knee. VM and VL were palpated without hip flexion. BF and ST were found by having the subject visualize flexing their knee or "balling up" the muscles in the posterior aspect of their residual limb. ST was palpated medially and BF was palpated laterally on the posterior aspect of their residual limb. AM was found by providing resistance as the subject attempted to adduct their residual limb.

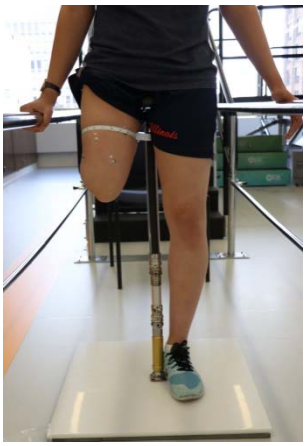

Figure 1 Example of patient on measurement stand

Subjects were asked to stand with partial weight resting on a bicycle seat measurement stand (Figure 1) such that their contralateral limb was fully extended and the subject's ischial tuberosities were resting on the bicycle seat. The height of the bicycle seat was adjusted for each subject. The subject's residual limb was held as close to a vertical position as possible with minimal hip flexion and abduction. A horizontal tape measure was wrapped around the subject's leg just distal to the bicycle seat to be used as a horizontal reference following the flexion and abduction angles of the residual limb (Figure 2). The subject's greater trochanter was marked. A

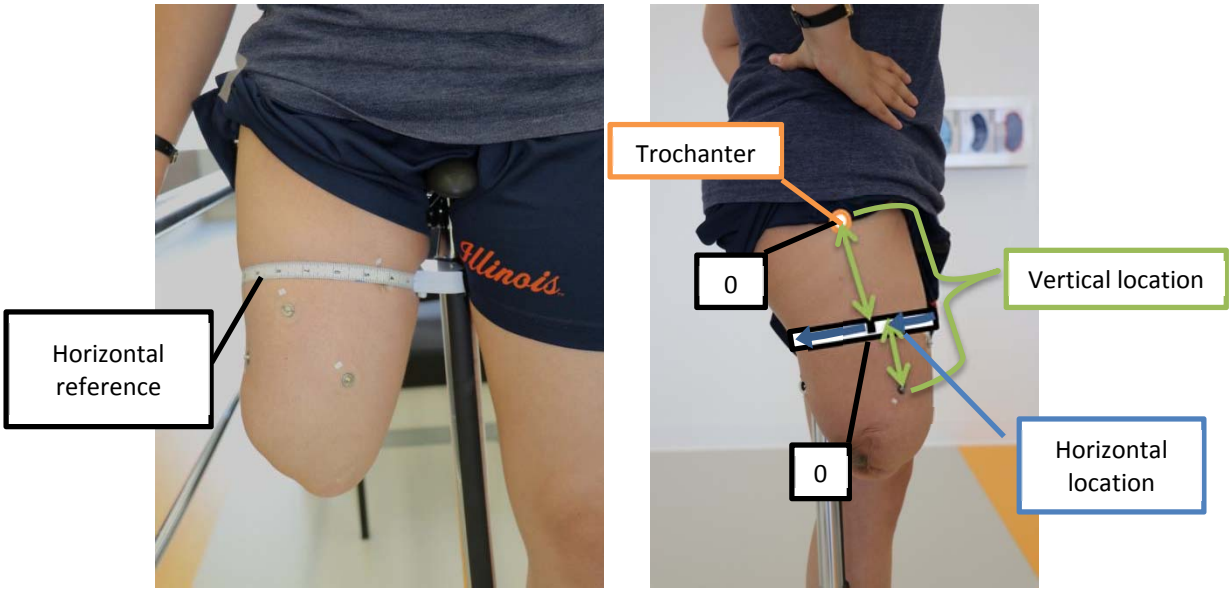

Figure 2 Left: Example subject indicating horizontal reference tape measure; Right: Measurement technique

measurement was taken using the horizontal tape measure as the horizontal measurement and a vertical measurement up to the greater trochanter. A similar measurement technique was used to measure the locations of the different muscles. The muscle location was converted to use the greater trochanter as a zero-zero reference point (Figure 2). Additional measurements were taken to collect information regarding limb size and shape. Compressed and uncompressed lengths were taken of the subject's residual limb from greater trochanter to the distal end of the residual limb. A measurement of the subject's contralateral trochanter to knee center (KC) was taken. Circumference measurements of the subject's residual limb were taken every 4 cm from the horizontal reference tape measure.

The subject was then asked to don an Össur Iceross Seal-in liner. The sticky electrodes on the muscles were palpated through the liner and marked. The subject was asked to doff the liner, completely reflect it, and radon the liner. The locations of the electrodes were re-marked. This process was repeated three times. Following the third donning, the subject was again asked to stand in the bicycle seat measurement stand. Greater trochanter and muscle locations were determined in the same manner as described previously while wearing the liner. A measurement was taken from the greater trochanter to the distal end of the subject's residual limb while wearing the liner. Donning variability was examined after the subject doffed the liner by measuring the horizontal and vertical shift for each of the three donning attempts for each muscle. Overall shift was determined using Pythagorean Theorem.

A similar procedure was followed for able-bodied subjects. The laterality of limb measured for able bodied subjects was selected to match the number of left vs right limbs measured in the subjects with transfemoral amputations. Muscle locations were found in sitting. Resistance was applied to all motions. Subjects with intact limbs were asked to internally and externally rotate their hip while flexing their knee to determine the location of ST and BF respectively. Subjects were asked to internally and externally rotate their foot while extending their knee to determine VM and VL respectively. The rotation portion of muscle contractions was not included in the determination of muscle locations in subjects with transfemoral amputations due to the difficulty of visualizing these motions. Muscle location measurements were taken using the same method described for the subjects with a transfemoral amputation. The distal circumference measurement was taken at 20cm distal to the horizontal reference location which was slightly proximal to the knee. No liner data was collected for subjects with intact limbs.

Statistical testing was completed in Excel with 95% confidence. One-tailed t-tests were conducted to compare the data from TF and AB subjects as well as between data without a liner and data with a liner. Pearson correlation values were calculated to determine the correlation between vertical muscle location and both residual limb length and distance from greater trochanter to knee center. The significance of these correlations was determined by finding their t-value.

Results

Measurements were taken from 9 people with transfemoral amputations (5 females, 4 males) who ambulate at a K3 or K4 level with a variety of predicate device suspension methods. The average time since amputation was 36±14 years. The average percent of limb remaining using measurements from the greater trochanter was 68±8% with an average distal circumference measurement of 37.2±5.8 cm (Appendix A and C). Measurements were also taken from 9 people with intact limbs (4 females, 5 males) (Appendix B and D).

The muscle locations (in cm) on each subject with a transfemoral amputation's residual limb are plotted in Appendix E with the zero point indicating the location of the greater trochanter. The figure identifies the generalized locations for the different muscles examined and the variation between subjects. When comparing directional variability in cm, there was larger variation in the vertical measurement than in horizontal measurement as seen in the standard deviation values presented in Appendix F. Horizontal measurements had standard deviations ranging from3.0 to 4.7cm while vertical measurements had standard deviations from 4.0 to 6.0cm. When the experiment was being conducted, it was noted that all of the vertical muscle locations appeared to be approximately where a liner seal would be. This observation along with the idea that the result of this experiment may be used to develop liners for EMG collection indicated that vertical measurements should also be examined in relation to the TF subject's distal end. There was decreased variation when the vertical muscle measurement was determined as a measurement from the distal end of the residual limb (Appendix G) compared to a measurement from the trochanter distally with standard deviations ranging from 1.7 to 2.5cm and 4.0 to 6.0cm respectively (Appendix F).

