

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

3

4 **Abstract**

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

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

12 Setting: University biomechanics laboratories.

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

16 Interventions: Not applicable.

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

22 Results: During the study period, the PROS group had higher FES-I scores ($U = 33.5, p$
23 $=0.02$), but experienced a similar number of falls, compared to the CON group. Increased
24 FES-I score were associated with decreased EPE ($R=-0.73, p=0.02$), MXE ($R=-0.83, p<0.01$)

25 and MVL ($R=-0.7$, $p=0.03$) in the PROS group, and DCL ($R=-0.82$, $p<0.01$) in the CON
26 group, all in the backwards direction.

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

30

31 **List of Abbreviations:** CoP – Centre of Pressure
32 CoG – Centre of Gravity
33 LOS – Limits of Stability
34 PROS – Prosthesis user group
35 CON – Control group
36 FES-I – Falls Efficacy Scale-International
37 RT – Reaction time
38 MVL – Movement velocity
39 EPE – Endpoint excursion
40 MXE – Maximum excursion
41 DCL – Directional control

42 **Introduction**

43

44 Lower limb amputation has an adverse effect on aspects of physical function such as strength,
45 walking ability and balance¹. Prosthesis users have an increased fear of falling and reduced
46 social participation because of this fear²⁻⁴. Approximately 1 in 5 lower limb prosthesis users
47 fall during rehabilitation^{5,6} with approximately 52% of community-living prosthesis users
48 reporting a fall in the previous 12 months^{2,3}. The link between fear of falling and falls risk
49 has been demonstrated in the elderly able-bodied population⁷, although no detailed
50 exploration of this relationship has yet been undertaken in prosthesis users.

51

52 In order to reduce falls and falls-related injury in older individuals, research has investigated
53 whether quantitative measures of postural control, such as the motion of the centre of
54 pressure (CoP) during stable and unstable conditions, are related to a person's risk of falling
55 in the future⁸⁻¹¹. In older individuals, variables related to increased CoP movement in the
56 mediolateral plane were strongly associated with future falls⁸⁻¹¹. The observation that
57 impaired balance is broadly associated with increased falls risk in older individuals¹² may be
58 of some relevance to prosthesis users, as even highly active prosthesis users have been shown
59 to have reduced balance ability when compared to able-bodied individuals^{13,14}. Therefore,
60 investigation is warranted into whether prosthesis users' postural control is associated or able
61 to predict a future risk of falling and/or decreased falls efficacy.

62

63 Thus far, only clinical outcome measures of functional capacity have been used to identify
64 prosthesis users who fall¹⁵. However, quantitative laboratory-based outcome measures may
65 enhance our mechanistic understanding of this relationship. Previous studies assessing
66 volitional CoP movement in prosthesis users, have investigated the re-organization of

67 postural control following rehabilitation ¹⁶ and the effects of a novel somatosensory input
68 device ¹⁷. This has been achieved using test protocols such as the limits of stability (LOS)
69 test, which assesses participants' ability to perform targeted volitional centre of mass (CoM)
70 movements during upright posture. In addition, the LOS test has been validated for
71 expressing volitional postural movement in prosthesis users ¹⁸. These test protocols are
72 important as they assess voluntary postural control and demand utilisation of the range of
73 motion of the prosthetic ankle/foot componentry, reflecting the daily challenges faced by
74 prosthesis users. However, to date, no studies have established whether measurements of
75 postural control obtained during volitional displacements of the CoP, such as those required
76 in the LOS protocol, are sensitive enough to predict those prosthesis users that have reduced
77 falls efficacy, defined the perceived self-efficacy of avoiding falls during activities of daily
78 living¹⁹. Understanding of the relationship between postural control and falls efficacy could
79 allow for the pre-screening of prosthesis users, to identify those at risk of developing
80 decreased falls efficacy, in order to target further rehabilitation or prosthetic intervention.

81

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

92 prosthesis users would report more falls and decreased falls efficacy compared to matched
93 controls.

