DO PREDICTIVE RELATIONSHIPS EXIST BETWEEN POSTURAL CONTROL AND FALLS EFFICACY IN UNILATERAL TRANSTIBIAL PROSTHESIS USERS?

Abstract

Objective: To assess whether variables from a postural control test relate to and predict falls efficacy in prosthesis users.

Design: Twelve-month within and between subjects repeated measures design. Participants performed the Limits of Stability (LOS) test protocol at study baseline and at 6-month follow-up. Participants also completed the Falls Efficacy Scale-International (FES-I) questionnaire, reflecting the fear of falling, and reported the number of falls monthly between study baseline and 6-month follow-up, and additionally at 9- and 12-month follow-ups.

Setting: University biomechanics laboratories.

Participants: A group of active unilateral transtibial prosthesis users of primarily traumatic etiology (PROS) (n=12) with at least one year of prosthetic experience and age and gender matched control participants (CON) (n=12).

Interventions: Not applicable.

Main Outcome Measure(s): Postural control variables derived from centre of pressure data obtained during the LOS test, which was performed on and reported by the Neurocom Pro Balance Master, namely; reaction time (RT), movement velocity (MVL), endpoint (EPE) and maximum (MXE) excursion and directional control (DCL). Number of falls and total FES-I scores.

Results: During the study period, the PROS group had higher FES-I scores (U = 33.5, p =0.02), but experienced a similar number of falls, compared to the CON group. Increased FES-I score were associated with decreased EPE (R=-0.73, p=0.02), MXE (R=-0.83, p<0.01) and MVL (R=-0.7, $p=0.03$) in the PROS group, and DCL (R=-0.82, $p<0.01$) in the CON group, all in the backwards direction.

Conclusions: Study baseline measures of postural control, in the backwards direction only, are related to and potentially predictive of subsequent 6-month FES-I scores in relatively mobile and experienced prosthesis users.

List of Abbreviations:

CoP – Centre of Pressure
CoG – Centre of Gravity
LOS – Limits of Stability
PROS – Prosthesis user group
CON – Control group
FES-I – Falls Efficacy Scale-International
RT – Reaction time
MVL – Movement velocity
EPE – Endpoint excursion
MXE – Maximum excursion
DCL – Directional control

Introduction

Lower limb amputation has an adverse effect on aspects of physical function such as strength, walking ability and balance[1]. Prosthesis users have an increased fear of falling and reduced social participation because of this fear [2-4]. Approximately 1 in 5 lower limb prosthesis users fall during rehabilitation [5, 6] with approximately 52% of community-living prosthesis users reporting a fall in the previous 12 months [2, 3]. The link between fear of falling and falls risk has been demonstrated in the elderly able-bodied population [7], although no detailed exploration of this relationship has yet been undertaken in prosthesis users.

In order to reduce falls and falls-related injury in older individuals, research has investigated whether quantitative measures of postural control, such as the motion of the centre of pressure (CoP) during stable and unstable conditions, are related to a person's risk of falling in the future [8-11]. In older individuals, variables related to increased CoP movement in the mediolateral plane were strongly associated with future falls [8-11]. The observation that impaired balance is broadly associated with increased falls risk in older individuals [12] may be of some relevance to prosthesis users, as even highly active prosthesis users have been shown to have reduced balance ability when compared to able-bodied individuals [13, 14]. Therefore, investigation is warranted into whether prosthesis users' postural control is associated or able to predict a future risk of falling and/or decreased falls efficacy.

Thus far, only clinical outcome measures of functional capacity have been used to identify prosthesis users who fall [15]. However, quantitative laboratory-based outcome measures may enhance our mechanistic understanding of this relationship. Previous studies assessing volitional CoP movement in prosthesis users, have investigated the re-organization of postural control following rehabilitation [16] and the effects of a novel somatosensory input device [17]. This has been achieved using test protocols such as the limits of stability (LOS) test, which assesses participants' ability to perform targeted volitional centre of mass (CoM) movements during upright posture. In addition, the LOS test has been validated for expressing volitional postural movement in prosthesis users [18]. These test protocols are important as they assess voluntary postural control and demand utilisation of the range of motion of the prosthetic ankle/foot componentry, reflecting the daily challenges faced by prosthesis users. However, to date, no studies have established whether measurements of postural control obtained during volitional displacements of the CoP, such as those required in the LOS protocol, are sensitive enough to predict those prosthesis users that have reduced falls efficacy, defined the perceived self-efficacy of avoiding falls during activities of daily living[19]. Understanding of the relationship between postural control and falls efficacy could allow for the pre-screening of prosthesis users, to identify those at risk of developing decreased falls efficacy, in order to target further rehabilitation or prosthetic intervention.

