Determining the Potential Benefit of Powered Prostheses

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Specific Aims

In 2005, 1.6 million people in the United States were living with limb loss and this number is projected to more than double to 3.6 million by the year 2050, due, in part, to the increased prevalence of diabetes[1] and increased amputations from military combat. With prosthetic technology, most individuals with lower limb loss are able to remain physically active. The World Health Organization (WHO) advises people with disability to undertake regular exercise and walk as much as able bodied individuals [2, 3]. However, persons with transtibial amputation (TTA) are less likely to get the suggested amount of physical exercise[5] and correspondingly are at a greater risk of death from cardiovascular disease[6]. The reduction in activity may be attributed to a 10 - 30% increase in energetic cost during walking in persons with TTA compared to able-bodied individuals [7-11]. Almost all commercially available prostheses are passive elastic devices that can only provide about half of the power that a human ankle generates [12-14]. Thus additional muscular effort from the residual limb[12] or compensation from their intact limb may be required. With this in mind, it is easy to speculate that persons with TTA will fatigue faster than able bodied individuals, but as yet, this has not been tested. *The goal of this project is to* determine how the addition of power to the push-off phase of gait affects the amount of effort required to walk, the time of muscle fatigue onset, and overall activity level of patients with TTA.

Twelve adults with transtibial amputations will participate in four test sessions; two with their clinically prescribed unpowered prostheses and two with a prosthesis that provides mechanical power during push-off. We will test the following aims:

Aim 1: Determine if the addition of prosthetic ankle power reduces energetic costs and compensatory muscle activity during gait. Measures of indirect calorimetry (VO2) can provide an estimate of metabolic costs and a reflection of the net muscle activity. Simultaneous measures of metabolic cost and muscle activity via electromyography (EMG) may indicate the contribution of muscle activity patterns to whole body metabolic costs [15]. We will measure metabolic costs and EMG, bilaterally (where possible), from sixteen lower limb muscles during walking. We will test the hypotheses:

H1a: Muscle activity in the intact limb will decrease when ankle power is provided.

H1b: The observed changes in metabolic costs and EMG will be positively correlated.

Aim 2: Determine if the addition of ankle power delays the onset of muscular fatigue during an extended bout of walking. On each visit, participants will walk continuously for 30 minutes, or until voluntary exhaustion, while movement kinematics and muscle activity (EMG) are recorded from 10 muscles (gluteus maximus, iliopsoas, rectus femoris and biceps femoris bilaterally, and the gastrocnemius and tibialis anterior on the intact limb only). We will calculate EMG median power frequencies as well accepted measures of neuromuscular fatigue. We will test the following hypotheses:

H2a: The addition of ankle power will delay the onset of fatigue in the residual limb hamstrings and the intact limb plantarflexors as measured by a decrease in the slope of the mean power frequency of the EMG signals, thus enabling patients to walk for a longer duration.

H2b: Participants will perceive that walking is easier when power is supplied.

Aim 3: Determine if the addition of ankle power increases physical activity level, community reintegration and quality of life. It is important to promote physical activity in the amputee population as they often have significant comorbidities and face challenges in conventional exercise approaches. Studies have shown that people with transtibial amputation take far fewer than the recommended 10,000 steps per day, potentially leading to a decline in mobility over time (Stepien et al. 2007). If a powered prosthesis makes walking less energetically costly, then patients may walk for longer durations, improving their quality of life, and enabling them to 're-integrate' into their communities. Activity level and location of activity (from GPS) will be monitored for two weeks with each prosthesis. We will quantify quality of life using questionnaires including the Prosthetic Evaluation Questionnaire (PEQ) and SF-36. . We will test the following hypothesis:

H3a: Subjects will have a higher activity levels and be physically active outside the home more during the time they wear the powered prosthesis.

H3b: Subjects will report higher levels of quality of life after wearing the powered prosthesis for two weeks compared to their levels after wearing their prescribed prosthetic for two weeks.

The experiments proposed here will help determine if the lack of powered push-off is a limiting factor for patients with TTA and if filling this gap will enable them to increase their overall activity level. This line of research will help us fulfill our long-term goal of determining what features of prosthetic devices are the most influential in successful outcomes for patients with TTA and designing a lost-cost device that optimizes these features.

