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#### Original Article

## Development of a limits of stability protocol for use in transtibial prosthesis users: Learning effects and reliability of outcome variables<sup>★</sup>



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#### ABSTRACT

The aims of this study were to empirically quantify reliability and learning effects of a Limits of Stability protocol for transtibial prosthesis users. Outcome variables from center of pressure and center of mass were tested on: 1) multiple test repetitions within a single test occasion; and 2) between multiple test occasions. Trantibial prosthesis users (n=7) and matched controls (n=7) executed five trials of the Limits of Stability protocol on two occasions per day, on two consecutive days. Inter-trial learning effects and reliability of outcomes extracted via center of mass and center of pressure were evaluated utilizing standard biomechanics laboratory equipment. Reliability was good to excellent except the reaction time variable which was poor (Pooled 95%CI of ICC = 0.248–0.484). An inter-trial learning effect was present in directional control for prosthesis users when the first trial was included in analysis (center of mass: 95%CI of r=0.065-0.239; center of pressure: 95%CI of r=0.076-0.249). The use of standard biomechanics lab equipment can produce reliable results for the Limits of Stability protocol. Researchers should be aware of low reliability of reaction time variable in the protocol assessed and should execute at least one practice trial prior to that which is used in subsequent analysis.

#### 1. Introduction

In order to stand and ambulate, an individual must be able to coordinate complex movements in an appropriate fashion without falling, thus allowing them to execute activities of daily living (ADLs) [1-3]. Individuals who have undergone a transtibial amputation and utilize a prosthesis for ambulation, have increased fear of falling [4,5], increased incidence of falling [6,7], decreased access to meaningful physical activity [8], with research suggesting compromised postural stability and postural control in this group [9]. Therefore, research into postural control of prosthesis users is necessary to direct future treatment of these individuals with the hope of reducing fall injuries, increasing access to physical activity, increased ability to execute ADLs. Much of what is known about postural stability in transtibial prosthesis users (TPUs) comes from static measures [9-12] that show prosthesis users have increased movement of the center of pressure (CoP) in the mediolateral (ML) and anteroposterior (AP) directions [11,13] and that measures associated with instability in the AP direction are also present when the postural task is more challenging [12,13]. Additional research into dynamic tasks has also included the Limits of Stability (LoS) protocol, which assesses volitional control of body movements and has been utilized in able-bodied individuals [14,15], elderly [14,16], elderly fallers [17], stroke patients [18] and prosthesis users [19–23]. Results have shown that prosthesis users have compromised accuracy directed posteriorly, and both accuracy and stability limits towards the prosthetic side [22], although variables associated with accuracy improve in the 6 month period following amputation [20]. It has also been shown that angular alignment adjustments of the foot up to 5° (plantarflexion/dorsiflexion) do not have an effect on outcome of the LoS

There are multiple systems that can evaluate LoS [24,25]. These different systems typically rely on extracting outcomes from forceplate data which is proprietary to manufacturers. Recently a validation of the LoS protocol was conducted using motion analysis and center of mass (CoM) of able-bodied and transtibial prosthesis users [23]. Results indicated varying levels of correlation between resultant CoP data from a single forceplate and CoM data for outcomes in the LoS protocol. As these studies rely on procurement of manufacturer specific proprietary equipment, it is also imperative to develop a non-proprietary method of evaluating LoS using equipment such as multiple forceplates and motion analysis systems that are often times already available in many biomechanics laboratories.

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Currently, reliability of the LoS protocol has been documented in multiple patient groups including young able-bodied individuals (Intraclass Correlation Coefficient (ICC) = maximum excursion range (0.88–0.93)) [15], able-bodied young and elderly (ICC = path length (0.78)), movement time (0.83) [14], stroke patients (ICC = movement path (0.88)), movement time (0.84) [18], elderly fallers (Generalizability coefficient = 0.58–0.87) [16–18]. Although these values suggest moderate to high reliability of at least path length and movement time, empirical reliability of all outcome variables in the LoS protocol in TPUs is unknown. This is significant as measures of postural control, such as the LoS, must be both valid and reliable in order to draw sound conclusions from results. So as to empirically evaluate reliability of the LoS from both CoM and CoP it is necessary to develop a non-proprietary method for use clinically with prosthetic users.

Therefore, the aims of this study were to empirically quantify, for transtibial prosthesis users, both reliability and learning effects present in Limits of Stability outcome variables from center of pressure and center of mass on: 1) multiple test repetitions within a single test occasion; and 2) between multiple test occasions. Experimental hypotheses are that: 1) there will be adequate reliability of methods of LoS calculation based on CoP and CoM, 2) there will be variation between outcome variables in their reliability, and 3) there will be learning effects present.

