Cover Page

Title: What is the optimal stiffness and height of a running-specific leg prosthesis?

NCT #: N/A

Date of Document: 9/30/2014

COMIRB Protocol

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Project Title: What is the optimal stiffness and height of a running-specific leg prosthesis?

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I. Hypotheses and Specific Aims:

Our ***primary objective*** is to optimize prescription of **running-specific prostheses (RSP)** for Soldiers and Veterans with transtibial amputations by systematically varying RSP stiffness and height during running and sprinting.

Specific Aim 1: We aim to quantify the biomechanics (how someone moves), metabolic demands (how much energy is required to move), socket pressures (pressure within a prosthetic socket), and socket pistoning (axial displacement of the residual limb relative to the socket) of subjects with transtibial amputations using three brands (Ossur, Ottobock, and Freedom Innovations) of distance-running RSPs of different stiffness and height.

Hypothesis 1: The optimal stiffness and height distance-running RSP for each subject will minimize asymmetry and metabolic demand, without excessive socket pressure or socket pistoning.

Specific Aim 2: We aim to quantify the biomechanics, performance, socket pressures and socket pistoning of subjects with transtibial amputations using three brands (Ossur, Ottobock, and Freedom Innovations) of sprint-running RSPs of different stiffness and height.

Hypothesis 2: The optimal stiffness and height sprint-running RSP for each subject will minimize asymmetry and maximize top speed, without excessive socket pressure or socket pistoning.

II. Background and Significance:

Currently, there are no science-based objective methods for prescribing **running specific leg prostheses (RSPs)**. Thus, existing clinical practices waste time, money, and resources and do not necessarily optimize RSP prescription for Soldiers with leg amputations. Our **overall goal** is to develop a science-based method for optimal prescription of RSPs so that Soldiers and Veterans with leg amputations can regain the greatest possible level of functional ability and return to an active lifestyle and/or active duty.

Over one million people in the United States live with lower leg amputation (Adams, Hendershot, & Marano, 1999; CDC, 2005) and this number continues to grow appreciably due to the increased prevalence of diabetes and ongoing military conflicts. Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and unaffiliated conflicts have accounted for more than 1200 major limb amputations (Fischer, 2010). It is estimated that the number of Americans living with limb loss will more than double, to 3.7 million, by 2050 (Adams et al., 1999; CDC, 2005). Though advancements in prosthetic device designs have led to improved clinical outcomes, a significant number of individuals develop debilitating secondary physical conditions such as osteoarthritis, osteoporosis and chronic back pain due to asymmetrical loading patterns and increased loading of the remaining musculoskeletal structures. In addition, ill-fitting prostheses may result in inactivity, which increases the risk of cardiovascular disease and diabetes. Due to the severity of impairment caused by an amputation, it is extremely important to improve prosthetic prescription.

Previous studies of non-amputees with serious health challenges show a positive effect of recreational activities on functional capacity and quality of life (Garg et al., 2009; Nakamura et al., 2008; Wohlgemuth et al., 2008). In a study that assessed Veterans with amputations, Gailey et al. (Gailey et al., 2010) found that the use of *specialty-sports prosthetic devices* was significantly associated with a high functional ability and higher quality of life. Thus, it is very desirable to maximize the functional ability of Service Members with limb loss and increase their use of

specialty-sports prosthetic devices, such as RSPs, to improve their quality of life. Use of modern lower limb RSPs can enable individuals to comfortably participate in activities such as recreational running, and allow some athletes to perform and compete at elite levels. Despite the high-level performances of elite Paralympic athletes with leg amputations, remarkably little is known about how prosthetic stiffness and height affect running and sprinting performance (Buckley, 2000; Grabowski et al., 2010; McGowan, Grabowski, McDermott, Herr, & Kram, 2012; Weyand et al., 2009; Wilson, Asfour, Abdelrahman, & Gailey, 2009). Therefore, it is imperative to comprehensively understand the underlying effects of prosthetic stiffness and height in order to develop more appropriate prosthetic prescriptions, improve functional outcomes, and decrease disability.