Therefore, the primary aim of the current study was to prospectively assess the extent to which the LOS test variables relate to and are able to prospectively predict unilateral transtibial prosthesis users' falls efficacy. Analysis of a control group of able-bodied participants was also conducted in order to identify amputation specific effects. Specific objectives included: (1) to assess whether indices of postural control at study baseline prospectively predicted falls efficacy at 6-month follow-up in both unilateral transtibial prosthesis users and able-bodied controls; (2) to record falls efficacy and the number of falls over a 1-year period in both prosthesis users and controls; and (3) to report postural control at study baseline and 6-month follow-up assessment. It was hypothesized (1) that better postural control in prosthesis users would relate to and predict increased falls efficacy, and (2) that prosthesis users would report more falls and decreased falls efficacy compared to matched controls.

Methods

Participants

A convenience sample of unilateral transtibial prosthesis users (PROS) were recruited from a local prosthetic clinic using consecutive sampling. Inclusion criteria stipulated that participants were a prosthesis user for over one year, were able to use their prosthesis without pain or discomfort, were able to stand for at least two minutes at a time without a walking aid in order to complete the LOS test. Prosthesis users were excluded if they had current concomitant health issues, had ongoing issues with the contralateral or residual limb, or were taking medication known to affect balance. All prosthetic foot-ankle complexes used by participants were categorized as energy storing and returning[20]. In order to provide an amputation independent reference for the PROS group, an age- and gender-matched control group (CON) were recruited from the local community using the same inclusion and exclusion criteria as the PROS group, excluding factors related to prosthesis use. All participants gave written informed consent to participate in the study, which was approved by ethical review boards.

Experimental Design

Data collection for all participants extended over a period of one year and included three forms of assessment: 1) measuring postural control, 2) recording number of falls experienced and, 3) recording falls efficacy. The study employed a repeated measures experimental design that consisted of study baseline and six-month follow-up assessments of postural control using the Limits of Stability (LOS) test. The number of falls, assessed using a custom self-report questionnaire, and falls efficacy, assessed using the Falls Efficacy Scale-International (FES-I) scale [21, 22] were assessed monthly from study baseline up to a six-month follow-up and then at nine and twelve month follow-ups.

Experimental Protocol

Postural Control

Data collection was conducted in a University biomechanics laboratory. Participants' height (m) and mass (kg) were recorded using a free-standing stadiometer and scales, respectively[a] and entered, along with age, into the NeuroCom software[b]. Postural control was evaluated by conducting the Limits of Stability (LOS) test using a NeuroCom Pro Balance Master[b]. This test protocol, which has been explained elsewhere[17, 23, 24], evaluates a participant's ability to volitionally move their CoM, following a visual cue, from a central starting point to a maximum distance and maintain this position for approximately 10 seconds, without falling [17, 23, 24]. The LOS test measures a participant's ability to complete this test in 8 directions (anterior, posterior, left, right, and the 4 ordinal directions bisecting these directions).

Participants wore their own, same comfortable flat footwear at each visit. During the LOS test, they were fitted with a safety-harness to prevent injury in the case of a loss of balance and were informed not to move their feet unless necessary to avoid falling. Foot positioning (i.e., width of base of support) was determined using the manufacturer's guidelines whereby the prosthetic ankle joint on the affected limb and the malleoli of the intact limbs were aligned with the axis of rotation of the support platform. Where no discernible prosthetic ankle joint was present, foot position (i.e., toe position), was matched to that of the intact limb, which was aligned as described. The support platform consisted of two force plates, connected by a central pin joint that sampled vertical and shear forces at 100 Hz. In order to ameliorate any learning effects, and to improve the reliability of measures, participants completed three tests of the LOS at both study baseline and six-month visits; the first two being practice tests, with scores from the third test used in subsequent analyzes [25].