The vertical muscle location was found to be significantly ($p<0.05$) linearly correlated with both the distance from the greater trochanter to contralateral knee center and the greater trochanter to the distal end of the residual limb. The vertical muscle location was more highly correlated with the residual limb length than with the contralateral trochanter to knee center measurement with the exception of ST (Appendix H).

In order to account for limb size, the horizontal muscle locations were scaled by the horizontal reference circumference and the vertical muscle locations were scaled by the distance from the trochanter to the contralateral knee center. Average scaled locations for both people with a transfemoral amputation and people with intact limbs are shown in Appendix J. Scaled horizontal muscle locations were not significantly different ($p>0.05$) for people with a transfemoral amputation from those found in people with intact limbs with the exception of VM ($p=0.04$). Scaled vertical muscle locations were significantly different for people with a transfemoral amputation than people with intact limbs ($p\geq0.05$).

In addition to scaling the vertical muscle location by the contralateral trochanter to knee center measurement to simulate if the limb were intact, muscle locations were examined by scaling the vertical location by the residual limb length (Appendix K). When the vertical muscle locations were scaled by residual limb length for the subjects with a transfemoral amputation, there were no statistically significant differences between the vertical location and the vertical location scaled by trochanter to knee center of the subjects with intact limbs with the exception of VM ($p=0.03$).

Measurements of muscle locations while wearing a liner were not statistically significantly different from those found without a liner on with the exception of the vertical location scaled by residual limb length of ST ($p= 0.01$) (Appendix L). There was also a significant difference between the measurements taken from the distal end of the residual limb for ST and BF ($p=0.01$ and 0.02 respectively). The average donning variability for the three liner donning instances for all subjects across all muscles was 1.1 cm (0.9 cm horizontal, 0.5 cm vertical).

Discussion:

To our knowledge, this is the first study to report on generalized muscle locations in individuals with a transfemoral amputation.

Determining the area of greatest contraction was more difficult in subjects with a transfemoral amputation than it was in subjects with intact limbs. When palpating the subjects with a transfemoral amputation's residual limb the muscle location was sometimes shifted medially or laterally compared to what would be typical in an intact limb. Generally, when the muscles were shifted it was all of the quadriceps muscles being shifted in the same direction, which is likely due to surgical technique. It was also difficult for some subjects to complete the desired contractions, likely due to muscle disuse given the length of time since amputation. Having subjects complete the desired contraction bilaterally would sometimes improve the subject's ability to achieve the contraction. One subject also had scar tissue that made palpation of the area of greatest contraction more difficult. Subjects with more redundant tissue were also generally more difficult to palpate specific muscles. Even with these challenges, all of the desired muscles were able to be found with reasonable confidence. This process of determining muscle locations could be difficult and time consuming. Using the generalized muscle locations found in this study as a starting location would potentially decrease difficulty in targeting muscles in people with a transfemoral amputation.

Generalized muscle locations were able to be determined with increased variation in muscle location in the vertical direction compared to the horizontal direction when measuring from the greater trochanter. It was noted when taking measurements while the subject was wearing a liner that the vertical muscle location was often located in the area of the seal on the seal-in liner. This observation along with the potential future application of our data for the

development of a liner led us to examine muscle locations in reference to the distal end of the residual limb. When variation was examined as referenced from the distal end, variation in the vertical direction was decreased. This finding could be due to surgical technique of resecting the nerve ending two to four centimeters from the cut end of the bone or the method of attaching the muscle following amputation. Additionally, the fact that the distance from the trochanter down to the area of greatest contraction is further than the distance from the distal end to the same area may affect the variation.

We found that the vertical location varied linearly with both residual limb length and distance from greater trochanter to knee center. There was a stronger linear relationship between residual limb length and vertical location which may be due to the change in muscle attachment location or amount of limb that was amputated. Muscle locations were scaled to account for residual limb size. The vertical muscle location was scaled by the distance from the greater trochanter to the knee center on the contralateral side to simulate if the subject still had an intact residual limb. Additionally, the vertical muscle location was scaled by the distance from greater trochanter to the distal end of the residual limb to simulate the current muscle attachment location. Variation was similar in the two instances. All scaled horizontal muscle locations varied by an average of 6%. When vertical muscle locations were scaled by contralateral knee center, the average variation was 9%. When vertical muscle locations were scaled by the length from the greater trochanter to the distal end, the average variation was 10%.

The results from the subjects with a transfemoral amputation were compared to those of the subjects with intact limbs. The variation in muscle location was larger in subjects with a transfemoral amputation than in able bodied subjects likely due to variations in amputation surgical technique. We did not have access to the subjects' surgical reports to confirm this hypothesis. Horizontal location was not significantly different between people with a transfemoral amputation and people with intact limbs with the exception of VM ($p=0.04$). There was a significant difference between the vertical muscle location of people with a transfemoral amputation and people with intact limbs when the vertical location was scaled by the distance from the greater trochanter to knee center. Several of the muscle locations in people with intact limbs were found to be distal to end of the residual limb in people with a transfemoral amputation.

When the vertical muscle location was scaled to simulate the new muscle attachment point either into the distal femur or to each other just distal to the femur, there was no significant differences in vertical muscle location between people with intact limbs and people with a transfemoral amputation with the exception of VM ($p=0.03$). This muscle organization to match the previous muscle location may be attributable to changes in residual limb muscle following amputation. Research has been done on changes to muscle composition in people with a transfemoral amputation,[7-10] however little has been done to investigate changes in the area of greatest contraction. More research would be necessary to determine the cause of the muscle reorganization to match the intact limb.

Muscle locations were also examined while subjects with a transfemoral amputation were wearing an Ossur Iceross Seal-In liner. There were no statistically significant differences in horizontal location between measurements with and without the liner on. Hamstring muscles showed variation in vertical location in several of the measurement techniques. This variation could be attributable to the method of donning that could bring the posterior tissue more proximal as the liner is rolled up. The marks made on the liner also appeared to be more proximal than on the residual limb after the liner was doffed. This shift could be due to donning the liner with distal umbrella slightly anterior to midline in addition to the movement of tissue under the liner and the variation of stretch of the liner. Anecdotally, the majority of muscle locations were found to be at the level of the seal indicating that a different liner or method of suspension may be necessary for use with a prosthesis to avoid interfering with EMG quality, causing excessive pressure at the EMG sites, or disrupting the seal leading to a loss of suspension.

There were several limitations of this study. The sample size was small and the residual limb sizes and shapes of the subjects with a transfemoral amputation were similar. The similar limb shapes is likely due to the fact that the subjects were recruited from a convenience sample of individuals also enrolled in a powered knee and ankle prosthesis study. These individuals are relatively strong and higher level ambulators, which could be influenced by the length and shape of their residual limb. This sample may make the muscle locations found in the study generalizable for people walking on the powered leg, but further investigation may be necessary to determine the applicability for people with other residual limb characteristics.

In addition to limited variation between residual limb shapes, all of the subjects have had their amputations for a minimum of 13 years. Given the time since amputation, the muscles in their residual limbs are likely to have become higher in fat content and decreased in muscle.[7-10] These muscle composition changes may have not been as far along in people with new amputations, which may affect the location of muscles' areas of greatest contraction.

In addition to limitations due to the sample, there were also limitations to the study design. Given that the area of greatest contraction was determined through palpation, it is possible that a stronger EMG signal maybe found in a slightly different location. The measurement technique also assumed a cylindrical shape of the residual limb.