Research Strategy

Significance

Significance of Lower Extremity Amputation: In 2005, 1.6 million people in the United States were living with limb loss. Of these, there are close to 1 million who are below the age of 65 and 302,000 below the age of 45 years. These individuals will "have prosthetic and health service needs for many years to ensure high-quality, active, and productive lives"[1]. Additionally, the number of persons with limb loss is projected to more than double to 3.6 million by the year 2050, in part due to the increased prevalence of diabetes. Importantly, these numbers exclude amputations performed at Veterans Health Administration hospitals and those resulting from armed conflict. Thus the true number is likely more than 10 percent higher[1].

State of Current Prosthetic Technology: As the number of people with amputation has increased, so has the available technology. There are currently more than 50 prosthetic feet commercially available[16]. Despite the presence of this technology, persons with unilateral transtibial amputation (TTA) still exhibit walking patterns that are significantly different from healthy individuals. Specifically, TTA gait is characterized by slower walking speeds[17], decreased step length and time on their prosthetic limb compared to their intact limb[18, 19], increased loading on their intact limb[20, 21], and asymmetric lower extremity kinematics and kinetics[21]. Additionally, individuals with TTA expend 10 to 30% more energy during walking than able-bodied individuals[7-11].

The main reason for these differences is that individuals with TTA are missing the ankle plantarflexors which are essential to body support, forward propulsion, and initiating leg swing[22-24]. Current commercially-available prosthetic ankles are predominantly passive-elastic devices that consist of carbon fiber springs. These springs can store and release energy when in contact with the ground, but cannot perform net work, and only produce about an eighth the power of the intact gastrocnemius and soleus muscles[25, 26]. This deficit causes individuals with individuals with TTA to compensate at other proximal joints and with their intact limb.

In an effort to 'normalize gait', recent research has focused on the design of devices capable of supplying additional power for push-off. Several devices have been proposed, including the spring ankle with regenerative kinetics (SPARKy) at Arizona State University[27], the AMP-Foot from Vrije Universiteit Brussel[28], and the controlled energy storage and return (CESR) foot at University of Michigan[29]. At present, however, there is only one commercially available ankle prosthesis that can provide net positive work during walking: the BiOM (iWalk, Bedford, MA, USA). This device uses a series-elastic actuator and reflexive control to provide power during push-off[30]. An onboard microcontroller is used to provide real-time adaptation in ankle position and power based on activity type[31].

Cost/Benefit of Adding Ankle Power: While technology continues to advance in the direction of increased power, it remains unclear whether this additional power can be incorporated into the body effectively by the user. It is crucial to examine these effects to determine if the benefits warrant the nearly 3 fold increase in price. Only a few recent studies have begun to examine patients in these devices. Herr and Grabowski found reduced energy costs across a range of speeds when patients with unilateral TTA wore the BiOM compared to passive elastic prostheses[32]. A second study, done while the PI was at the Brooke Army Medical Center in San Antonio, TX, looked at gait in 11 patients with unilateral TTA during walking over level ground[33], on stairs[34], and on an uneven rock surface[35]. On all the surfaces, the BiOM led to increased walking speed, peak ankle plantarflexion angle and peak ankle power generation. Participants also completed prosthetic evaluation (PEQ) and preference questionnaires as part of this study. Of 10 participants that completed the forms, 7 preferred the BiOM while 3 preferred their current prosthesis. The amount of ankle power that the device generates is variable and can be set by the prosthetist. Participants responded that they preferred greater levels of ankle power[33]. One limitation of this study is that we used a subset of the amputee population that was highly active and trained military personnel who received months of intense training. Thus it is unclear whether the results will extend to a less active population without this extensive training. In this study, we did not quantify patient use of device during their three week acclimation period, so we do not know how often they actually wore the prosthesis.

Additionally, we only looked at gait in the laboratory over a few steps, so we do not know how the patients would respond to walking over a long duration. Finally, neither study looked at muscle activity to see how changes in energy costs or kinetics might be linked to muscle activation patterns. Therefore*, there is a significant need for further evaluation of the device in a less active patient group, during longer duration walking, both in the lab, and their daily lives*. These studies will help us determine what, if any, clinical benefits there are to adding external ankle power in this population.

