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The number of falls recalled in the past year and balance confidence predict the frequency of injurious falls by unilateral lower limb prosthesis users

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Abstract
Introduction: Several personal characteristics have been associated with an increased risk of injurious falls by lower limb prosthesis (LLP) users. To date, however, none have been used to effectively predict the occurrence of injurious falls.
Objective: To develop a model that could predict the number of injurious falls over the next 6 months and identify fall-related circumstances that may increase the odds of a fall being injurious in unilateral LLP users.
Design: A secondary analysis of a prospective observational study.
Setting: Research laboratory.
Participants: Sixty unilateral LLP users with a transtibial or transfemoral amputation.
Intervention: Not applicable.
Main outcome measure(s): Participants' characteristics were recorded at baseline. Falls and their circumstances and consequences were collected prospectively over 6 months via monthly telephone calls. Multivariate negative binomial regression was used to predict the number of injurious falls over the next 6 months in LLP users. Incidence rate ratios (IRRs) were derived to determine the risk of an injurious fall. Bivariate logistic regression was used to identify the associations between injurious falls and fall-related circumstances. Odds ratios (ORs) were derived to characterize the odds that a fall would be injurious.
Results: The final multivariate model, which included the number of falls recalled in the past year (IRR = 1.31, 95% confidence interval [CI]: 1.01–1.71, $p = .045$) and balance confidence ($p = .120$), predicted the number of injurious falls in the next 6 months (χ^2 (2) = 8.15, $p = .017$). Two fall-related circumstances were found to increase the odds that a fall would be injurious, fatigue due to activity (OR = 13.5, 95% CI: 3.50–52.3, $p = .001$), and tiredness from a lack of sleep (OR = 5.36, 95% CI: 1.22–23.6, $p = .026$).
Conclusion: The results suggest that the number of falls recalled in the past year and balance confidence scores predict the number of injurious falls an LLP user will experience in the next 6 months.

INTRODUCTION

The frequency of falling among lower limb prosthesis (LLP) users has remained high and largely unchanged over the past 25 years (i.e., ∼50% of LLP users fall once or more a year).[1–6] Particularly concerning to the health of LLP users is the proportion of injurious fallers. Historical data suggest that 18% to 26% of LLP users report one or more injurious falls a year.[1,2,5,7] Injurious falls carry substantial health-related consequences including financial costs, activity restrictions, and reduced quality of life.[1,2,8] Practical methods for assessing the risk of injurious falls in LLP users are required to identify those individuals at greatest risk for injurious falls, and guide clinical decision-making intended to reduce the numbers of injurious falls experienced by LLP users.[6]

Several multivariate models for predicting all types of falls in LLP users have been developed and tested.[6,9] Although promising, these models were not intended to predict falls that matter most to LLP users injurious falls.[10] The prediction of injurious falls in LLP users is presently limited to the individual effects of a handful of non-modifiable personal characteristics like gender, race, and to a lesser extent, level of amputation, cause of amputation, and age.[5,7] Other factors including body mass index (BMI), balance performance, and balance self-efficacy should be considered, as they may provide rehabilitation targets amenable to intervention. Although previous models have established an important baseline for prediction, the identified risk factors were not presented in a comprehensive multivariate model (i.e., equation) that could be used by clinicians to generate user-specific predictions. In addition, prior research examining injurious falls in LLP users has not addressed the important statistical properties of falls.[11–13] Specifically, the use of negative binomial regression has been recommended to address the recurrent and dependent nature of falls within participants, the type of data (i.e., counts), their non-normal distribution (i.e., Poisson), and accompanying overdispersion.[11,12,14] Multivariate models that consider a broader range of personal characteristics, and the dependent nature of falls within individuals,[11–13] are required to improve the prediction of injurious falls in LLP users. A predictive model (i.e., equation) could help clinicians identify LLP users at greatest risk for injurious falls and assist researchers in screening and selecting participants for studies that seek to study factors that contribute to an elevated risk for injurious falls. Beyond predicting individuals at risk for injurious falls, identifying modifiable risk factors is central to developing, evaluating, and applying interventions that might reduce injurious falls in LLP users.[15]