94

95 **Methods**

96

97 **Participants**

98 A convenience sample of unilateral transtibial prosthesis users (PROS) were recruited from a
99 local prosthetic clinic using consecutive sampling. Inclusion criteria stipulated that
100 participants were a prosthesis user for over one year, were able to use their prosthesis without
101 pain or discomfort, were able to stand for at least two minutes at a time without a walking aid
102 in order to complete the LOS test. Prosthesis users were excluded if they had current
103 concomitant health issues, had ongoing issues with the contralateral or residual limb, or were
104 taking medication known to affect balance. All prosthetic foot-ankle complexes used by
105 participants were categorized as energy storing and returning²⁰. In order to provide an
106 amputation independent reference for the PROS group, an age- and gender-matched control
107 group (CON) were recruited from the local community using the same inclusion and
108 exclusion criteria as the PROS group, excluding factors related to prosthesis use. All
109 participants gave written informed consent to participate in the study, which was approved by
110 ethical review boards.

111

112 **Experimental Design**

113 Data collection for all participants extended over a period of one year and included three
114 forms of assessment: 1) measuring postural control, 2) recording number of falls experienced
115 and, 3) recording falls efficacy. The study employed a repeated measures experimental design
116 that consisted of study baseline and six-month follow-up assessments of postural control

117 using the Limits of Stability (LOS) test. The number of falls, assessed using a custom self-
118 report questionnaire, and falls efficacy, assessed using the Falls Efficacy Scale-International
119 (FES-I) scale^{21, 22} were assessed monthly from study baseline up to a six-month follow-up
120 and then at nine and twelve month follow-ups.

121

122 **Experimental Protocol**

123 *Postural Control*

124 Data collection was conducted in a University biomechanics laboratory. Participants' height
125 (m) and mass (kg) were recorded using a free-standing stadiometer and scales, respectively^a
126 and entered, along with age, into the NeuroCom software^b. Postural control was evaluated by
127 conducting the Limits of Stability (LOS) test using a NeuroCom Pro Balance Master^b. This
128 test protocol, which has been explained elsewhere^{17, 23, 24}, evaluates a participant's ability to
129 volitionally move their CoM, following a visual cue, from a central starting point to a
130 maximum distance and maintain this position for approximately 10 seconds, without falling
131^{17, 23, 24}. The LOS test measures a participant's ability to complete this test in 8 directions
132 (anterior, posterior, left, right, and the 4 ordinal directions bisecting these directions).

133

134 Participants wore their own, same comfortable flat footwear at each visit. During the LOS
135 test, they were fitted with a safety-harness to prevent injury in the case of a loss of balance
136 and were informed not to move their feet unless necessary to avoid falling. Foot positioning
137 (i.e., width of base of support) was determined using the manufacturer's guidelines whereby
138 the prosthetic ankle joint on the affected limb and the malleoli of the intact limbs were
139 aligned with the axis of rotation of the support platform. Where no discernible prosthetic
140 ankle joint was present, foot position (i.e., toe position), was matched to that of the intact
141 limb, which was aligned as described. The support platform consisted of two force plates,

142 connected by a central pin joint that sampled vertical and shear forces at 100 Hz. In order to
143 ameliorate any learning effects, and to improve the reliability of measures, participants
144 completed three tests of the LOS at both study baseline and six-month visits; the first two
145 being practice tests, with scores from the third test used in subsequent analyzes ²⁵.

146

147 *Falling and Falls Efficacy*

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

165

166 *Outcomes Measures*

167 The LOS test protocol yielded a number of dependent variables, defined in detail elsewhere¹⁶,
168 ¹⁷, which characterize a participant's postural control: (1) Reaction time (RT) - time for a
169 participant to voluntarily shift their centre of gravity (CoG) in an intended direction following
170 a visual cue; (2) maximum excursion (MXE) - angular displacement between the angular
171 position at trial initiation and the maximum angle during the trial; (3) endpoint excursion
172 (EPE) - angular displacement between the angle of inclination at trial initiation and the
173 maximum angle during the first movement towards the target; (4) Movement angular velocity
174 (MVL) - Average angular velocity of the movement; and (5) Directional control (DCL) - total
175 angular distance travelled by the CoG towards the intended target compared to extraneous
176 movement away from the intended target, expressed as a percentage. In the current study,
177 reduced RT, and increased MXE, EPE, MVL and DCL were assumed to be indicative of
178 better postural control ²⁵. These variables were recorded and analyzed in the forwards,
179 backwards, intact (left in CON group) and prosthetic (right in CON group) directions.