Approach

We will recruit 12 adults with unilateral transtibial amputation through the University of Michigan (U-M) Orthotics and Prosthetics Center. Prosthetists will target patients with a functional level of K-2 to K-4 on Medicare's 5-level functional classification scale (K-0 to K-4) who self-report difficulty walking long distances. We will then quantify their position in each level using the Amputee Mobility Predictor Score without their prosthesis (AMPnoPRO)[8]. A K-2 level corresponds to a AMPnoPRO score between 25.28 and 31.36, while a K-3 level corresponds to a score greater than 31.36 of 38 total points[36]. Using a health history questionnaire, potential subjects who have any history of serious cardiovascular, neurological, respiratory, or visual problems or who are taking medications that might interfere with their capacity to perform the required tasks will be excluded.

- Inclusion Criteria
  - Adult (over 21 yrs)
  - Has unilateral transtibial amputation
  - Has used prosthesis for at least 6 months
  - Is currently using an unpowered prosthesis or the BiOM
- Exclusion Criteria:
  - History of orthopedic or neurologic disorders to their intact limb
  - History of cardiovascular disease
  - Unable to walk for 30 minutes at a time

Patients will come to the laboratory for four separate visits (Fig. 1). First they will come to the lab wearing their clinically prescribed unpowered prosthesis. They will be consented, screened to ensure eligibility in the study, and given a clinical evaluation of range of motion and strength. On this first day in the laboratory, half of the participants will be fitted with a powered prosthesis (BiOM, iWalk, Cambridge, MA) by a certified prosthetist. They will then do a brief training with them in the clinic. The other half of the participants will be tested in their current prosthesis. All subjects will then fill out several questionnaires, followed by metabolic and muscle activity testing (described in detail below). On their next visit (within one week), participants will return to the lab for a biomechanical gait analysis and fatigue testing. They will then be given an activity monitor and mobile phone two weeks of at home monitoring. After this period, they will be fitted with aParticipants will then undergo the same procedrues with their prescribed prosthesis (Group 1) or the BiOM (Group 2). Participants will be asked to wear the same footwear for all testing sessions.

Questionnaires: On the first visit, patients will complete a health history questionnaire to ensure eligibility as well as the AMPnoPRO to determine their functional level. During Sessions 1 & 3, participants will be questioned about their pain level, medications they are taking, and socket discomfort or sores. They will also be asked to complete a survey of different activities that they are, or are not, able to accomplish when wearing the different devices. Quality of Life (QoL) surveys will be administered after each period of home monitoring period when the participants return the monitoring devices. General health related quality of life will be measures with the Medical Outcomes Study 36-Items Short-Form Health Survey (SF-36) while condition-specific QoL will be measured with the Prosthetic Evaluation Questionnaire (PEQ) (Legro et al. 1998). The SF-36 is a widespread generic measure with documented validity and reliability (Ware and Sherbourne 1992, Beaton et al. 1997, Andresen and Meyers 2000). The results are presented in eight separate scales each one representing different dimensions of health related QoL; Physical Functioning, Role functioning from a Physical Perspective, Bodily Pain, General Health, Vitality, Social Functioning, Role functioning from an Emotional perspective and Mental Health. Each scale can take a value between 0 and 100 and a higher figure represents better health (Hagberg et al. 2008). The PEQ consists of 82 questions that describe the function of a lower-limb prosthesis and assess prosthesis-related quality of life. The questionnaire is divided into ten functional scales, addressing four major domains: prosthetic function, mobility, psychosocial experience, and well-being. Finally, we will have the patients complete a Prosthetic Evaluation Questionnaire (PEQ) for each device[17] and a Prosthetic Preference

Questionnaire at the conclusion of the study. Participants will mark which device they prefer on a 100 mm visual analog scale from BiOM to Current Prosthesis[33].

Metabolic Testing: Energy costs will be estimated from O_2 consumption and CO_2 production measured by a portable metabolic system (K4b^2, Cosmed, Rome IT)[37]. Participants will be instructed not to eat for two hours prior to testing. They will be fitted with a portable system that consists of a mask that covers the nose and mouth, a collection unit that attaches to the front and back of a harness about the torso, and a base station where the data is recorded. To capture a baseline recording, the participants will be asked to remain seated and still for a period of five minutes. They will then walk on a treadmill for a period of 5-10 minutes. The speed of the treadmill will be set to a value that approximates their self-selected walking speed[18], based on their leg length, *l*, according to $Speed = \sqrt{Fn \cdot g \cdot l}$, where *Fn* is the Froude number and *g* is gravity[38]. Steady-state is generally reached after the first couple of minutes and will be determined by observing a plateau in the graph. Once this plateau is reached, the participant will walk for an additional three minutes at steady-state.