Specialized carbon-fiber RSPs (Fig. 1) emulate the spring-like function of biological tendons and ligaments during level-ground steady-speed running (Ker, Bennett, Bibby, Kester, & Alexander, 1987) and allow considerable elastic energy return (Bruggemann, Arampatzis, Emrich, & Potthast, 2008). However, unlike biological legs, passive-elastic RSPs cannot generate mechanical power anew (Czerniecki, Gitter, & Beck, 1996), cannot vary stiffness (McGowan et al., 2012), nor can the prosthetic foot be dorsiflexed to allow foot-ground clearance during the swing phase. Because RSPs cannot adapt in a manner comparable to a biological limb, people with an amputation typically have asymmetrical biomechanics (Grabowski et al., 2010; McGowan et al., 2012) and may initially have increased metabolic demands. Nevertheless, studies show that after individuals re-learn to run and their prostheses are fine-tuned, their metabolic costs are eventually comparable to those of non-amputees (Brown, Millard-Stafford, & Allison, 2009; Weyand et al., 2009; Wygand et al., 2010). If a prosthetist could initially prescribe an RSP with an optimal stiffness and height, Service Members with amputations may be able to more easily re-learn to run and more quickly realize normative biomechanical symmetry and metabolic demands.

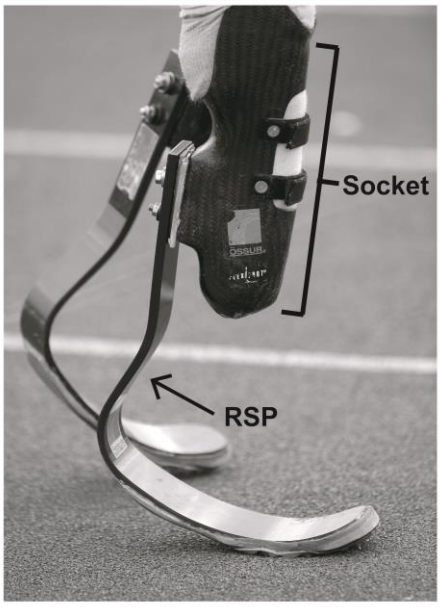

Figure 1. J-shaped carbon fiber sprint-running running-specific prostheses (RSPs) attached to the socket of an athlete with bilateral trans-tibial amputations.

III. **Preliminary Studies/Progress Report:**

We do not yet know how prosthetic stiffness affects overall leg stiffness while running and sprinting. During running in non-amputees, the overall biomechanics of the body are well-characterized and predicted by a spring-mass system that represents the body's mass as a point mass and the legs as mass-less linear springs (Blickhan, 1989; Brughelli & Cronin, 2008; Farley & Ferris, 1998; Farley, Glasheen, & Mcmahon, 1993; He, Kram, & McMahon, 1991; McMahon & Cheng, 1990). During the first half of the stance phase of running, the kinetic and gravitational potential energies of the body are stored as elastic energy in the leg. During the second half of the stance phase, this elastic energy is returned to the body. At slow to moderate speeds (2–6 m/s), previous studies have shown that leg stiffness is independent of speed in non-amputees (Farley et al., 1993; He et al., 1991; McGowan et al., 2012; Morin, Dalleau, Kyrolainen, Jeannin, & Belli, 2005). Thus, an optimal distance-running RSP stiffness for an individual with a unilateral amputation would be expected to result in an overall affected leg + prosthesis stiffness that is equal to the overall unaffected leg stiffness. This optimal stiffness would likely minimize biomechanical asymmetry and metabolic demand. At speeds greater than 6 m/s, non-amputee runners progressively increase their leg stiffness with speed (McGowan et al., 2012). Thus, it is probable that a stiffer prosthesis is required to maximize top speed (McMahon & Greene, 1979). Given that the biological leg spring compresses by only 2.0-2.5 cm during the stance phase of running (Farley & Gonzalez, 1996; McGowan et al., 2012), changing the height of an RSP by just one cm could also profoundly affect the dynamics of the spring mass model.