#### 2. Methods

#### 2.1. Participants

An experimental group of unilateral transtibial prosthesis users (TPU; n = 7, (mean(SD)): age = 54.1(10.7)years, weight = 81.4(16.2) kg, height = 177.6(6.7)cm; Table 1) was recruited on the basis that they; had a unilateral transtibial amputation with no concomitant health issues, no current issues regarding fit or function of the prosthesis including wounds, blisters, or skin breakdown and had been a regular prosthesis user for at least one year. A matched control group (CON; n = 7) was also recruited (mean(SD): age = 49.3(12.7)years, weight = 83.0(7.5)kg, height = 180.0(6.9)cm; Table 1). All participants gave written, informed consent to participation which was approved by the Regional Ethical Review Board in Linköping, Sweden.

Participants received no practice session, simply an explanation of the test protocol. Individual trials towards 8 goal positions from each test session were completed in a randomized order. Following test session completion, there was a rest period of 1–2 min before beginning subsequent test sessions. In total, participants completed the LoS protocol 20 times over four test sessions in two days. Each occasion consisted of five repetitions of the LoS protocol. Duration for each occasion was 20–25 min. There were two test sessions on both day one and a second day separated by 24–48 h. Within day test occasions were separated between 3 and 6 h.

Passive-reflective markers (69) were placed on anatomical land-marks and joints in order to define the body as a 13-segment system (head, upper and lower arms, hands, torso, pelvis, thigh, shank and foot segments bilaterally). Full-body kinematics were collected using an 11-camera Oqus motion analysis system (Qualisys AB; Gothenburg, Sweden) with marker coordinate and force data sampled at 100 Hz using Qualisys Track Manager (Qualisys AB; Gothenburg, Sweden). All data were then exported to Visual 3D (C-Motion, Inc.; Germantown, USA) for post-processing.

#### 2.3. Data analysis

Prior to data collection, a standing calibration file was collected to determine position of center of mass (CoM) for each participant. Mean height of CoM was then utilized to create LoS goal positions for each participant. Using theoretical LoS angular goals which have been published elsewhere (7° anterior, 5° posterior, 8° left/right, 6° left/right posterior, 7.45° left/right anterior) [15] goal positions were determined individually for each participant representing 110% of theoretical maximum angle of inclination goal angles. These goal positions were then projected on the screen in front of participants in combination with real-time projection of the CoP.

Following data collection, identical analysis was conducted on CoM and CoP coordinates to extract outcome variables. The coordinate system for analysis was converted from the global lab-based system to a local goal-based coordinate system where x-y-z referred to: movements not towards goal (x) (positive x-direction defined as 90° to the right (clockwise) from the positive y-direction; negative x-direction defined as 180° from the positive x-direction), movements towards goal (y)

Table 1

Participant characteristics for TPU-group (white section) and CON-group (shaded section). Sex (M = male, F = Female), Height, Weight, Age, YSA = years since amputation, Cause = amputation cause. Foot = prosthetic foot classification as defined by Hafner [33]. Suspension = suspension form of prosthesis.

Partici pant	Sex	Height (cm)	Weight (kg)	Age (years)	YSA	Cause	Foot	Suspension	Control	Sex	Height	Weight	Age
1	М	183	81	66	18	Trauma	ESAR	Vacuum	C1	М	177	81	37
2	M	187	87	45	27	Trauma	ESAR	Seal-in	C2	М	186	88	39
3	M	179	70	49	6	Trauma	<b>ESAR</b>	Vacuum	C3	M	183	87	48
4	M	176	87	52	8	Trauma	ESAR	Vacuum	C4	M	176	73	65
5	M	179	58	62	21	Trauma	<b>ESAR</b>	Pin	C5	M	191	92	49
6	M	167	110	39	18	Trauma	ESAR	Vacuum	C6	M	176	87	68
7	M	172	77	66	10	Trauma	ESAR	Pin	C7	M	171	73	39
mean(SD)	M=7; F=0	177.6(6.7)	81.4(16.2)	54.1(10.7)	15.4(7.7)					M=7; F=0	180.0(6.9)	83.0(7.5)	49.3(12.7)

#### 2.2. Experimental protocol

Prior to testing participants were fitted with a safety harness. Participants stood with each of their feet located on one of two forceplates (BP400600, AMTI, Inc.; Watertown, USA). Foot position on the forceplates was determined and maintained based on dimensions used within the Limits of Stability (LoS) protocol [26]. Participants then completed the LoS test protocol while facing a projector screen showing them real-time position of their resultant center of pressure. The LoS protocol is a test of participant's ability to voluntarily shift their body, following a visual and auditory cue, from a central position out towards one of eight goals located anteriorly, anterior/right, right, posterior/right, posterior, posterior/left, left, anterior/left.

(positive y-direction defined as that towards the goals; negative defined as 180° from positive y-direction), and movements in vertical direction (z–perpendicular to plane formed by x and y) (positive z-direction defined as superior/up and negative z-direction defined as inferior/down). This transformation aided analysis as movements both towards – and deviations from – the goal were defined in the same coordinate system, regardless of which goal was under consideration. This meant, for instance, a movement towards the goal would always be in the positive y-direction, irrespective of goal direction. Raw marker coordinate and CoP data were low-pass filtered using a second-order Butterworth filter with a cut-off frequency of 3 Hz. This processed data was used in all subsequent analyses.

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