Muscle locations that were determined while wearing the liner assumed that the dome placed on the skin of the residual limb remained over the area of greatest contraction given the difficulty of palpating muscle contraction locations through the liner. It is possible that some of the variations in muscle locations while wearing the liner could be attributed to skin movement rather than muscle movement. Finally, while the subjects were asked to completely doff and reflect the liner prior to redonning, there was a relatively short period between donning sessions. It is possible that given longer time between donning sessions, there would be greater deviation in muscle location on the liner.

The results from this study will help to decrease EMG set up time on people with a transfemoral amputation. Future development may help to produce a set of generic grid liners based on the muscle locations found in this study that can capture relevant EMG information for the control of a powered transfemoral prosthesis.

Conclusion

Generalizable muscle locations were found in both people with a transfemoral amputation and people with intact limbs. The generalizable muscle locations may help to reduce set up time for EMG collection in people with a transfemoral amputation.

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Appendices

Appendix A: Demographic information for subjects with a transfemoral amputation.

Subject ID	Gender	Side	Cause of amputation	Predicate suspension	Age (yrs)	Time since amputation (yrs)	Height (m)	Weight (kg)
TF1	M	L	Trauma	Silesian belt	56	42	1.86	111.6
TF2	F	R	Trauma	Lanyard	66	58	1.65	68.0
TF3	F	R	Trauma	Subischial vacuum	50	28	1.65	61.7
TF4	F	R	Cancer	Seal-in suction	52	37	1.63	68.0
TF5	F	R	Infection	Pin	58	34	1.75	69.4
TF6	M	R	Trauma	Subischial vacuum	69	42	1.75	86.2
TF7	M	L	Cancer	Seal-in suction	32	13	1.93	104.0
TF8	M	L	Trauma	Skin fit suction	61	48	1.80	83.9
TF9	F	R	Cancer	Skin fit suction	31	17	1.71	70.3
Avg [sd]	--	--	--	--	56 [11]	35 [14]	1.75 [0.10]	80.4 [17.5]

Appendix B: Demographic information for subjects with intact limbs.

Subject ID	Gender	Side	Age (yrs)	Height (m)	Weight (kg)
AB1	M	L	33	1.91	93
AB2	M	R	29	1.81	74
AB3	M	L	27	1.83	70.3
AB4	F	R	25	1.70	54.4
AB5	F	R	25	1.68	55.8
AB6	F	R	25	1.63	56.7
AB7	M	R	28	1.85	97.1
AB8	F	L	24	1.70	72.6
AB9	M	R	23	1.87	108.9
Avg [sd]			**26 [3]**	**1.78 [0.10]**	**75.9 [19.7]**

Appendix C: Limb measurements for subjects with a transfemoral amputation.

	Contralateral limb measurements	Residual limb measurements			
Subject ID	**Trochanter to knee center (cm)**	**RL length (cm)***	**% limb remaining***	**Circumference at horizontal reference (cm)**	**Distal circumference (cm)**
TF1	42.5	24	56%	43	37.5
TF2	41.5	24.3	58%	42.9	39.5
TF3	41	26	63%	34	24
TF4	41.5	27	65%	45.2	41
TF5	41.5	27.8	67%	47.7	33.4
TF6	42	29.5	70%	46	41
TF7	52	37.8	73%	53.3	36
TF8	39.8	29	73%	48	43.8
TF9	36.2	30	83%	49.3	39
Avg [sd]	**42.0 [4.2]**	**28.4 [4.1]**	**68% [8%]**	**45.5 [5.4]**	**37.2 [5.8]**

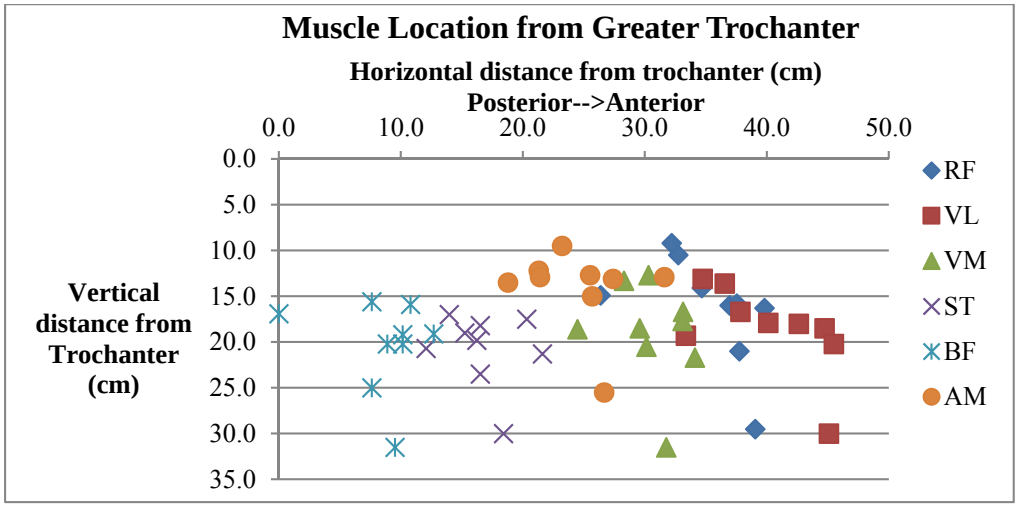
*Measured from greater trochanter

Appendix D: Limb measurements for subjects with intact limbs.

Subject ID	**Trochanter to knee center (cm)**	**Circumference at horizontal reference (cm)**	**Distal circumference of thigh proximal to femoral condyles(cm)**
AB1	41.5	60.4	45
AB2	37	53	39
AB3	32	54.5	39.5
AB4	38.5	49.5	36
AB5	32.7	50	35.2
AB6	36.2	52.5	35.5
AB7	31.2	63	44.5
AB8	39.5	58.8	43.2
AB9	33.2	65.5	49.5
Avg [sd]	**35.8 [3.7]**	**56.4 [5.8]**	**40.8 [5.0]**

*Measured from greater trochanter

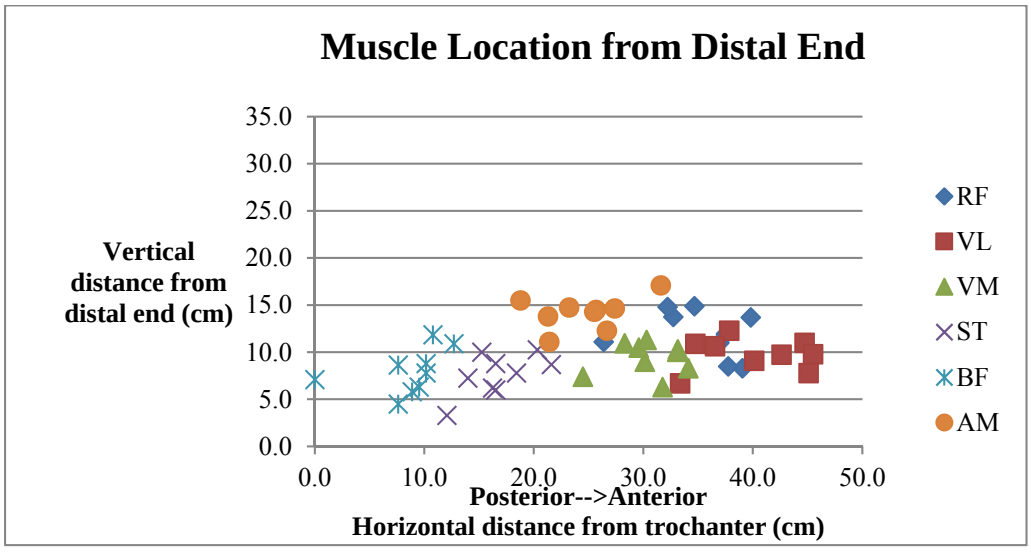
Appendix E: Area of greatest contraction for all six muscles (RF, VL, VM, ST, BF, and AM) of all subjects with a transfemoral amputation referenced to the greater trochanter.