The potential effects of increasing leg prosthetic height were brought to light in the 2012 Paralympic games. It appeared that athletes with bilateral transtibial amputations were able to boost their speed by increasing the height of their RSPs. The International Paralympic Committee (IPC) recently changed its rules for the allowable height of a leg RSP ("IPC Athletics Classification Rules and Regulations: 3.2.10.10 Determining prosthesis length for lower limb amputees," 2011). The new measurement techniques utilized by the IPC in combination with the range of allowable heights have resulted in a rule that seems to dramatically affect bilateral amputee performance. Though the fairness of the new IPC rules for competitive athletics may be in question, there is a possibility that increasing the height of a leg prosthesis for Soldiers with bilateral amputations could enhance their ability to run at their maximum speed. No one has yet analyzed the effects of prosthetic height on performance.

IV. Research Methods

Our ***primary objective*** is to optimize prescription of **running-specific prostheses (RSP)** for Soldiers and Veterans with transtibial amputations by systematically varying RSP stiffness and height during running and sprinting. Three major prosthetic manufacturers (Ossur, OttoBock and Freedom Innovations) have agreed to donate distance-running RSPs and sprint-running RSPs for our proposed study. Prior to our experimental measurements on human subjects, we will quantify the stiffness of each prosthesis using an MTS mechanical testing machine within the Department of Mechanical Engineering at the University of Colorado Boulder.

A. Outcome Measure(s):

All outcome measures are shown in Figure 2. These outcomes include leg stiffness, leg symmetry, peak forces, metabolic costs, performance, peak socket pressure, and maximum socket motion, which will be derived from ground reaction forces, metabolic rates, top speeds, socket pressure, and socket pistoning. The descriptions for each of these outcomes and measures are explained in more detail in the study design and research methods section below.

B. Description of Population to be Enrolled:

Specific Aim 1. We will recruit 15 runners; ten with unilateral and five with bilateral transtibial amputations that currently use and have at least one year of experience with distance-running RSPs. Subjects will be between 18-55 years old and have no current problems with their prosthesis or residual limb. There will be no restrictions on sex, race, or ethnicity for inclusion. Subjects will be at a K4 Medicare Functional Classification Level, which is defined as a person who has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Subjects will have no known cardiovascular, pulmonary, or neurological disease or disorder. These inclusion/exclusion criteria will minimize any potential confounding variables, thereby increasing the internal validity of the proposed studies. Any person matching the inclusion criteria of the study, regardless of race or gender, will be recruited to participate.

Specific Aim 2. We will recruit 15 sprinters; ten with unilateral transtbial amputations and five with bilateral transtibial amputations that currently use and have at least one year of experience with sprint-running RSPs. Subjects will be between 18-55 years old and have no current problems with their prosthesis or residual limb. There will be no restrictions on sex, race, or ethnicity for inclusion. Subjects will be at a K4 Medicare Functional Classification Level, which is defined as a person who has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Subjects will have no known cardiovascular, pulmonary, or neurological disease or disorder. These inclusion/exclusion criteria will minimize any potential confounding variables, thereby increasing the internal validity of the proposed studies. Any person matching the inclusion criteria of the study, regardless of race or gender, will be recruited to participate.