Circumstances associated with injurious falls among LLP users have not been studied thoroughly. Several studies have identified the circumstances of all falls in LLP users,[2,10,16,17] but only one has characterized the circumstances of injurious falls in LLP users.[7] The documented circumstances were limited to a small set of activities (e.g., walking, stairs), and analyzed using descriptive statistics (i.e., frequency). A detailed assessment of the circumstances that increase the odds that a fall will be injurious is needed to help identify risk factors for injurious falls in LLP users; develop fall-related outcome measures that reflect where, how, and why LLP users fall; and suggest potential design or control features for prosthetic componentry to improve patient safety.

The primary objective of this secondary analysis was to develop a model to predict the number of injurious falls an LLP user would experience over the next 6 months. Using demographic, amputation, health, mobility, and balance-related characteristics collected at baseline, and fall events recorded over the next 6 months, we sought to derive a predictive regression equation (i.e., model) to predict injurious falls in unilateral LLP users. A secondary objective was to identify fall-related circumstances (i.e., activities, situations, surroundings, and mechanics) that increase the odds of a fall being injurious.

METHODS

Study design

This study was a secondary analysis of falls data collected during a longitudinal multi-site study to evaluate the psychometric properties of performance-based balance tests in established unilateral LLP users.[18,19] The primary study followed the guidelines for reporting observational studies (i.e., Strengthening the Reporting of Observational studies in Epidemiology [STROBE]),[20] as well as diagnostic and prognostic studies (i.e., Standards for Reporting of Diagnostic Accuracy Studies [STARD]).[21] Study protocols were approved by institutional review boards at the University of Illinois at Chicago and University of Washington. All participants provided written informed consent prior to participation.

Participants

Participants were recruited from local prosthetic clinics in the Chicago and Seattle metropolitan areas. Inclusion criteria for the parent study were age of 18 years or older; a unilateral transtibial or transfemoral amputation; use of a prosthesis for at least 1 year (i.e., established LLP users); able to walk a short distance (i.e., 10 m) without an assistive device; and able to read, write, and speak English. Exclusion criteria included having an amputation of another limb; contralateral complications (e.g., hip replacement); or any condition that would prevent participants from completing the study protocol. The inclusion and exclusion criteria were applied by two of the study authors.

Procedures

Participants' personal characteristics and balance performance were assessed at baseline via self-report, participant interview, and/or performance-based balance tests. They were subsequently followed for 6 months, during which the incidence of and details (i.e., circumstances and consequences, including injuries) of any falls were recorded during monthly telephone calls.[22]

Measurements

Personal characteristics

BMI was measured with participants' prosthesis to categorize weight status.[23] The Charlson Comorbidity

Index (CCI), which includes 10 prevalent comorbidities,[24] was used to record the number of comorbidities. The 12-item short-form Prosthetic Limb Users Survey-Mobility (PLUS-M) was used to assess perceived mobility of the study participants,[25] whereas the Medicare Functional Classification Level (MFCL) system was used by a certified prosthetist to evaluate participants' functional status based upon self-reported activities and use of their prosthesis.[26] The five-point version of the Activities-specific Balance Confidence (ABC) scale was used to assess balance confidence.[27] The Patient-Reported Outcomes Measurement Information System (PROMIS) four-item fatigue short form was used to assess participants' degree of overall fatigue.[28,29] Several of these self-report measures, specifically those assessing perceived mobility and balance confidence, have been used to assess fall risk in LLP users,[9,30] and possess evidence of validity[25,31,32] and reliability[31–33] in unilateral LLP users.