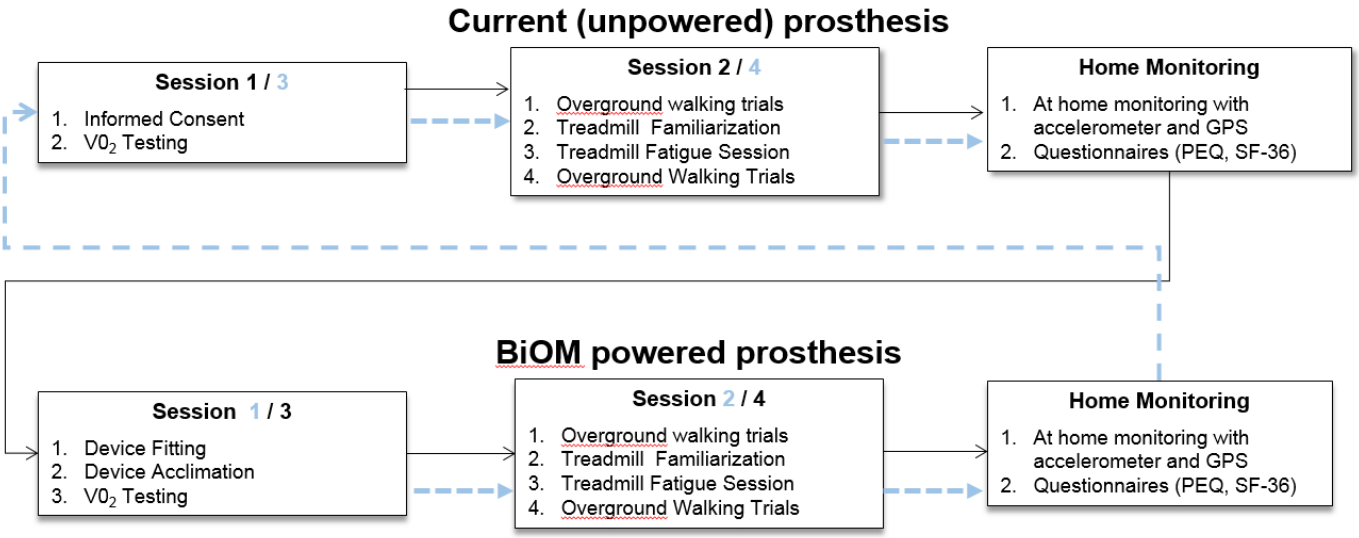

Figure 1. Experimental Design. Group 1 will be tested first in the BiOM powered prosthesis and then in their current unpowered prosthesis (blue dashed line). Group 2 will be tested in their current prosthesis and then the BiOM (solid black).

Perceived Effort: Participants perceived effort during walking will be quantified using ratings of perceived exertion (RPE) according to a Borg CR-10 scale[39, 40], on which subjects subjectively rate their level of effort on a scale from 0 ("none at all") to 10 ("maximal exertion"). Participants will only be questioned at the end of the metabolic testing session as they will be wearing a mask during the duration of the treadmill walking trial.

Muscle Activity Testing: During the treadmill walking period, sixteen pairs of pre-amplified electromyography (EMG) surface electrodes will be attached to the muscles of the gluteus maximus, gluteus medius, iliopsoas, rectus femoris, vastus medialis, and biceps femoris bilaterally, and the gastrocnemius (medial and lateral), soleus, and tibialis anterior on the intact limb only. Electrodes will be positioned over each muscle according to accepted recommendations [41] and data will be collected at 1080 Hz.

Gait Analysis: Kinematics and kinetic data will be collected before and after an extended bout of walking. Markers will be placed on the lower extremities using a six degree of freedom marker set[42]. The 3-D movements of these markers will be recorded continuously during all trials at 120 Hz using a 12-camera motion capture system (Motion Analysis, Santa Rosa, CA). Participants will walk back and forth across an 8-m walkway until at least five trials for the right and left side with full kinematics and kinetics are obtained. Walking trials will be performed at both the same controlled speed as treadmill trials, and free walking speed.

Fatigue Testing: During the fatigue trial, participants will walk on a treadmill at a slightly faster than comfortable (+10% controlled or up to10% incline) speed for 30 minutes or until they feel that they can no longer continue.