Falling and Falls Efficacy

The number of falls and falls efficacy were evaluated using two questionnaires. Firstly, a custom falls self-report questionnaire asked how many times the participant had fallen in the previous 30 days. Participants were asked to report all falls and to provide detail about the circumstance of the fall(s). The total number of falls that satisfied the definition of 'an unexpected event in which the participant comes to rest on the ground, floor or lower level' were included for each individual in statistical analyses [26]. Secondly, participants completed the FES-I, which is an assessment of falls efficacy under different circumstances, [21, 22] designed and validated for use in older adults, but has been used with unilateral transtibial prosthesis users previously in the form of the modified Falls Efficacy Scale [23]. The FES-I is validated in English and Swedish languages, as used in the current study [22, 27]. The FES-I asks the participant to rank on a scale of 1 to 4 (1 = no fear whatsoever, 4 = very fearful) how fearful they were of falling during 16 various activities of daily living. Prosthesis users were instructed to respond to the FES-I questions assuming the use of their prosthesis and this was confirmed with each participant upon completion of the questionnaire. Following study baseline data collection, participants posted both completed questionnaires to the investigators monthly, from months one to six and at nine and twelve months, resulting in a total of 9 occasions.

Outcomes Measures

The LOS test protocol yielded a number of dependent variables, defined in detail elsewhere[16, 17], which characterize a participant's postural control: (1) Reaction time (RT) - time for a participant to voluntarily shift their centre of gravity (CoG) in an intended direction following a visual cue; (2) maximum excursion (MXE) - angular displacement between the angular position at trial initiation and the maximum angle during the trial; (3) endpoint excursion (EPE) - angular displacement between the angle of inclination at trial initiation and the maximum angle during the first movement towards the target; (4) Movement angular velocity (MVL) - Average angular velocity of the movement; and (5) Directional control (DCL) - total angular distance travelled by the CoG towards the intended target compared to extraneous movement away from the intended target, expressed as a percentage. In the current study, reduced RT, and increased MXE, EPE, MVL and DCL were assumed to be indicative of better postural control [25]. These variables were recorded and analyzed in the forwards, backwards, intact (left in CON group) and prosthetic (right in CON group) directions.

All falls were scored as a single sum for each participant at each time point. The FES-I yielded a total falls efficacy score which was the arithmetic mean of each item score. FES-I scores were adjusted for time of year thus study baseline scores relate falls efficacy reported in January, with the exceptions of PROS participants 11 and 12, whose FES-I scores started in February.

Statistical Analysis

Initially, normality of data were assessed quantitatively, using a Shapiro-Wilk test, and visually, using normal Q-Q plots, which informed the choice of the following statistical analyses. The alpha level for all statistical analyses was set at 0.05. All statistical analyses were conducted in SPSS v.23[c].

Group Demographics

An independent samples t-tests were used to compare demographics (age, height and mass).

Relationship Between Falls Efficacy and Postural Control

In order to address hypothesis (1) and investigate the relationship between and ability of indices of postural control at study baseline to predict FES-I scores at six-month follow-up, data from the LOS test at study baseline and FES-I scores at six-month follow-up were assessed. Data were initially plotted on XY scatter graphs to visually identify outliers, which were removed if they exceeded three standard deviations of the remaining group mean. Although individual Likert scale items of the FES-I are ordinal, previous research outlining the development and validation of the FES-I does not state the requirement for ordinal assumptions for the total FES-I scores [22]. Therefore, Pearson's product-moment correlation coefficients were used to assess whether relationships existed between data, and simple linear regression was used to establish the predictive ability of postural control for falls efficacy.

To correct for multiple correlation and regression analyzes, the false discovery rate (FDR) method was implemented by group using the Benjamini-Hochberg procedure, with an FDR threshold set at 20% [28].

Falling and Falls Efficacy

In order to address hypothesis (2), Mann-Whitney U tests compared differences in mean FES-I scores and the total number of falls reported between groups (PROS and CON) across the 12-month study period (study baseline to 12 months). The circumstances around falls were also summarized.

Limits of Stability

In order to account for any within-group variation in postural control over time, separate one-way analyses of variance were used to compare indices of postural control between study baseline and six-month follow-up, in both the CON and PROS groups. Where the assumption of sphericity was violated, a Greenhouse-Geisser correction factor was applied and multiple post-hoc comparisons were accounted for using a Bonferroni correction. Paired-samples t-tests were used to compare whether indices of postural control were different between the limbs (right/left) of the CON group, in order to assess inter-limb symmetry when comparing data to the PROS group. The PROS group intact limb was compared to CON left limb and PROS group prosthetic limb compared to CON right limb in group main effect analyses.