180

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

186

187 **Statistical Analysis**

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

192

193 *Group Demographics*

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

195

196 *Relationship Between Falls Efficacy and Postural Control*

197 In order to address hypothesis (1) and investigate the relationship between and ability of

198 indices of postural control at study baseline to predict FES-I scores at six-month follow-up,

199 data from the LOS test at study baseline and FES-I scores at six-month follow-up were

200 assessed. Data were initially plotted on XY scatter graphs to visually identify outliers, which

201 were removed if they exceeded three standard deviations of the remaining group mean.

202 Although individual Likert scale items of the FES-I are ordinal, previous research outlining

203 the development and validation of the FES-I does not state the requirement for ordinal

204 assumptions for the total FES-I scores²². Therefore, Pearson's product-moment correlation

205 coefficients were used to assess whether relationships existed between data, and simple linear

206 regression was used to establish the predictive ability of postural control for falls efficacy.

207

208 To correct for multiple correlation and regression analyzes, the false discovery rate (FDR)

209 method was implemented by group using the Benjamini-Hochberg procedure, with an FDR

210 threshold set at 20%²⁸.

211

212 *Falling and Falls Efficacy*

213 In order to address hypothesis (2), Mann-Whitney U tests compared differences in mean

214 FES-I scores and the total number of falls reported between groups (PROS and CON) across

215 the 12-month study period (study baseline to 12 months). The circumstances around falls

216 were also summarized.

217

218 *Limits of Stability*

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

228

229 **Results**

230 *Demographics*

231 Twelve unilateral transtibial prosthesis users (females=2, age 53.6 ± 14.0 years, height $1.77 \pm$
232 0.07 m and mass 78.3 ± 11.4 kg) and twelve age and gender matched controls (females=2, age
233 53.6 ± 13.4 years, height 1.77 ± 0.07 m and mass 81.5 ± 10.5 kg) participated in the study.

234 There were no statistically significant differences between the two groups in relation to age
235 ($t(22) = 0.00, p=1.0$), height ($t(22) = 0.31, p=0.76$) or mass ($t(22) = -0.70, p=0.49$) (Table 1).

236

237 *Falling and Falls Efficacy*

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

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

243

244 *Limits of Stability*

245 As shown in Figure 2, there were no statistically significant differences between the right and
246 left side LOS scores in RT ($t(23) = 0.57, p = 0.76$), MVL ($t(23) = 0.73, p = 0.47$), EPE ($t(23) = -$
247 $0.98, p = 0.34$), MXE ($t(23) = -1.02, p = 0.32$) or DCL ($t(23) = -0.04, p = 0.97$) in the CON
248 group. Scores from the LOS test did not change significantly between study baseline and 6-
249 month follow-up in either the PROS or CON groups with the exceptions of EPE (Intact)
250 ($F(1,21) = 4.54, p < 0.05$) in the PROS group and MVL (right back) ($F(1,22) = 5.77, p = 0.03$)
251 and DCL (back) ($F(1,22) = 5.74, p = 0.03$) in the CON group.

252

253 *Relationship Between Falls Efficacy and Postural Control*

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

266

267 **Discussion**

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

277

278 These relationships in transtibial prosthesis users support previous research that found EPE in
279 the backwards direction was most sensitive to prosthetic alignment changes among transtibial
280 prosthesis users²⁹. From a biomechanical perspective, this may be explained by the absence
281 of active dorsiflexion and subsequent internal dorsiflexor moment in the affected limb when
282 leaning backwards. Use of the ankle strategy during smaller, low frequency perturbations to
283 balance has been reported in transtibial prosthesis users¹⁶. In the current study, transtibial
284 prosthesis users' inability to produce an internal dorsiflexor moment on the affected side may
285 have reduced their confidence in leaning backwards both in terms of the spatial excursions
286 possible and the speed and accuracy with which these movements were performed. Thus,
287 they would not have been as able to counteract any excessive CoM movement, possibly
288 reducing their confidence in performing movements such as leaning/moving backwards.
289 Furthermore, postural control in the backwards direction did not predict falls efficacy in
290 controls as well as it did in the transtibial prosthesis users. This further supports the idea that

291 postural control deficits during backwards leaning may be specific to the mechanical
292 constraints of unilateral transtibial amputation.