Appendix F: Average location of the area of greatest contraction for subjects with a transfemoral amputation.

	RF (cm)	VL (cm)	VM (cm)	ST (cm)	BF (cm)	AM (cm)
Horizontal distance from trochanter	35.2 [4.2]	40.1 [4.7]	30.5 [3.0]	16.8 [3.0]	8.6 [3.6]	24.6 [3.9]
Vertical distance from trochanter	16.4 [6.0]	18.6 [4.9]	19.0 [5.5]	20.8 [4.0]	20.4 [5.0]	14.1 [4.5]
Vertical distance from distal end	12.0 [2.5]	9.8 [1.7]	9.3 [1.7]	7.6 [2.2]	8.0 [2.4]	14.2 [1.7]

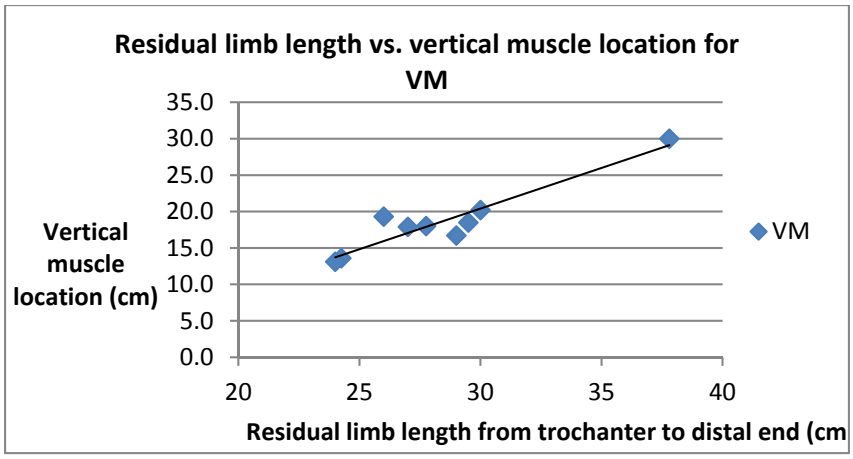
Appendix G: Area of greatest contraction for all six muscles of all subjects with a transfemoral amputation referenced vertically from the distal end and horizontally from the greater trochanter.



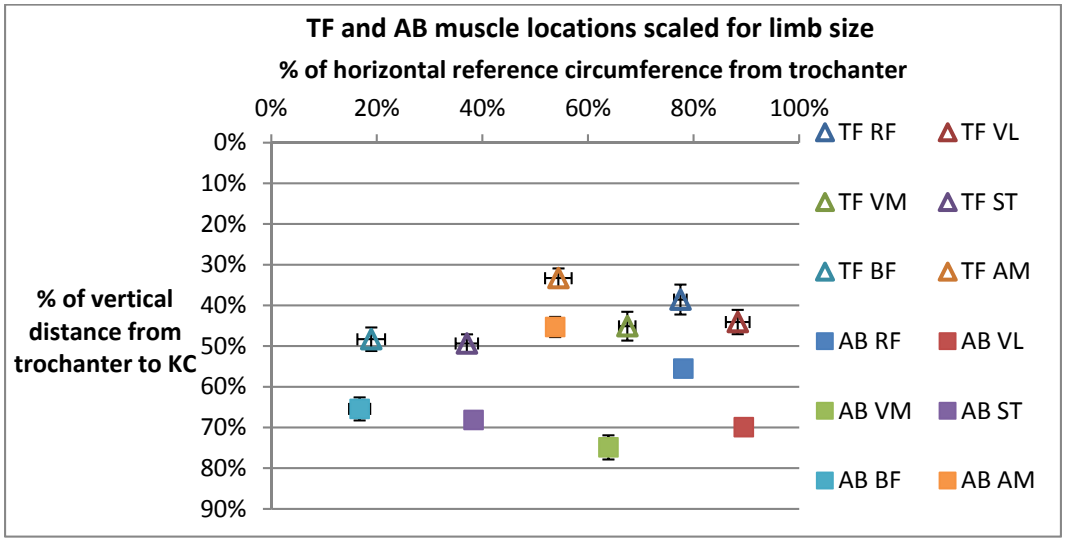
Appendix H: Pearson correlation values between vertical location of the area of greatest contraction and limb length measurements.

Correlations between vertical muscle location and:	RF	VL	VM	ST	BF	AM
Contralateral trochanter to KC length	0.69	0.66	0.61	0.74	0.73	0.84
Uncompressed residual limb length	0.94	0.94	0.98	0.86	0.88	0.92
Compressed residual limb length	0.94	0.95	0.99	0.86	0.91	0.91

Appendix I: Sample plot for VM comparing residual limb length to vertical location of area of greatest contraction.



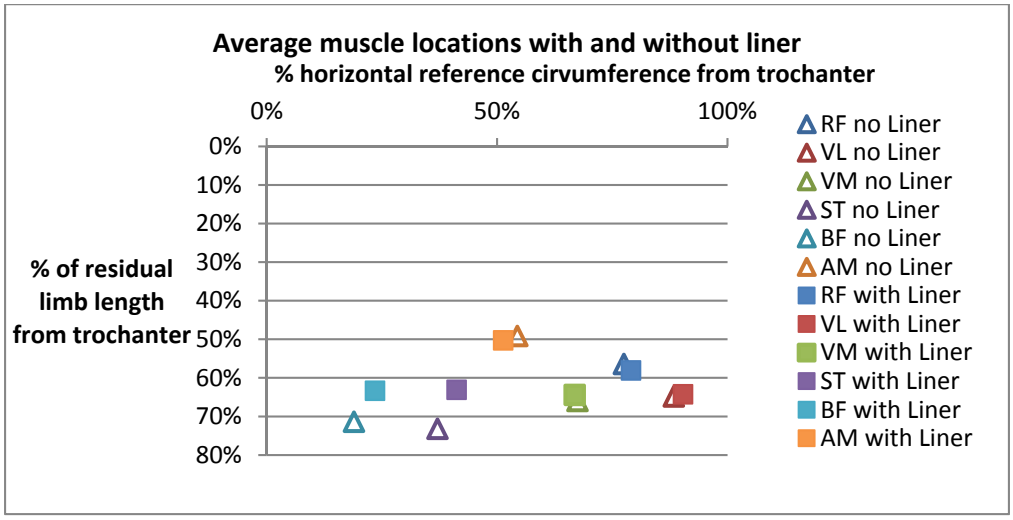
Appendix J: Scaled muscle locations for both subjects with a transfemoral amputation and subjects with intact limbs referenced to the greater trochanter. Horizontal locations are scaled by the horizontal reference circumference. Vertical locations are scaled by the distance from greater trochanter to knee center.



Appendix K: Scaled muscle locations for both subjects with a transfemoral amputation and subjects with intact limbs.

	Scaled location by:	RF_x	RF_y	VL_x	VL_y	VM_x	VM_y	ST_x	ST_y	BF_x	BF_y	AM_x	AM_y
Transfemoral	Contralateral KC	77% [4%]	38% [12%]	88% [7%]	43% [8%]	67% [5%]	42% [10%]	36% [6%]	48% [6%]	18% [8%]	48% [9%]	53% [7%]	33% [7%]
	Residual limb length	77% [4%]	57% [13%]	88% [7%]	64% [9%]	67% [5%]	65% [10%]	36% [6%]	73% [8%]	18% [8%]	72% [9%]	53% [7%]	50% [8%]
Able-bodied	Contralateral KC	78% [3%]	56% [6%]	90% [3%]	70% [5%]	64% [3%]	75% [8%]	38% [3%]	68% [5%]	17% [6%]	65% [8%]	54% [2%]	45% [7%]

Appendix L: Scaled muscle locations both with and without a liner on for subjects with a transfemoral amputation.