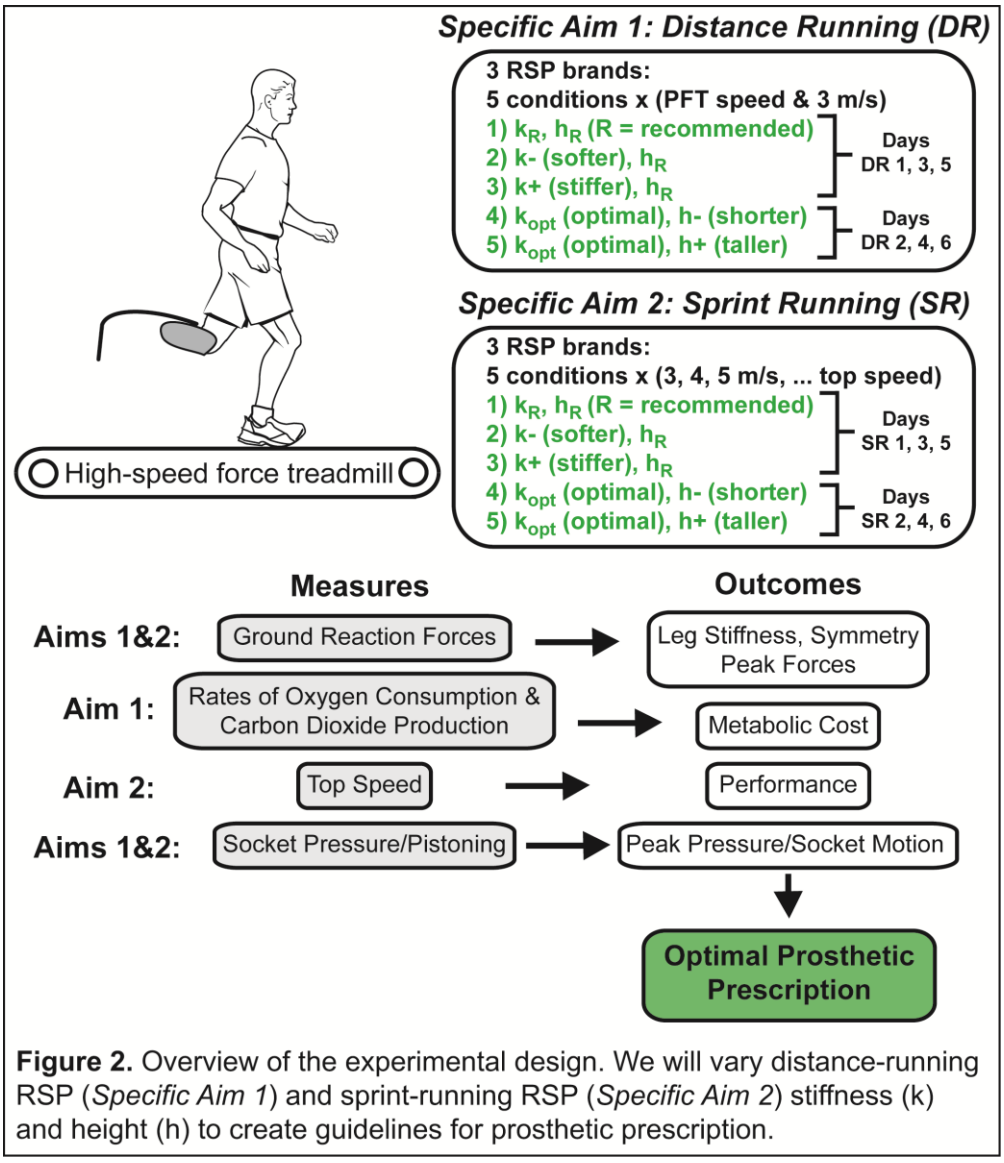

Figure 2. Overview of the experimental design. We will vary distance-running RSP (*Specific Aim 1*) and sprint-running RSP (*Specific Aim 2*) stiffness (k) and height (h) to create guidelines for prosthetic prescription.

C. Study Design and Research Methods

The study will be a repeated-measures design. We will calculate subject and group averages for each condition from data normalized to a gait cycle. The data analyzed will include: leg stiffness, peak vertical and horizontal ground reaction forces, stance time, leg swing time, metabolic costs, top speed, peak socket pressure, and maximum socket motion. We will use repeated measures analysis of variance (ANOVA) to compare each variable across all conditions. Any significant differences will be further analyzed with either a Tukey HSD or Newman-Keuls follow-up procedure. In the case of an unequal number of subjects, we will use a Sheffe follow-up procedure. We will use $p < 0.05$ as a criterion for determining statistical significance. All statistical analyses will be performed with JMPIN software (JMPIN, SAS Institute, Cary, NC).