Results

Demographics

Twelve unilateral transtibial prosthesis users (females=2, age 53.6 ± 14.0 years, height 1.77 ± 0.07m and mass 78.3 ± 11.4kg) and twelve age and gender matched controls (females=2, age 53.6 ± 13.4 years, height 1.77 ± 0.07m and mass 81.5 ± 10.5kg) participated in the study. There were no statistically significant differences between the two groups in relation to age ($t(22) = 0.00$, $p=1.0$), height ($t(22) = 0.31$, $p=0.76$) or mass ($t(22) = -0.70$, $p=0.49$) (Table 1).

Falling and Falls Efficacy

Table 2 displays the number of falls by participant and Figure 1 displays the group mean FES-I scores from both the PROS and CON groups. Mean FES-I scores across the study period were higher in the PROS group compared to the CON group ($U = 33.5$, $p = 0.02$)

although there was no statistically significant difference in the total number of falls between the CON and PROS groups (U = 61, p =0.55).

Limits of Stability

As shown in Figure 2, there were no statistically significant differences between the right and left side LOS scores in RT (t(23) = 0.57, p=0.76), MVL (t(23) = 0.73, p=0.47), EPE (t(23) = -0.98, p=0.34), MXE (t(23) = -1.02, p=0.32) or DCL (t(23) = -0.04, p=0.97) in the CON group. Scores from the LOS test did not change significantly between study baseline and 6-month follow-up in either the PROS or CON groups with the exceptions of EPE (Intact) (F(1,21) = 4.54, p<0.05) in the PROS group and MVL (right back) (F(1,22) = 5.77, p=0.03) and DCL (back) (F(1,22) = 5.74, p=0.03) in the CON group.

Relationship Between Falls Efficacy and Postural Control

Predictors of FES-I scores and relationships between LOS and FES-I scores are presented in Table 3. Statistically significant results that also satisfied the criteria of the FDR method are shaded (Table 3). One participant from the PROS group (participant 11) was identified as an outlier and removed from this analysis. Generally, LOS variables that related strongly to FES-I scores indicated that increased FES-I scores were associated with increased reaction time, decreased maximum and endpoint excursion, movement velocity and directional control. This was particularly the case in the PROS group. All regression and correlation analysis that revealed statistically significant effects were in the backwards direction (Table 3) and indicated that LOS scores were better able to predict FES-I scores in the PROS versus the CON group. For example, the maximum excursion, endpoint excursion and movement velocity in the backwards direction were able to explain 69%, 53% and 49% of the variance in FES-I scores, respectively (p<0.05).

Discussion

The primary aim of the current study was to prospectively assess whether LOS test variables related to, and were are able to predict, FES-I scores in transtibial prosthesis users. The hypothesis that better postural control would relate to and predict an increased falls efficacy in prosthesis users was partially supported, as statistically significant effects were only observed between LOS variables and FES-I scores in one (backwards) of the four test directions. Where LOS test variables significantly predicted FES-I scores in prosthesis users, the data suggested that a decreased falls efficacy, was associated with a reduced ability to move towards targets in terms of spatial magnitude (EPE, MXE) and speed of movement (MVL).

These relationships in transtibial prosthesis users support previous research that found EPE in the backwards direction was most sensitive to prosthetic alignment changes among transtibial prosthesis users [29]. From a biomechanical perspective, this may be explained by the absence of active dorsiflexion and subsequent internal dorsiflexor moment in the affected limb when leaning backwards. Use of the ankle strategy during smaller, low frequency perturbations to balance has been reported in transtibial prosthesis users [16]. In the current study, transtibial prosthesis users' inability to produce an internal dorsiflexor moment on the affected side may have reduced their confidence in leaning backwards both in terms of the spatial excursions possible and the speed and accuracy with which these movements were performed. Thus, they would not have been as able to counteract any excessive CoM movement, possibly reducing their confidence in performing movements such as leaning/moving backwards. Furthermore, postural control in the backwards direction did not predict falls efficacy in controls as well as it did in the transtibial prosthesis users. This further supports the idea that postural control deficits during backwards leaning may be specific to the mechanical constraints of unilateral transtibial amputation.

Whilst the activities assessed in the FES-I likely include elements involving backwards leaning, the FES-I does not specifically assess this task. Therefore, interpretations are made with caution. Nonetheless, it would seem reasonable that an individual's volitional ability to perform postural movements (LOS test) would be related to their self-reported efficacy of completing everyday tasks (FES-I), which include such volitional movements. Thus, a clinical implication of these findings is that a prosthesis users' ability to perform postural movements in the backwards direction has some potential to be used as a screening tool, adding to the known risk factors for falls and fear of falling in prosthesis users [3].