Outcome Testing of Two Commercially Available Myoelectric Hands with Wrist Rotation Units Using Pattern Recognition on Transradial Amputees.

A Prosthetic Resident Research Project

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December 12, 2016

Abstract

In-lab testing of two commercially available hands, one a multifunctional hand, the other a one degree of freedom hand. Both hands also were tested with wrist rotation units using Pattern Recognition (*PR)* on three individuals with a right transradial amputation; two of the three subjects had also undergone Targeted Muscle Reinnervation *(TMR)* for neuroma management. After the test subjects were fitted and trained on the devices, subjects were evaluated using the following outcome measures: Box and Block Test, Clothespin Placement Task, the Southampton Hand Assessment Procedure *(SHAP)* and *a Hand/ Wrist Evaluation Questionnaire*. Both hands could be controlled with commercially available PR, however the multifunctional hand was more challenging for the research subjects.

Introduction

Approximately 1.6 million Americans live with limb loss and 40,000 of those amputees have upper-limb loss (*ULL*). Millions of others, around the world also are affected by ULL. Dysvascular disease, with and without diabetes as a comorbidity and trauma are some of the leading causes for limb loss (1).

The loss of an upper limb can greatly effect everyday activities for the amputee. The range and scope of the challenges the amputee faces vary greatly but, in general, upper limb amputations present as a loss or significant reduction in bimanual motor function and dexterous hand movements in the affected limb(s). The inability to easily perform activities of daily living results in a reduction in the quality of life for the person affected by ULL (2).

Advancements have been made in externally powered upper limb prosthetics and multifunctional hand and wrist rotation units have allowed for new possibilities that were somewhat limited prior to these advanced devices. Multiple-degree of freedom (DOF) prostheses

may better allow amputees to perform many daily complex tasks like opening a lid of a jar or cutting food (3) (4) (5).

Multifunctional hands provide additional grip options for amputees, but being able to truly utilize the additional functions can be challenging, and the controls in these latest myoelectrical prostheses appears to be the weak link. For upper-limb amputees, there are traditionally very few ways to be able to control externally powered prostheses. If myoelectrical control is used as the input, then traditionally you would use direct control, a pair of electromyographic (*EMG*) electrodes placed over the agonist-antagonist muscle belly to control both directions of movement of the motor used in the prosthetic component. Additionally, other control strategies like co-contraction or double open can act as triggers or mode switches which can be utilized to alternate between multiple motors in the system but can be awkward for the user (6), (7).

Targeted Muscle Reinnervation (TMR) is another recent advancement that can assist in prosthetic control, where a broader spectrum of EMG information of additional individual muscle activity is made available but requires different control strategy to fully capture and take advantage of this added information (8). With TMR, nerves in the residual limb are redirected and transplanted to denervated donor muscle sites, which will reinnervate in time and provide new purposeful connections with the muscles they now control. The newly targeted muscles enable amputees to gain additional simultaneous control over prosthetic components (9). Even with this additional EMG data that TMR can deliver, traditional two-site myoelectric control are unable to fully harness this additional information and thus do little to help the users control the more complex multifunctional prosthetic hands or effectively control multiple simultaneous movements (2).

One innovative and emerging prosthetic control system, called Pattern Recognition (*PR*), was developed to address some of the current short comings of traditional externally powered prosthetics. PR uses multiple EMG signals as well as algorithms to gather and classify the muscles activity. This additional EMG information, coupled with the PR algorithms, has the potential to allow the prosthetic user much greater control over higher DOF prostheses while also feeling more intuitive to operate (10).

With the introduction of TMR, PR and increasing multiple-DOF devices, another challenge is how best to quantify the user's ability to harness this advanced technology. One way is to use a real-time virtual reality (*VR*) test that uses a multiple-DOF classifier that provides real-time closed-loop performance measures to capture how well test subjects complete arm motions. One such test is the Target Achievement Control Test (*TAC Test*). (11) Virtual training has also shown to increase effective strategies for improving controlling phantom limb movements for the user. Powell's research study, training in such an environment, found that "The transradial research subjects saw an average increase in movement completion percentage from 70.8% to 99.0%, an average improvement in normalized movement completion time from 1.47 to 1.13, and an average increase in movement classifier accuracy from 77.5% to 94.4% ($p<0.001$)." (12)

Purpose

This research project was a part of a larger study to confirm the ability of up to six (4 transradial non-TMR, and 2 TMR) subjects to control three hands: the Michelangelo multifunctional hand (*MAH*) (Ottobock, Austin, TX), Bebionic hand (Steeper, San Antonio, TX), and VariPlus Speed hand (*1-DOF*), (Ottobock, Austin, TX), along with wrist rotation units, using Coapt's commercially available PR control system. To evaluate PR control with a physical

device, users performed functional outcomes with each device and pre-study/post-study VR TAC testing.

The initial research study protocol and subject questionnaire were developed, and the initial recruitment was performed within this portion of the research paper timeline, and will extend into the larger study. However, due to delays in development of the Bebionic hand, the scope of this portion of the research project was revised to test two commercially available hands (the Michelangelo multifunctional hand (*MAH*), (Ottobock, Austin, TX) and VariPlus Speed hand (*1-DOF*), (Ottobock, Austin, TX), with wrist rotation units. Both systems were used to evaluate three users' ability to control the devices with PR. Also, pre-study training and virtual reality testing were only completed and was not included in the findings. This research project had IRB approval from Northwestern University.

Materials and Methods

To help reduce time and resources in switching out components between visits, two separate quick interchange suspension interface (*ISI*) units were specifically designed and utilized in this research project (Fig. 1). These devices consisted of three thermoplastic struts that secured the Ottobock lamination collar or the Axon Rotation wrist connector (Fig. 2) to the test subjects Vivak transradial sockets by way of velcro. A neoprene cuff was also designed to hold all of the electronics required for each system, including the EMG preamplifier, Coapt controller, calibration switch, battery and device controller when necessary. This cuff could be wrapped around the socket or around the upper arm.

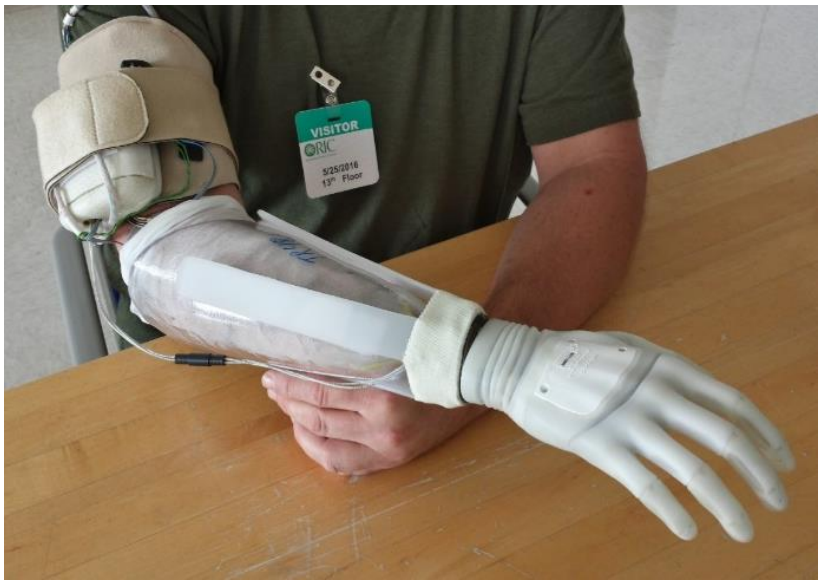


Figure 1: *Left* Quick interchange suspension interface for attaching the hand to the wrist and socket.
Figure 2: *Right* Transradial subject using the Michelangelo hand with a wrist rotator during testing.