Balance assessment

The Narrowing Beam Walking Test (NBWT),[34] Four Square Step Test (FSST),[35] and Timed Up and Go (TUG)[36] were used to measure participants' balance and mobility. Performance tests were administered and scored according to standardized instructions.[18] These three tests were selected because they possess evidence of validity[6,34,35,37,38] and reliability[19] among unilateral LLP users.

Fall assessment

The number of falls in the past 12 months was determined by interview at baseline and coded as 0, 1, 2, 3, 4, or ≥5 falls. Participants were asked '*in the past year have you lost your balance and landed on the ground or lower level, other than as a result of a loss of consciousness, a violent blow, stroke, or epileptic seizure?*'[22,39,40] Falls experienced over the next 6 months were collected prospectively via monthly telephone calls. Participants were asked, '*We last saw you/spoke to you on [date]. Since then, have you lost your balance and landed on the ground or lower level?*' If participants reported one or more falls, they were asked to describe the circumstances and injuries associated with each fall. Fall circumstances were collected using a preliminary version of the Lower Limb Prosthesis Users Fall Event Survey, which classifies fall circumstances into four categories: activity, surroundings, situation, and mechanics.[41] To ascertain whether a fall was injurious, participants were asked '*did you experience an injury because of this fall?*' If participants reported an injury, they were asked to describe the nature of the injury including the type (e.g., fracture, sprain, pain) and location of the injury (e.g., arm, leg), and whether they sought and/or received medical attention. For this secondary analysis, injurious falls were any fall that resulted in a physical injury (e.g., bruise, cut, subluxation, or fracture). As a result, injuries related to falls in the present study were likely to range from minor to severe. To ensure consistency in data collection and facilitate aggregation of comparable data across fall events and study participants, research team members used a fixed set of questions to document fall-related injuries.

Statistical analysis and data interpretation

The normality of all continuous variables was assessed using Shapiro–Wilk tests.[42] Measures of central tendency and dispersion, as well as frequency and percentage, were calculated to describe continuous and categorical variables, respectively.

Initial associations between injurious falls and available demographic (i.e., gender and age), health (i.e., BMI, fatigue, and number of comorbidities), amputation (i.e., time since amputation, etiology, and amputation level), mobility (i.e., MFCL and PLUS-M), and balance-related variables (i.e., ABC score, number of falls in past year, NBWT, FSST, and TUG performance) were identified by running bivariate generalized linear models, with a negative binomial distribution and log-link function.[6,9,11,12,14] A negative binomial model was selected owing to the recurrent and dependent (i.e., within-participant) nature of falls, the type of data (i.e., counts), and the non-normal distribution and accompanying overdispersion of fall count data.[6,9,11–14,43,44] Any variables found to have a significant bivariate association with injurious falls at a p value of <.20 were considered candidate predictor variables for the multivariate analysis to ensure that borderline association would not be overlooked.[2,45] Pearson correlation tests were performed to examine collinearity between candidate predictor variables.[45] In the case of a correlation between two candidate predictor variables that was greater than or equal to .7, the candidate predictor variable with the higher incidence rate ratio (IRR) in the bivariate analysis was carried forward into the multivariate analysis.

A predictive model for injurious falls in unilateral LLP users was developed using a multivariate generalized linear model, with a negative binomial distribution and log-link function. The initial model was populated with the candidate predictor variables found to be associated with injurious falls in the bivariate analyses, and free from collinearity. In an iterative backward stepwise elimination procedure, candidate predictor variables were removed from the initial model if they were not significantly associated and not a confounding variable. Significance was evaluated at an α-level of .15[9,43] and confounding as a change in any parameter estimate (i.e., ß-value) greater than 20% upon removal of a candidate variable.[46] Model reduction continued until a statistically significant omnibus test ($p < .05$) was achieved (i.e., the final model was significantly better than a null model at predicting the incidence of injurious falls), and all remaining predictor variables had a p value < .15. Pearson chi-square goodness-of-fit tests were used to assess the fit of the model at each stage of development. Regression coefficients of those variables making statistically significant contributions ($p < .05$) in the final model were exponentiated to derive IRRs and accompanying 95% confidence intervals (CI).