Ratings of perceived exertion (RPE) will be recorded on the modified Borg scale[39, 40] on which subjects subjectively rate their level of fatigue on a scale from 0 ("none at all") to 10 ("maximal"). RPE will be taken every two minutes. Heart rate will also be monitored using a Polar heart rate monitor (Polar Electro Inc., Lake Success, NY). Lower extremity kinematic and electromyography data will be collected continuously throughout this session. Participants will be able to stop the testing at any time they feel they can no longer continue walking.

Activity Monitoring: Our study will employ accelerometers to objectively measure physical activity levels and step count, as has been done previously in subjects with prosthetics (Chou et al. 2009, Albert et al. 2013). Specifically, an ActiGraph Link accelerometer (ActiGraph, Pensacola, Florida) will be secured to the participant's prosthesis. The ActiGraph Link is a waterproof device that measures 3.5 x 3.5 x 1 cm and weighs 14 grams. The sampling frequency will be set to 30 Hz, which will allow for 14 days of raw data collection. Using data from the ActiGraph Link we will calculate the total volume of activity, average acceleration per day, the average acceleration during the participant's most active 5 hours, and number of steps taken per day. We can also examine only activity that occurs in bouts (i.e., activity that lasted for at least 3 minutes). Finally, we will calculate these outcomes for the time periods where the subject was inside their home and the time periods when they were in the community. This will be achieved by linking the time-stamped accelerometer data to time-stamped latitude and longitude data derived from a global positioning satellite data (GPS). Participants will be given a mobile phone with GPS capabilities to carry during the study period. Given known problems with obtaining GPS signals indoors, the subject will be considered in their home during the time when the GPS waypoints are within 75 meters of their home (and subsequent time if the signal is lost) until the time when the GPS waypoints are consistently further than 75 meters from their home. Although the mobile phone will need to be carried by study participants, and charged nightly, mobile phones have the advantage of collecting both GPS and wireless local area networks (Wi-Fi) data. Thus we can further refine a participant's location by examining recorded available Wi-Fi networks. We will utilize the iEpi platform on the mobile phone to obtain these data. iEpi is an end-to-end mobile phone application for collecting and analyzing data (Hashemian et al. 2012). iEpi can transmit these data in encrypted form from the device to secure servers during the study period to check on patient compliance. Depending on the participant's phone, we may be able to collect these data using their own phone by loading the iEpi mobile application on their phone, which would further aid in compliance.

Fatigue Testing Only in Prescribed Prosthesis

We will also recruit 10 subjects for the fatigue session testing only. Participants will come to the lab for one testing session lasting about 4 hours. Subjects will be compensated $20 per hour for their time. The protocol for the fatigue session is the same as listed above with the same inclusion criteria. These subjects will be consented separately for this session only and will not receive the BiOM or complete any other testing.

STATISTICAL PLAN AND DATA ANALYSES

Aim 1: Determine if the addition of ankle power reduces energetic costs and compensatory muscle activity during gait.

Data Analysis: The metabolic cost of transport (COT) will be calculated for patients when wearing their clinical prescribed passive prosthesis and the powered BiOM. This measure has been used previously to evaluate the performance of various prosthetic devices[43-45]. The COT is defined as the metabolic energy needed to transport unit weight a unit distance according to:

$$COT = E_m/(Body\ Weight\ *\ Distance\ Traveled) \quad (1)$$

where the body weight for a person with TTA consists of the weight of the participant plus the weight of any prosthetic component worn[45]. The distance traveled will be obtained by multiplying the treadmill speed by the time period over which the total energy is calculated. We will estimate the metabolic energy expenditure, E_m,

from the rate of oxygen consumption and carbon dioxide production recorded by the portable metabolic system[46]. The metabolic rate during the rest period will be subtracted from the gross rate during walking to give the net metabolic rate. The cumulative metabolic energy consumed will be plotted versus time. When the plotted data show a line of constant slope, steady state energy consumption will be assumed. Only the steady state portion of the energy versus time curve will be used to compute the COT for each walking trial[45].

The raw EMG signals will be filtered and processed in Matlab (Mathworks, Natick, MA). The data will be demeaned, filtered to a band width of 20-400 Hz, and then smoothed using a 6 Hz low pass filter. Smoothed data will be time-normalized to 0 to 100% of the gait cycle based on the heel contact times. Integrated EMG (iEMG) will be calculated for each gait cycle. Differences in metabolic costs (ΔCOT) and muscle activity (ΔEMG) between prostheses will be calculated to identify relationships between variables.