The test subjects were measured and fitted with an appropriate fitting Iceross silicone liner (Ossur, Foothill Ranch, CA) or Alpha Classic upper limb liner (Ohio Willow Wood, Mt. Sterling, Ohio) with a lanyard strap that held the thermoplastic socket onto the subjects' arm. The liners had eight sets along with ground snap electrodes attached by the best judgment of a certified clinical prosthetist strategically over the main flexion and extension muscle groups of the forearm in a grid-like pattern.

After the electrodes were attached, an impression was taken of the research subjects' residuum over top of the liner and electrodes domes. A clear thermoplastic socket was fabricated from the modified positive model. Self-adhesive velcro strips were placed on the socket to allow the ISI unit to secure the hand to the socket. One of the added benefits of this ISI system was that it allowed us to custom position the hand at the most appropriate length and angle for each subject's prosthesis by quickly moving one or more of the velcro struts to flex/ extend, radial

deviate or lengthen the wrist/ hand with ease.

Pictures along with documentation were used to capture the initial setup for each subject and much care was taken to ensure that the liner was donned in the same orientation and the correct PR color coded wire snaps attached to the corresponding electrode for each visit. In figure 3, an example PR liner and electrode setup is shown. Electrode wires were held in place with coban to prevent them from being distracted during socket donning.

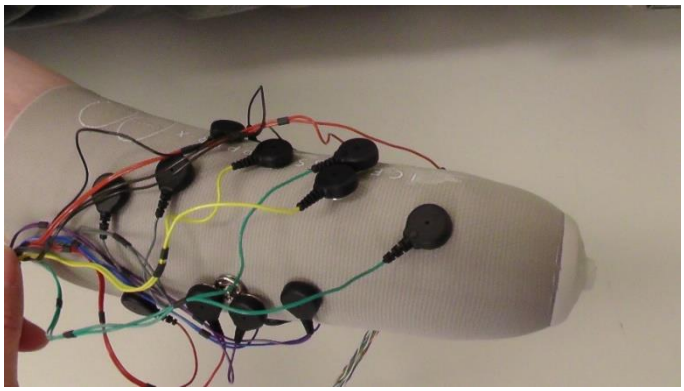


Figure 3: Silicone liner with PR electrode and snaps connected.

The inclusion criteria were that the subjects needed to be at least eighteen years of age, have had a right transradial amputation and prosthetic user at least twelve months prior to recruitment, and live in the greater Chicago area. Subjects were limited to right side amputations due to the availability of the hand systems.

A total of three research participants completed our research study protocol (Table 1). Two of the test subjects were middle-aged males with transradial limb loss who used a myoelectric device with a multifunction hand. The other subject was a young male in his twenties who used a body powered hook. Two of the subjects also had prior TMR surgery. All three subjects were right hand dominant prior to having right transradial amputations secondary to trauma. The medium age of the participants was forty-three.

Subjects	Age	Side	Handed-ness (Pre-Amputated)	Home Device
A.	51	Right TT	Right Hand Dominance	Myo – PR – Bebionic Hand
B.	25	Right TT	Right Hand Dominance	BP – 5XA Hook
C.	53	Right TT	Right Hand Dominance	Myo – DC – Bebionic Hand

Table 1

After the test subjects were fitted, they had both VR control practice working with a licensed OT, and physical acclimation to the hands/ wrist devices. Subjects were tested using the following outcome measures:

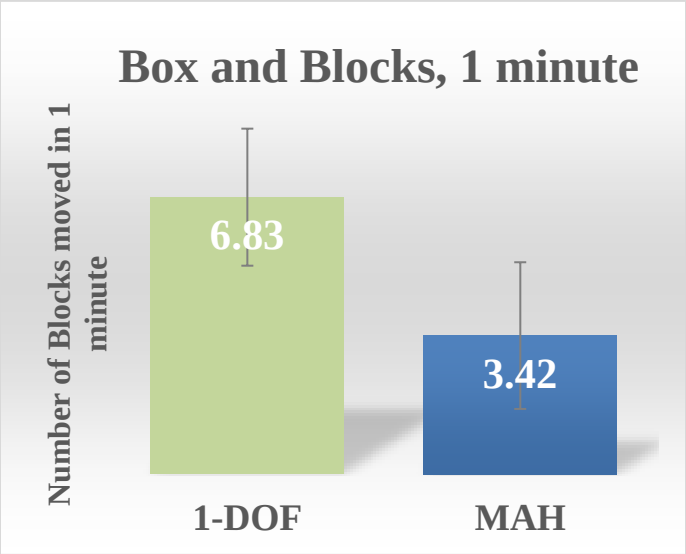
- Box and Block Test (13),
- Clothespin Placement Task (6), and
- Southampton Hand Assessment Procedure (*SHAP*) (14).

A *Hand/Wrist Evaluation Questionnaire* (Appendix A) was also used to document subjective impressions of each device. The survey used was comprised of sixteen closed-ended questions and incorporated a five order Likert scale. The survey was not validated but provided subjective information that was deemed useful for our current and future research.

Control testing of a virtual hand and wrist was to be evaluated pre-training and post-training. The virtual hand and wrist assessment provided feedback of efficiency and speed of the users' control and was gathered through using the Target Achievement Control Test. Practice with the virtual hand and wrist in the early stage of the socket casting and fitting also provided the users feedback, which can positively motivate them using pattern recognition control (15).

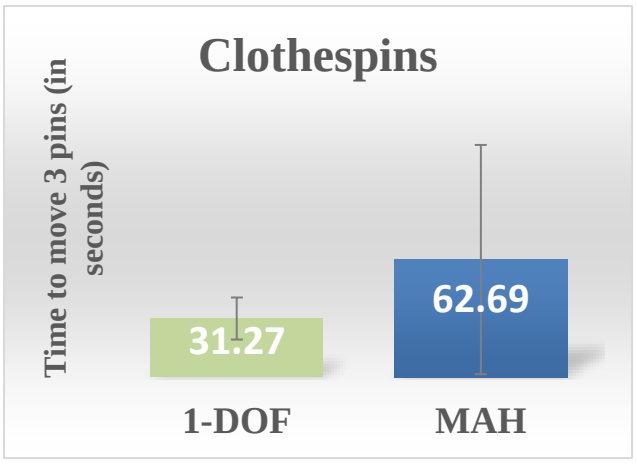
Results

In the one-minute Box and Blocks outcomes test, the subject try to pick up as many small wooden blocks in one box and move them over to the adjacent box in one minute. Each subject performed 3 trials of the Box and Blocks for each hand/wrist combination. The 1-DOF system had an average block count for all three subjects in all three trials of 6.83 ± 1.69. However, the same test on the MAH yielded fewer blocks. With the MAH system, only 3.42 ±1.81 blocks were successfully recorded (graph 1).