Fall circumstances associated with injurious falls were identified by running bivariate generalized estimation equations[47,48] with a logistic regression model (i.e., injurious or non-injurious fall).[45,49] Generalized estimation equations are recommended for analyzing non-normal response variables collected during longitudinal and repeated measures study designs to produce more efficient and unbiased regression estimates.[47,48] Fall circumstances significantly associated with injurious falls ($p < .05$) were interpreted as scenarios that may increase the odds of a fall being injurious. Fall circumstances, however, were not included in the development of the multivariate predictive model because they occurred at the time of the fall, rather than being recorded at baseline prior to the fall, and, therefore, could not be used to predict the outcome of a future event. The results were interpreted using odds ratios (ORs) and their 95% CI. All statistical analyses were performed using SPSS version 28 (Chicago, IL).

RESULTS

Fall incidence

Sixty established unilateral transtibial and transfemoral prosthesis users were recruited and participated in the parent study.[18] All 60 participants were included in the current analysis. Over 6 months of prospective reporting, 28 participants reported a total of 53 falls, for a 6-month rate of 0.88 falls per participant. Twenty participants reported 29 injurious falls, for a 6-month rate of 0.48 injurious fall per participant.

Participant characteristics

Except for BMI ($W = .976$, $p = .293$), PLUS-M T-scores ($W = .986$, $p = .729$), and NBWT scores ($W = .974$, $p = .239$), all continuous variables, including fall counts, were non-normally distributed ($W = .622$–$.972$, $p \leq .03$). Demographic, amputation, health, balance and mobility-related characteristics of study participants are presented in Table 1 based on fall injury status.

TABLE 1 Demographic, health, amputation, mobility, and balance-related characteristics of the study sample grouped by prospective fall injury status

		All participants ($n = 60$)	Injurious fallers ($n = 20$)	Non-injurious fallers and non-fallers ($n = 40$)
Gender	Male	42 (70%)	13 (21.7%)	29 (48.3%)
	Female	18 (30%)	7 (11.7%)	11 (18.3%)
Amputation etiology	Dysvascular	24 (40%)	8 (13.3%)	16 (26.7%)
	Non-dysvascular	36 (60%)	12 (20.0%)	24 (40.0%)
Amputation level	Transtibial	45 (75%)	14 (23.3%)	31 (51.7%)
	Transfemoral	15 (25%)	6 (10.0%)	9 (15.0%)
MFCL	K1 and K2	18 (30%)	7 (11.7%)	11 (18.3%)
	K3 and K4	42 (70%)	13 (21.7%)	29 (48.3%)
Age (years)	Median (Q1, Q3)	58.5 (45.8, 67.0)	58.0 (48.0, 71.0)	58.5 (42.0, 65.5)
Time since amputation (years)	Median (Q1, Q3)	11.5 (3.25, 26.0)	12.0 (3.0, 28.5)	10.5 (5.0, 23.5)
Body mass index (kg/m^2)	Mean (SD)	27.8 (5.13)	28.8 (6.03)	27.4 (4.68)
Number comorbidities	Median (Q1, Q3)	1.0 (0, 2.0)	1.0 (0, 2.0)	0 (0, 1.5)
PROMIS Fatigue (*T*-score)	Median (Q1, Q3)	46.0 (33.7, 51.0)	48.6 (42.9, 51.0)	46.0 (33.7, 51.0)
PLUS-M (*T*-score)	Mean (SD)	56.1 (6.82)	54.5 (7.57)	56.9 (6.43)
ABC scale score (0–4)	Median (Q1, Q3)	3.28 (2.60, 3.63)	2.94 (2.32, 3.53)	3.35 (2.72, 3.66)
Number of falls in the past year	Median (Q1, Q3)	1.0 (0, 2.0)	1.0 (0, 3.0)	1.0 (0, 2.0)
NBWT score (0–1)	Mean (SD)	.414 (.204)	.360 (.177)	.441 (.214)
FSST time (s)	Median (Q1, Q3)	9.10 (7.01, 11.9)	9.09 (7.80, 12.2)	8.84 (6.77, 11.9)
TUG time (s)	Median (Q1, Q3)	9.92 (8.27, 11.5)	10.5 (9.32, 11.5)	9.71 (7.88, 11.5)