Specific Aim 1. Subjects will complete six experimental sessions at the University of Colorado Locomotion Lab; each session on a separate day and requiring approximately two hours of time. During each experimental session, subjects will run at two speeds, the speed required for their age/sex 50th percentile PFT (Physical Fitness Test) 2 mile run and a standard speed of 3 m/s on a force measuring treadmill while we measure their ground reaction forces, metabolic demand, socket pressures, and socket pistoning. Subjects will run with three different brands (Ossur,

Ottobock, and Freedom Innovations) of distance-running RSPs with three different stiffnesses at one height and three different heights at one stiffness of each brand, a total of five or more different conditions per brand at two speeds. Individual trials will be five minutes long with at least 2 minutes rest between trials.

Day DR0: Subjects will be asked to give informed written consent and then will be fit and aligned by a certified prosthetist with three different distance-running RSP brands, one from each company. We will measure each subject's height, weight, and limb segment lengths. Then, we will select an RSP stiffness category based on the subject's weight and manufacturer's recommendation. An appropriate RSP height for each subject will be chosen according to conventional practice. Our prosthetist will ensure that the prosthetic fit and alignment are adequate. Then, subjects will have time to accommodate to treadmill running with each distance-running RSP.

Day DR1: We will first vary the distance-running RSP stiffness (k) while keeping height (h) at the traditionally recommended level. Subjects will use an RSP with the manufacturer's recommended stiffness category based on their weight, an RSP that is one category softer (k-) and an RSP that is one category stiffer (k+) than the manufacturer's recommended stiffness. We will measure ground reaction forces, metabolic demand, socket pressures, and socket pistoning while subjects run at the speed required for their age/sex 50^{th} percentile PFT (Physical Fitness Test) 2 mile run and at 3 m/s, a total of six trials. If the data warrant it, we may add an additional stiffness category to further fine tune the optimal stiffness. The optimal stiffness (k_{opt}) distance-running RSP will be the RSP that minimizes metabolic cost. This RSP stiffness will be used for Day DR2.

Day DR2: We will keep RSP stiffness constant (k_{opt}) and vary the distance-running RSP height (h). Subjects will have used an RSP with an optimal stiffness (k_{opt}) at the recommended height (h_R) on day Day DR1. On Day DR2, they will also use and RSP with an optimal stiffness (k_{opt}) that is 2 cm shorter (h-), and 2 cm taller (h+). We will measure ground reaction forces, metabolic demand, socket pressures, and socket pistoning while they run at their PTF speed and at 3 m/s; a total of four trials. If the data warrant it, we may further fine tune RSP height in 1 cm increments. We will analyze the results of DR2 to identify the optimal height (h_{opt}) for each subject for one brand of a distance-running RSP.

Days DR3 and DR5: We will repeat the trials of Day DR1 and vary stiffness (k) for a different distance-running RSP brand. We will analyze the results of Days DR3 and DR5 to identify the optimal RSP stiffness (k_{opt}) to be used for Days DR4 and DR6.

Days DR4 and DR6: We will repeat the trials of Day DR2 and vary height (h) for a different distance-running RSP brand. We will analyze the results of Days DR4 and DR6 to identify the optimal height (h_{opt}) for each subject using the respective brand of a distance-running RSP.

Specific Aim 2. Subjects will complete six experimental sessions at the University of Colorado Locomotion Laboratory; each session on a separate day and requiring approximately two hours of time. During each experimental session, subjects will run and sprint over a range of speeds, from 3 m/s up to top speed on a force measuring treadmill while we measure their ground reaction forces, socket pressures, and socket pistoning. Subjects will run with three different brands (Ossur, Ottobock, and Freedom Innovations) of sprint-running RSPs with at least three different stiffnesses at one height and three different heights at one stiffness of each brand, a total of five or more different conditions per brand. Individual trials at each speed will be approximately 15-30 seconds long with at least 2 minutes rest between trials.