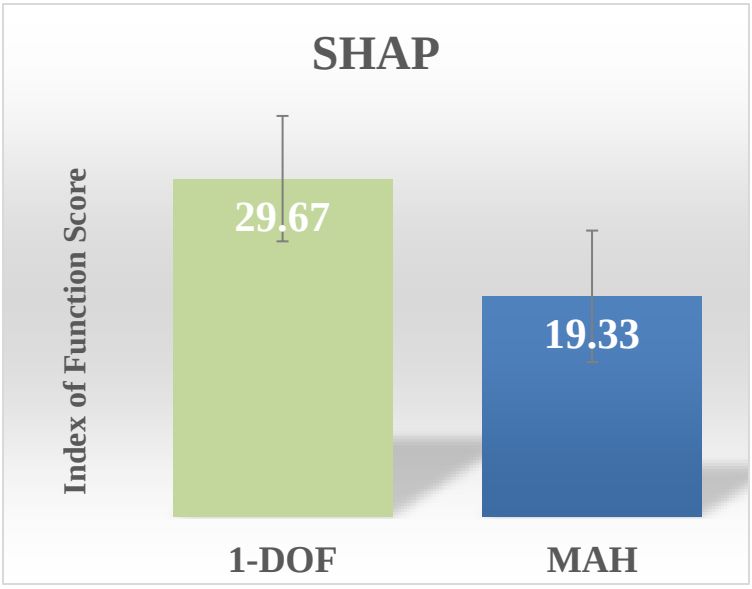


graph 1

In Clothespins outcomes test the subject moves three clothespins from one horizontal bar to a vertical bar in front of them are timed and encouraged to use the prosthetic rotation wrist instead of compensatory body movement. Similarly, times scores were lower on the MAH than the 1-DOF system at 62.69 ±61.11 and 31.27 ±11.21 seconds respectively (graph 2). Test subject (A) struggled greatly during his first trial with the MAH, in which it took him 213.63 seconds to complete the test. With this data point removed, the average was 32.5 ±8.53 seconds.



graph 2



graph 3

Lastly, the SHAP test has the subject perform 26 timed tasks, fourteen of which fall into ADL-like tasks and eight abstract object tasks repeated with light and heavy objects that can be classified into six prehensile patterns with an overall index of function score of 0 (minimum) to 100 (maximum) based on non-amputee controls.(14) The SHAP had an average Index of Function Score of 29.67 ± 5.51 with the 1-DOF system, while the average MAH score was 19.33 ±5.77 (graph 3).

The *Hand/Wrist Evaluation Questionnaire* handout, along with the numbered responses in graph form for both 1-DOF and MAH on all three research subjects, can be found in Appendix A and B. Although the results on the surveys were insightful, they were never intended to be statistically relevant to this study. However, the subjects scoring and responses do give subjective information that can be useful in future research and developments.

Conclusions

Both the 1-DOF and MAH wrist/ hand systems could be controlled by Coapt's commercially available PR system and subjects were able to perform all of the outcome tests. The multifunctional Michelangelo hand was more challenging to control for the test users, and this can be seen in the results of the timed outcome tests. There may be a couple reasons for this. We were working with early enhanced versions of the commercially available software for the Michelangelo hand and some minor software optimization settings needed to be adjusted during the course of our testing which may have restricted the hand's full potential. One subject specifically struggled with the system during multiple sessions as this was resolved, which may have frustrated him enough to lose confidence in the system overall.

Some limitations in the study were the small sample size, hardware delays, and necessary software optimizations. Future studies would also benefit from increasing the sample size. We had a limited number of participants. A larger pool of subject would better represent the ULL population. The research subjects also had limited time to acclimate to the hands/wrist. This was most evident in the multifunctional Michelangelo hand. Additionally, it is likely that additional VR training time would improve their control and grip selections which would most likely lead to improved outcome times. Implementing future home trials would allow the users time to acclimate to the PR prosthesis, which would paint a more accurate picture of how well PR can control multifunctional hand and wrists.

Acknowledgements

I would like to acknowledge and thank The Center for Bionic Medicine and the director Dr. Kuiken for the support and the resources made available to help make this research project and residency such an incredible learning opportunity. There are a few specific individuals that I also need to recognize for their help. Dr. Hargrove, the project director, provided a wealth of knowledge and guidance for this study and working with him was a real honor. Dr. Miller, CP, the lead Prosthetist and residency project mentor, is another individual who helped facilitated both the freedom to take on responsibilities, while creating an environment of support. And lastly, I would like to thank Kristi Turner, OTR/L for also being such a great resource and for being a vital part of this research project.

Levi Hargrove, PhD, Director, Neural Engineering for Prosthetics & Orthotics Lab
Todd Kuiken, MD, PhD, Director, Center for Bionic Medicine
Laura Miller, CP, PhD, Research Scientist/Prosthetist and Project Mentor
Kristi Turner, OTR/L, Research Occupational Therapist

Funding: This project is funded by an SBIR Grant (National Institutes of Health grant number 5R44HD076496-03). The prosthetic research residency is also completed *under a grant from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR grant number 90RE5014). NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this paper do not necessarily represent the policy of NIDILRR, ACL, or HHS, and you should not assume endorsement by the Federal Government.*

Disclaimer: Coapt LLC was launched in 2012 and has a technology transfer and license agreement with the Rehabilitation Institute of Chicago for the development of certain control technologies. Several current and former members of the Center for Bionic Medicine at RIC have management and ownership interests in Coapt LLC.

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Appendix A.

SBIR Hand/ Wrist Evaluation Questionnaire

For administrative use only:

Study Staff Member:_____ Date survey completed:_____

Subject Code:_____

Comparison to your previous device(s):

_____

Please circle one: Lab trial – 1 2 3 TD – A B C

Test subject instructions:
Please complete the following survey based on your experience with the control system you have been using for the most recent test period. If you require additional room for your comments, please continue on the back of this survey.
Please answer the following questions by circling the number which most accurately represents your opinion, for example, circling #5 would indicate that you strongly agree with the statement. Selecting #3 would indicate no opinion.

1. The prosthetic hand responded as I expected.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

2. I felt that I had to watch the hand when I was moving it.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

3. It was easy to make the prosthetic hand move when I wanted.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

4. There were a lot of unintended movements of the prosthetic hand.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

5. I was frustrated using the prosthetic hand.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

6. The prosthetic hand moved at a desirable speed.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

7. The prosthetic wrist responded as I expected.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

8. I felt that I had to watch the wrist when I was moving it.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

9. It was easy to make the prosthetic wrist move when I wanted.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

10. There were a lot of unintended movements of the prosthetic wrist.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

11. I was frustrated using the prosthetic wrist.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

12. The prosthetic wrist moved at a desirable speed.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

13. It was hard to perform two-handed tasks.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

14. It was hard to plan my movements.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

15. I felt fatigued after using the system.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

16. I would like to continue to use this control at home.

Strongly Disagree 1 2 3 4 5 Strongly Agree N/A
Comments: _____

Additional comments:

_____

_____

_____

_____

_____

Following the final trial please answer the following questions:

I preferred

Please circle one: Lab trial – 1 2 3

Please provide comments on why you selected this trial:

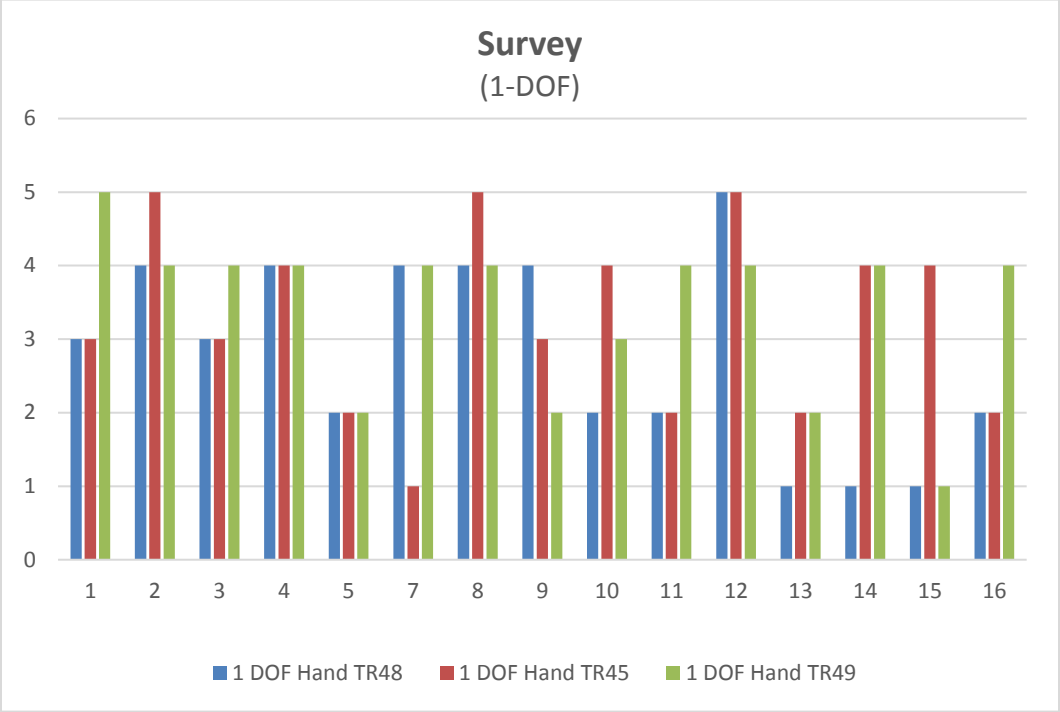
_____

_____

_____

_____

Appendix B.


Survey
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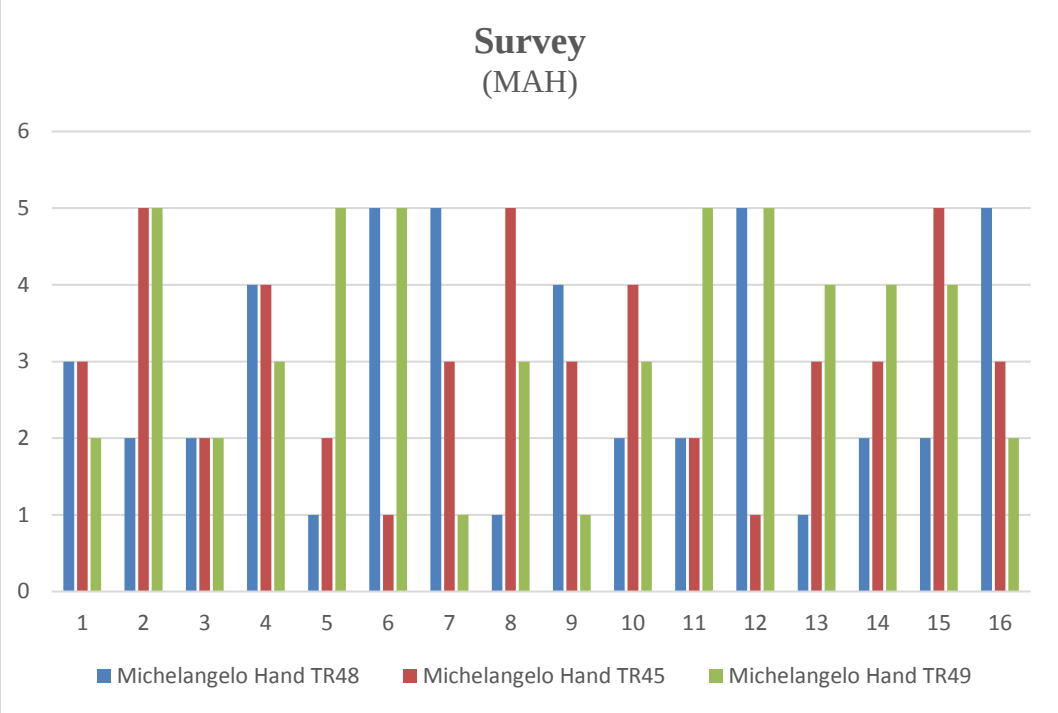
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Development and Evaluation of a Novel Connector, the Magnetic Locking Interface (MLI), for attachment of a Lower Limb prosthesis

A Prosthetic Resident Research Project

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My prosthetic research residency project involved the development and testing of a novel connector to attach a lower limb prosthesis to the user. This connector, the Magnetic Locking Interface (MLI), attaches a lower limb prosthesis to the user through a prosthetic liner. Various types of connectors and locking mechanisms are often used in conjunction with a prosthetic liner to suspend a prosthesis from the user's residual limb. However, the current options for locking mechanisms have limitations. The goals of the project were (1) to refine the existing design of the MLI connector to improve its clinical viability, and (2) to test the MLI in a laboratory setting with human subjects with lower limb amputations and compare it to a commercially available pin locking system.

The MLI is composed of two sections: a proximal section, which bolts onto a standard prosthetic liner, and a distal section, which is fabricated into the bottom of a prosthetic socket. Both sections contain magnets, which pull the MLI together. Once the magnets are engaged, there is an external latch that the user closes, providing a mechanical lock to keep the MLI from rotating or separating. In a pin locking system, a cylindrical pin that contains notches around its circumference is secured to the liner. There is also a locking system that is fabricated into the prosthetic socket. When the user inserts the pin into the lock, a spring-loaded catch extends into the notches on the pin, preventing the pin from pulling out.

Figure 1. *(A) MLI, separated with latch open. (B) MLI, engaged with latch closed. (C) Pin and lock, separated. (D) Pin and lock, engaged.*

The development phase of the project is ongoing and has involved collaboration with a larger design team that includes engineers, prosthetists and a physician. One of the focuses of design development is to reduce the size of the MLI such that it is comparable to commercially available locking mechanisms. Another focus is to alter the MLI design so that the connector is easier to attach to a prosthetic liner and a prosthetic socket, ultimately making the design more viable in a clinical setting. A final focus of the development phase of the project is to select the most appropriate materials for the MLI, including materials for the structural elements of the design and the actual magnets used in the connector.

Currently, the human subjects testing phase of the project is approximately half-way finished. Individuals with transfemoral amputations are completing an IRB-approved protocol in the laboratory setting that involves using a prosthesis with the MLI connector and comparing it to a prosthesis with a commercially available pin locking mechanism. The target number of subjects for the study is 7. Currently, the 4th subject is at the beginning stages of the protocol. During testing, the MLI has been exposed to the similar forces and moments during dynamic activities as the pin system and has proven to be robust in those conditions. Preliminary results also suggest that the MLI provides superior control of socket rotation relative to the residual limb compared to the pin system. This is a significant finding because minimizing movement of the socket relative to the residual limb is a primary goal of prosthetic fitting in that it improves the user's control over their prosthesis. Other preliminary results suggest that there is minimal difference in the time and effort to don and doff a prosthesis using the MLI compared to the pin system. This is another significant finding because the convenience and ease of use is one of the primary advantages of the pin system, which has been replicated with the MLI.

Overall, we believe that the MLI connector could pose benefits over some current options for mechanisms that suspend a lower limb prosthesis. Furthermore, we believe that the current study will demonstrate those benefits in a scientific manner. After the target number of subjects completes the experimental protocol, we

hope to publish the results of this study in a peer-reviewed journal. Additionally, we plan to present this work at 1 or more conferences that are relevant to the prosthetics community.