Statistical Analyses and Hypothesis Testing:

A paired t-test will be performed to test for differences in muscle activity between prostheses. Differences in metabolic costs (ΔCOT) and muscle activity (ΔEMG) between prostheses will be calculated to identify relationships between variables. Correlation and regression analyses will be performed on ΔCOT and ΔEMG to identify whether observed significant differences in EMG activity are associated with metabolic costs of walking [15]. We will use the results of these analyses to test the following hypotheses:

H1a: Muscle activity in the intact limb will decrease when ankle power is provided.

H1b: The observed changes in metabolic costs and EMG will be positively correlated.

Power Analysis: Using the five individual data points from Mancinelli [47] for metabolic costs, we calculated the effect size to be 1.302 (G*Power). Therefore, we would need 10 subjects to detect a significant difference in metabolic cost between the BiOM and ESR prostheses. Prior work varying the stiffness of an ESR prosthesis found significant changes in muscle activity in 12 participants [48]. Therefore, we believe a sample size of 12 should provide sufficient power to detect the larger differences in muscle activity expected by the more significant change in prosthesis. This is supported by the large changes seen in iEMG for preliminary data in two individuals walking with and without the prosthesis providing ankle power (Gardinier and Gates 2015).

Aim 2: Determine if the addition of ankle power delays the onset of muscular fatigue during an extended bout of walking.

Data Analysis: We will assess changes in dynamic fatigue using the EMG data recorded during the fatigue trials. Traditional measures of mean power frequency will be calculated to determine the fatigued state of the muscle. We will also calculate the *instantaneous* mean power frequency (IMPF) using wavelet transform methods, which are more accurate and robust for analyzing nonstationary signals[49] (Fig. 2). We will follow the procedures described by Hostens et al.[49]. Briefly, a continuous wavelet transform of the signal is taken in Matlab. The power density function or 'Scalogram' of the continuous wavelet transform is:

$$SCAL(\tau, s) = \left|CWT(s, \tau)\right|^2 \quad (2)$$

where s represents the scale (frequency band) and τ is time. The instantaneous mean frequency (IMPF) is then calculated by:

$$IMPF = \frac{\int_{ls}^{hs} s \times SCAL(s)\, ds}{\int_{ls}^{hs} SCAL(s)\, ds} \quad (3)$$

where ls is the lowest scale of interest and hs is the highest. As the muscle fatigues, the IMPF decreases. Therefore the slope of this line will be used as a measure of fatigue rate and compared between the two devices.

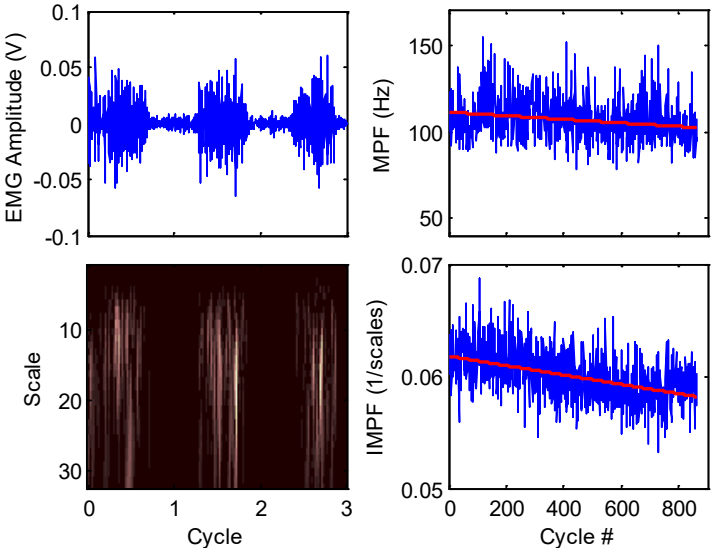

Figure 2. Illustration of the process of measuring muscle fatigue from EMG[4] **Top Left:** The raw amplitude of the EMG signal from a previous study of upper extremity repetitive movements. This same data is represented as a scalogram (**Bottom Left**). High scales represent low frequencies. Data for both instantaneous (IMPF) (**Bottom Right**) and mean power frequency (MPF) (**Top Right**) showed a significant decreasing trend ($p < 0.001$). This correlation was stronger for IMPF ($R^2 = 0.22$) than MPF ($R^2 = 0.04$)