A safety harness attached to the ceiling above the treadmill and handrails beside the treadmill will be used during all running/sprinting trials to ensure subjects' safety. Each running trial will consist of at least 10 strides. To begin each trial, subjects will lower themselves from the handrails on to the moving treadmill belt. For each prosthetic stiffness and height condition, subjects will start a series of trials at 3 m/s, each subsequent trial will be incremented by 1 m/s until subjects approach their top speed, and then smaller speed increments will be employed until subjects reach their top speed. *Top speed* will be determined when subjects put forth maximal effort but cannot maintain their position on the treadmill for ten strides (Weyand, Sternlight, Bellizzi, & Wright, 2000). Subjects will be given as much time between trials as needed to recover fully (at least 2 minutes). At least seven trials will be performed by each subject for each prosthetic condition (e.g. 3, 4, 5, 6,

7, 7.3, 7.5 m/s) and a maximum of three series of trials will be performed each day. Our results will allow us to determine the optimal RSP mechanical stiffness (k_{opt}) and height (h_{opt}) for each person. The optimal sprint-running (SR) RSP will be the prosthesis that maximizes top speed.

Day SR0: Subjects will be asked to give informed written consent and then will be fit and aligned by a certified prosthetist with three different sprint-running RSP brands, one from each company. We will measure each subject's height, weight, and limb segment lengths. Then, we will select an RSP stiffness category based on the subject's weight and manufacturer's recommendation. An appropriate RSP height for each subject will be chosen according to conventional practice. Our prosthetist will ensure that the prosthetic fit and alignment are adequate. Then, subjects will have time to accommodate to treadmill running and sprinting with each sprint-running RSP over a range of speeds.

Day SR1: We will first vary the sprint-running RSP stiffness (k) while keeping height (h) at the recommended level. Subjects will use an RSP with the manufacturer's recommended stiffness category based on their weight, an RSP that is one category softer (k-) and an RSP that is one category stiffer (k+) than the manufacturer's recommended stiffness. We will measure ground reaction forces, top speed, socket pressures, and socket pistoning while subjects run and sprint over a range of speeds from 3 m/s up to their top speed. If the data warrant it, we may add an additional stiffness category to further fine tune the optimal stiffness. The optimal stiffness (k_{opt}) sprint-running RSP will be the RSP that maximizes top speed. This RSP stiffness will be used for Day SR2.

Day SR2: We will keep RSP stiffness constant (k_{opt}) and vary the sprint-running RSP height (h). Subjects will have used an RSP with an optimal stiffness (k_{opt}) at the recommended height (h_R) on day Day SR1. On Day SR2, they will also use and RSP with an optimal stiffness (k_{opt}) that is 2 cm shorter (h-), and 2 cm taller (h+). We will measure ground reaction forces, top speed, socket pressures, and socket pistoning while they run across a range of speeds from 3 m/s up to their top speed. If the data warrant it, we may further fine tune RSP height in 1 cm increments. We will analyze the results of SR2 to identify the optimal height (h_{opt}) for each subject for one brand of a sprint-running RSP

Days SR3 and SR5: We will repeat the trials of Day SR1 and vary stiffness (k) for a different sprint-running RSP brand. We will analyze the results of Days SR3 and SR5 to identify the optimal RSP stiffness (k_{opt}) to be used for Days SR4 and SR6.

Days SR4 and SR6: We will repeat the trials of Day SR2 and vary height (h) for a different sprint-running RSP brand. We will analyze the results of Days SR4 and SR6 to identify the optimal height (h_{opt}) for each subject using the respective brand of a sprint-running RSP.

Measurements and Analysis:

Ground Reaction Forces. We will measure ground reaction forces at 1000 Hz using a 3-D force-measuring treadmill (Treadmetrix, Park City, UT) for at least 10 strides (approximately 15 sec) per trial. Then, we will filter the ground reaction forces using a 4^{th} order Butterworth low pass filter using a custom software program (Matlab, Mathworks, Natick, MA). We will then use a spring-mass model to calculate each leg's overall stiffness (Farley & Gonzalez, 1996). To understand the effects of multiple speeds and prosthetic stiffness during running, we will calculate and compare leg stiffness. Leg stiffness equals the peak ground reaction force divided by peak leg compression. Leg compression is calculated as the change in distance from the center of mass to the point of ground contact (Blickhan & Full, 1993; Cavagna, 1975; Farley & Ferris, 1998). We will calculate center of mass displacement by twice integrating center of mass acceleration, which is calculated from the ground reaction force.