293

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

302

303 The hypothesis that prosthesis users would experience more falls and report a decreased falls
304 efficacy when compared to the control group was only partially supported, given that while
305 falls efficacy was lower in prosthesis users, the number of falls experienced was similar
306 between groups. This was a surprising result given that both an increased fear of falling and
307 falls reported by prosthesis users is frequently and widely cited in literature ^{2,3}. Prosthesis
308 users' falls efficacy reported in the current study was higher when compared to that from
309 prosthesis users with less (<1 year) prosthetic experience, who were of mixed
310 vascular/traumatic etiology ²³. One explanation for this could be that, having been screened
311 against the stated inclusion and exclusion criteria, the prosthesis users of traumatic etiology in
312 the current study could be considered relatively active and mobile. Patient characteristics
313 including amputation etiology, activity levels and prosthetic experience may influence
314 falling, thus explaining the lack of significant between-group differences reported in this
315 study. Balance ability and postural control have also been shown to improve with prosthetic

316 experience ¹⁶. Therefore, it seems important to consider patient characteristics such as
317 different etiologies ^{2,3} or different levels of prosthetic experience ²³ when investigating the
318 relationships between, falls efficacy and postural control and when comparing falls efficacy
319 data to previous reports. This would also allow for improved interpretation of the falls
320 efficacy between sub-groups of prosthesis users.

321

322 With the exception of one participant in the PROS group, the number of falls reported was
323 relatively low in both groups compared to previous reports ^{2,3}. Increased prosthetic
324 experience has been reported to be protective in terms of falls risk in prosthesis users³ and the
325 high level of prosthetic experience in amputees in the current study may explain the relatively
326 low number of falls. Moreover, there were a similar number of fallers and non-fallers
327 between groups, with most fallers being recurrent fallers. The faller/non-faller split is similar
328 to previous reports from prosthesis users ⁴. This is of clinical significance, given that
329 prosthesis users who fall more than once a year may be at increased risk of fall-related injury,
330 exacerbating associated socio-economic costs. This also suggests that being able to predict
331 falls efficacy and subsequent falls in potential recurrent fallers is imperative for timely
332 intervention. Although not within the scope of the current study, future research should
333 attempt to ascertain whether differences in falls efficacy and postural control exist between
334 prosthesis users who do not fall and those who fall more often. This would further refine
335 understanding of the relationships between postural control and falls efficacy established by
336 the current study.

337

338 **Study Limitations**

339 In the current study, the two groups were well matched, meaning the effects of lower limb
340 amputation may have been more easily isolated. Whilst this benefits the comparisons made in

341 the current study, the prosthesis users had a wide range of ages and levels of prosthetic
342 experience, were relatively mobile, physically active and generally of traumatic etiology.
343 Less mobile prosthesis users of vascular etiology, with reduced and less varied levels of
344 prosthetic experience, may exhibit different balance issues compared to individuals from the
345 current cohort ³⁰. It is yet to be ascertained whether the relationships explored in the current
346 study could be generalized more broadly to such a group, or indeed a more homogenous
347 group, regardless of group characteristics. Finally, similar instruments to the FES-I and a
348 modified version of the FES-I have been used previously to assess falls efficacy and/or
349 confidence in prosthesis users²³. However, the FES-I specifically, has not been fully validated
350 in this population and it is not conclusive whether total FES-I scores should be treated as
351 ordinal data or not. Addressing these issues should be a future goal for researchers interested
352 in falls efficacy in prosthesis users.

353

354 **Conclusions**

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

361 **Suppliers**

362 ^aHultafors AB, Hultaforsvägen 21, Hultafors, Sweden.

363 ^bNeurocom International Inc., 9570 SE Lawnfield Rd, Clackamas, OR 97015, USA.

364 ^cIBM, North Harbour, Portsmouth PO6 3AU, UK.

365

366 **Figure Legends**

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

369

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

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