Statistical Analyses and Hypothesis Testing:
The primary dependent measures to be analyzed will be the EMG amplitude and duration, fatigue rate, and amount of fatigue. EMG amplitude and duration will be used to determine muscular effort. These values will be compared using a series of paired-tests to test for differences between prostheses (unpowered v powered). Recorded RPE measures will be subjected to a non-parametric ANOVA (Kruskal-Wallis test) to test for difference between prosthetic types in amount of fatigue. Fatigue rates (slope of the IMPF) will be compared using paired t-tests to test for differences between prosthetic types. We will use the results of these analyses to test the following hypotheses:

H2a: The addition of ankle power will delay the onset of fatigue in the residual limb hamstrings and the intact limb plantarflexors as measured by a decrease in the slope of the mean power frequency of the EMG signals, thus enabling patients to walk for a longer duration.

H2b: Participants will perceive that walking is easier when power is supplied.

Aim 3: Determine if the additive of ankle power increases physical activity level, community reintegration, and quality of life.

Data Analysis: The total volume of activity, average acceleration per day, and the average acceleration during the participant's most active 5 hours per day will be calculated in R using the GGIR package, an open source R-package for analysis of raw accelerometer data (http://cran.r-project.org/web/packages/GGIR/GGIR.pdf). The GGIR program 1) detects and corrects for: calibration error using local gravity as a reference (van Hees et al. 2014); unusually high sustained values (an indication of device malfunction); and non-wear and 2) calculates activity-related acceleration using all three axes (i.e., √(x^2+ y^2+ z^2)-1g). Step counts will be determined using the ActiLife Software package, ActiGraph's data analysis and management software program. GPS data will be imported and cleaned in Esri's ArcGIS and time intervals in the home and in the community will be determined by classifying each point as either within or outside a 75 meter Euclidean buffer around the home. GPS filtering algorithms will be applied. Given the number of subjects enrolled, we will have the ability to examine each file on an individual basis to make determinations about extraneous data points and integrate Wi-Fi data to help refine these calculations. Physical activity during the time intervals within the home versus in the community will then be calculated. Quality of life measures will be assessed using the PEQ and SF-36.

Statistical Analysis: Physical activity measures (i.e., total volume of activity, average acceleration, average acceleration during the participant's most active 5 hours per day, step counts) will be calculated for each day within the 2 week period. Since we are attaching the accelerometer to the prosthetic device, we do not need to specify a minimum threshold of wear time for a valid day (i.e., we do not need to require a specific number of hours and a minimum number of days of accelerometer wear time for a day to be considered valid). Daily activity levels will be averaged across all days in the two week period for an average activity level per day. Finally, we will compute the amount of time spent performing activities outside of the home and at the home for each prosthesis. These will be identified visually from GPS data. Comparisons between prostheses will be made using a series of paired t-test. We will use Wilcoxon's non-parametric test to test for differences between prosthetic devices in SF-36 and PEQ scores. We will use these results to test the hypotheses:

H3a: Subjects will have a higher activity level, and be active more outside the home during the time they wear the powered prosthesis.

H3b: Subjects will report higher levels of quality of life after wearing the powered prosthesis for two weeks compared to their levels after wearing their prescribed prosthetic for two weeks.

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Inclusion of Women and Minorities

Although it is not likely that different gender or minority populations would affect the results of the proposed research, we will try to recruit subjects so that the distribution of minorities among subjects match the distribution of minorities in the Ann Arbor population: American Indian or Alaskan Native 0.4%, Asian or Pacific Islander 6.6%, Black or African American 11.4%, Hispanic or Latino 2.6%. We anticipate the subjects will be predominately male, as there is a greater prevalence of amputation in the male population. A breakdown of the anticipated subject numbers is included.

Inclusion of Children

We do not intend to collect data on children.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Evaluation of a powered prosthesis on muscle activity, fatigue, and energy costs

Total Planned Enrollment: 12

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino	4	8	12
Ethnic Category: Total of All Subjects *			
Racial Categories			
American Indian/Alaska Native			
Asian		1	1
Native Hawaiian or Other Pacific Islander			
Black or African American		1	1
White	4	6	10
Racial Categories: Total of All Subjects *	4	8	12

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."