Metabolic Demand. Each running trial in Specific Aim 1 will be five minutes long with at least two minutes rest between trials. We will measure rates of oxygen consumption and carbon dioxide production using indirect calorimetry (ParvoMedics TrueOne 2400, Sandy, UT). We will calculate average steady-state metabolic power (W) from minutes 3-5 of each trial using a standard equation (Brockway, 1987). In our experience, a trial length of five minutes is sufficient for subjects to reach steady-state metabolic rate.

Socket Pressure. We will measure the pressure at the residual limb-socket interface using a thin wireless pressure sensor (Tekscan Wireless F-socket bipedal system, South Boston, MA) that attaches to the skin of the residual limb via adhesive spray. These data will be sampled at 160 Hz and synched with the ground reaction force data. The pressure sensor will provide information about peak pressure magnitude and location. Based on previous studies that have measured socket pressure during walking (Abu Osman, Spence, Solomonidis, Paul, & Weir, 2010; Ali et al., 2012; Dumbleton et al., 2009), we define excessive socket pressure as a peak socket pressure that exceeds 100 kPa. We have been unable to find any scientific reports of socket pressures during running. To further understand how subjects sense socket pressure, we will ask each subject to rate their perceived pressure on a scale of 0-10 following each trial, where 0 equals no pressure, 5 is perceived as "acceptable for a 10km run", and 10 equals intolerable pressure.

Socket Pistoning. We will measure the axial movement of the residual limb within the socket dynamically using reflective markers and a motion capture system (Vicon Motion Systems, Centennial, CO). Prior to data collection, a cluster of reflective markers will be placed on the socket and on the thigh of the residual limb to measure movement within the socket (pistoning) during running. These data will be sampled at 200 Hz and synched with the ground reaction force data. Based on previous studies that have measured socket pistoning during walking (Eshraghi, Abu Osman, Gholizadeh, Karimi, & Ali, 2012; Gholizadeh et al., 2011), we define excessive socket pistoning as a displacement of the residual limb relative to the socket that exceeds 8 cm. To further understand how subjects sense socket pistoning, we will ask each subject to rate their perceived pistoning on a scale of 0-8 following each trial, where 0 equals no pistoning, 5 is perceived as an "acceptable amount of pistoning" and 8 equals excessive pistoning.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

All investigators obtaining consent will have completed all VA and COMIRB mandatory annual training. Subjects will be allowed to read the consent form in a private and quiet room with just the investigator(s) present. All potential participants will be given adequate time to read the consent form. After the subject reads the consent form, an investigator will ask them if they have any questions, and answer any questions. The investigator will then follow-up with a few questions to ascertain whether the subject actually read and understood the consent form. If the subject's responses seem vague, the investigator will ask the subject to re-read the consent form and the investigator will explain any uncertainties. Consent will take less than 15 minutes and will be obtained immediately prior to the first session of the experiment.

Potential Risks.

1. There is a small risk of falling during the experimental trials.
2. There is a potential risk of physical discomfort from wearing any type of prosthesis.
3. The adhesive used for socket pressure and socket pistoning measurements may produce slight discomfort/irritation.
4. The metabolic analysis mouthpiece may produce slight discomfort/irritation.
5. Confidential information will be collected as part of this study; therefore there is a risk of disclosure.

Protections against Risks (corresponds directly to the Potential Risks listed above).

1. Subjects will have access to parallel bars on the treadmill and an overhead safety harness in case they need to catch themselves in the unlikely event of a fall.
2. If a subject becomes fatigued, he/she may ask to rest or stop the study at any time.
3. Before participating, all subjects will be asked if they have any adhesive or latex allergies. If they do, we will use a non-latex tape.
4. Subjects may ask to remove the mouthpiece, rest or stop at any time.
5. Significant efforts will be made to guard against the disclosure of confidential information. We will use de-identifying codes for all data and will implement a data and safety-monitoring plan to ensure subject's privacy.