The hypothesis that prosthesis users would experience more falls and report a decreased falls efficacy when compared to the control group was only partially supported, given that while falls efficacy was lower in prosthesis users, the number of falls experienced was similar between groups. This was a surprising result given that both an increased fear of falling and falls reported by prosthesis users is frequently and widely cited in literature [2, 3]. Prosthesis users' falls efficacy reported in the current study was higher when compared to that from prosthesis users with less (<1 year) prosthetic experience, who were of mixed vascular/traumatic etiology [23]. One explanation for this could be that, having been screened against the stated inclusion and exclusion criteria, the prosthesis users of traumatic etiology in the current study could be considered relatively active and mobile. Patient characteristics including amputation etiology, activity levels and prosthetic experience may influence falling, thus explaining the lack of significant between-group differences reported in this study. Balance ability and postural control have also been shown to improve with prosthetic experience [16]. Therefore, it seems important to consider patient characteristics such as different etiologies [2, 3] or different levels of prosthetic experience [23] when investigating the relationships between, falls efficacy and postural control and when comparing falls efficacy data to previous reports. This would also allow for improved interpretation of the falls efficacy between sub-groups of prosthesis users.

With the exception of one participant in the PROS group, the number of falls reported was relatively low in both groups compared to previous reports [2, 3]. Increased prosthetic experience has been reported to be protective in terms of falls risk in prosthesis users[3] and the high level of prosthetic experience in amputees in the current study may explain the relatively low number of falls. Moreover, there were a similar number of fallers and non-fallers between groups, with most fallers being recurrent fallers. The faller/non-faller split is similar to previous reports from prosthesis users [4]. This is of clinical significance, given that prosthesis users who fall more than once a year may be at increased risk of fall-related injury, exacerbating associated socio-economic costs. This also suggests that being able to predict falls efficacy and subsequent falls in potential recurrent fallers is imperative for timely intervention. Although not within the scope of the current study, future research should attempt to ascertain whether differences in falls efficacy and postural control exist between prosthesis users who do not fall and those who fall more often. This would further refine understanding of the relationships between postural control and falls efficacy established by the current study.

Study Limitations

In the current study, the two groups were well matched, meaning the effects of lower limb amputation may have been more easily isolated. Whilst this benefits the comparisons made in the current study, the prosthesis users had a wide range of ages and levels of prosthetic experience, were relatively mobile, physically active and generally of traumatic etiology. Less mobile prosthesis users of vascular etiology, with reduced and less varied levels of prosthetic experience, may exhibit different balance issues compared to individuals from the current cohort [30]. It is yet to be ascertained whether the relationships explored in the current study could be generalized more broadly to such a group, or indeed a more homogenous group, regardless of group characteristics. Finally, similar instruments to the FES-I and a modified version of the FES-I have been used previously to assess falls efficacy and/or confidence in prosthesis users[23]. However, the FES-I specifically, has not been fully validated in this population and it is not conclusive whether total FES-I scores should be treated as ordinal data or not. Addressing these issues should be a future goal for researchers interested in falls efficacy in prosthesis users.

Conclusions

Results from the current study suggest that the ability for measures of postural control to predict falls efficacy in prosthesis users is greatest using postural control in the backwards direction. Decreased falls efficacy is related to reduced magnitude, speed and accuracy of postural movements. In a group of mobile and experienced prosthesis users of traumatic etiology, falls efficacy is decreased but the number of falls the same when compared to age- and gender-matched able-bodied controls.

Suppliers

[a]Hultafors AB, Hultaforsvägen 21, Hultafors, Sweden.

[b]Neurocom International Inc., 9570 SE Lawnfield Rd, Clackamas, OR 97015, USA.

[c]IBM, North Harbour, Portsmouth PO6 3AU, UK.

Figure Legends

Figure 1. Group mean ± SD for Falls Efficacy Scale-International (FES-I) scores from both the PROS (black) and CON (white) groups across the 12-month study period.

Figure 2. Group mean Limits of Stability test scores for both the PROS and CON groups at study baseline and six-month follow up. Directional abbreviations are as follows: Forward (F), forward prosthetic (PF), prosthetic (P), backward prosthetic (PB), backward (B), backward intact (IB), intact (I), forward intact (IF). For the CON group the right limb was compared to the prosthetic side and left limb to the intact side of the PROS group.

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