Sensory-Motor Mechanisms Underlying Fall Risk in Transtibial Amputees

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Study Protocol

Prior to any involvement in the study, a study investigator read the VA-approved consent forms in full to the potential subject. Having been read the consent forms and provided with an explanation of the experimental tasks, the potential subject was provided an opportunity to ask questions. Following this, if they agreed to participate, they signed a consent form. Each prosthesis user subject was assessed using their clinically prescribed prosthesis (i.e., socket, suspension system, pylon, and foot).

Following demographic information data collection, retro-reflective markers were attached to the subject with hypoallergenic adhesive tape to anatomical landmarks as specified in the modified Helen Hayes full-body marker set with additional markers placed on the right and left acromion processes, lateral epicondyle of the humerus, and between the styloid process of the radius and ulna. Position of the markers on the prosthetic limb approximated matched those on the contralateral side. Additionally, surface electrodes for measurement of electromyography (EMG), or muscle activity, were placed and secured over the following muscles: tibialis anterior of the sound limb (or both limbs in case of control subjects), medial gastrocnemius of the sound limb (or both limbs in case of control subjects), rectus femoris of both limbs, medial hamstring of both limbs, and gluteus medius of both limbs.

Subjects were requested to perform three biomechanical tasks (randomized prior to their visit) at the JBVAMC Motion Analysis Research Laboratory:

1. Quiet standing with comfortable stance width and eyes open,
2. Quiet standing with comfortable stance width and blindfolded, and
3. Walking at two self-selected speeds (normal and fast) across a level walkway.

Walking Data Collection—During the walking trials, subjects walked at a comfortable, normal, self-selected speed down the center of a 10 meter level walkway. The subjects were requested to walk back and forth along this walkway as many times as necessary to produce 10 clean foot strikes (i.e., each foot within the boundaries of at least one force plate). After walking at their normal speed, subjects were then requested to perform the same walking task while at their self-selected "fast" speed, defined as "a speed as if you were hurrying for a bus."

Quiet Standing Data Collection—During standing trials, subjects stood quietly with a comfortable stance width, as determined during an initial practice trial, with each foot on one adjacent force plate. This allowed recording of the plantar center of pressure (CoP) under both limbs by each force plate. The stance position was marked by tracing the feet on the floor. The subject was asked to replicate this stance position for all subsequent trials. During the eyes open condition, subjects were instructed to focus on a visual target mounted at eye level on the wall 5 meters in front. During the eyes closed standing condition, a blindfold was worn by the subjects to remove all visual cues. For each task, data were recorded for 30 seconds. Three trials of both the eyes open and closed conditions will be performed.

Self-selected walking speeds and stance width were tested to better reflect real-life conditions and facilitate the subjects' comfort during testing. Subjects were provided with seated rest between the three tasks to successfully carry out all walking and standing trials.

Prospective fall data collection—Prospective data on falls were collected monthly over a 12 month period following their second visit using a validated, rigorous 'falls calendar' approach. Subjects were provided with twelve (prepaid postage) postcards that consist of a falls calendar. Subjects were instructed on how to use the postcards following established guidelines and post them to the primary investigator directly at the JBVAMC Motion Analysis Research Laboratory every month following the data collection session. This postcard was mailed with no return address to ensure confidentiality. The identity of each subject was determined by their unique subject code, which was written on the postcards before distribution and known only to the research team. Following receipt of a postcard that reported one or more falls during the month data collection period, the subject was contacted via telephone or email and asked standardized questions regarding the location and activity engaged in preceding the fall, what they felt caused the fall, and if injuries were sustained. Subjects were contacted via post, telephone or email if a postcard is not returned within 7 days after each month period and/or to query unclear entries.

Data Analysis—Kinematic data were filtered with a low-pass Butterworth filter with a 6Hz cut-off frequency and smoothed in post-processing software. Raw EMG signals were filtered and processed using custom Matlab software. EMG data were normalized to gait cycle time (initial contact to ipsilateral initial contact). To quantify differences in muscle activity during the gait cycle, the integrated EMG (iEMG) for each muscle was calculated as the integral of the EMG profile over time of four regions: 1) braking phase (0-50% of stance), 2) propulsive phase (50-100% of stance), 3) swing phase, and 4) over the entire gait cycle. The iEMG of each subject was normalized by their average iEMG magnitude over the entire gait cycle. Plantar CoP of each limb in the coronal plane (elliptical area) were derived.

Statistical Analysis Plan

The main effect of amputation and limb side on kinematic variables will be assessed using a linear mixed model analysis for each walking speed separately. The main effect of amputation and limb side on standing balance variables will be assessed using a linear mixed model analysis for each vision condition separately. The main effect of amputation and walking speed on EMG variables will be assessed using a linear mixed model analysis for each muscle group separately. The total number of falls for each group will be calculated for each group.