The Eastern Colorado Health Care System will provide necessary medical care and treatment for any injuries that result from participation in this study. Compensation for such an injury may be permitted by applicable federal laws and/or regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by non-compliance with study procedures. Any questions about an injury related to the research will be directed to Dr. Alena Grabowski at 720-435-4270. Adverse events will also be reported to the BADER Consortium. Please see Sources of Materials, listed above, for a general description of our plan for data and safety monitoring. Dr. Grabowski and Dr. Kram have conducted similar treadmill running and sprinting experiments on more than 15 sprinters with transtibial amputations without an incident or adverse event.

Potential Benefits of Research to Subjects and Others. During each experimental session, subjects will get a modest amount of physical exercise and learn about how their musculoskeletal system functions. Subjects with a lower limb amputation will be able to use and test multiple RSPs, and will get a recommendation for their optimal RSP at the end of the study. The testing of RSPs and development of RSP prescription guidelines will advance our understanding of how people with lower limb amputations run, which may enable people with lower limb amputations to run with better biomechanical symmetry and metabolic economy, and may enable people with a lower limb amputation to improve their fitness and function, with a choice to return to active duty.

E. Potential Scientific Problems:

In Specific Aim 1, we propose to have subjects complete a total of six running trials per day and each trial will last 5 minutes. In Specific Aim 2, we propose to have subjects complete three sets of running and sprinting trials from 3 m/s up to top speed and each trial will last approximately 30 seconds. The proposed experimental trials may be too difficult, long, and/or exhausting. However, we have previously conducted up to eight running economy trials without detecting any effects of fatigue (Grabowski & Kram, 2008; Teunissen, Grabowski, & Kram, 2007). Moreover, our previous studies of Paralympic athletes with transtibial amputations suggest that subjects can complete three sets of running and sprinting trials from 3 m/s up to top speed without showing effects of fatigue (Grabowski et al., 2010). Thus, we believe that our proposed experimental protocol will be adequate; however if we do see signs of fatigue, we may need to spread out the protocol over more days.

We expect to find that for some subjects the optimal stiffness is either softer or stiffer than the manufacturer's recommended stiffness or that the optimal height is taller or shorter that the traditionally recommended height. Therefore, it may be necessary to add conditions to our protocol so that we can establish the true minimum metabolic cost or maximum speed. On Days 2, 4, and 6, we would be able to test an additional stiffness and height condition without exceeding the recommended number of trials per session. If additional trials are necessary, we may need to add an additional day to our protocol.

F. Data Analysis Plan:

We will only use the medical records of potential subjects for study recruitment. We will obtain or measure all other information needed for the study directly from the subjects in the study, e.g. age, weight, height, length of residual limb, time since amputation, reason for amputation, etc. Experimental data collected from each individual will be used for research and development purposes only. All data collected will be de-identified according to VA policy so that each participant's identity is protected; however the data collected poses no apparent risk to an individual's privacy. We will keep all research records that contain identifiable health information confidential to the extent allowed by law. Written information (e.g. the consent form) will be kept in a locked filing cabinet within the PI's locked office (Clare Small Building, room 103). Identifiable data will not be shared with anyone outside of the immediate research team. Data security for storage and transmission of electronic data stored on desktop computers will be managed via a secure network and password access. Power-on passwords will be established for all portable computing devices. Electronic data (non-identifiable health information) that is collected during

experimental sessions will be stored on computers protected with passwords and only accessible to the research team.

G. Summarize Knowledge to be Gained:

Using the data collected in Specific Aims 1 and 2, we plan to develop clinically relevant, quantitative algorithms for RSP stiffness and height prescription based on a subject's weight, level of amputation, limb segment lengths, and desired running speed. In addition, we will establish a research protocol that is able to objectively evaluate the effects of an RSP during running and sprinting. This protocol may be further developed for improving clinical evaluations.

H. References:

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