Abbreviations: ABC, Activities-specific Balance Confidence; FSST, Four Square Step Test; MFCL, Medicare Functional Classification Level; NBWT, Narrowing Beam Walking Test; PLUS-M, Prosthetic Limb Users Survey of Mobility; PROMIS, Patient-Reported Outcomes Measurement Information System; s, seconds; SD, standard deviation; TUG, Timed Up and Go; Q1, first quartile; Q3, third quartile.

TABLE 2 Bivariate associations between the incidence of injurious falls and demographic, health, amputation, mobility, and balance-related characteristics in the study sample of 60 unilateral transtibial and transfemoral prosthesis users

	ß	IRR[a] (95% CI)	pvalue[b]
Gender (female vs. male)	.640	1.90 (.758, 4.74)	.171[e]
Age (years)	.010	1.01 (.981, 1.04)	.502
Body mass index (kg/m^2)	−.048	.953 (.879, 1.03)	.243
Number of comorbidities[c]	.061	1.06 (.700, 1.61)	.776
PROMIS fatigue (*T*-score)	.020	1.02 (.972, 1.07)	.414
Amputation etiology (dysvascular vs. non-dysvascular)	.057	1.06 (.430, 2.61)	.901
Amputation level (transfemoral vs. transtibial)	.457	1.58 (.603, 4.14)	.353
Time since amputation (years)	.013	1.01 (.986, 1.04)	.360
Medicare functional classification level (K1/K2 vs. K3/K4)	−.118	.889 (.332, 2.38)	.814
Prosthetic limb users survey of mobility (*T*-score)	−.071	.932 (.868, 1.00)	.049[e]
ABC scale score (0–4)	−.635	.530 (.283, .993)	.048[e]
Number of falls in the past year[d]	.312	1.37 (1.05, 1.77)	.019[e]
NBWT score (0–1)	−.084	.919 (.826, 1.02)	.122[e]
FSST time (s)	−.043	.958 (.861, 1.07)	.430
TUG time (s)	.024	1.02 (.866, 1.21)	.782

Abbreviations: ABC, Activities-specific Balance Confidence; ß, regression coefficients; CI, confidence interval; FSST, Four Square Step Test; IRR, incidence rate ratio; NBWT, Narrowing Beam Walking Test; PROMIS, Patient-Reported Outcomes Measurement Information System; TUG, Timed Up and Go.

[a]An IRR can take values = 1 (no risk), >1 (increased risk), or <<1 (decreased risk). An IRR whose 95% confidence interval includes 1 suggests that there is no significant increase or decrease in the risk for an injurious fall.

[b]Statistical threshold was set at .20.

[c]Number of comorbidities based on Charlson comorbidity index.

[d]Number of falls in the past year were coded as 0, 1, 2, 3, 4, or ≥≥5.

[e]Initial predictor variable carried forward to multivariate model.

Identification of candidate predictor variables

Bivariate negative binomial regression identified five variables; gender, PLUS-M *T*-scores, ABC scale scores, number of falls recalled in the past year, and NBWT scores that met the conservative a priori criteria to be considered candidate predictor variables (i.e., $p \leq .20$) (Table 2). Pearson correlation coefficients between each of the five candidate predictor variables indicated that PLUS-M T-scores and ABC scale scores were significantly correlated ($r = .789$, $p < .001$), suggesting collinearity. To reduce collinearity, PLUS-M T-scores were dropped, and ABC scale scores were carried forward into the initial multivariate model because of their stronger protective effect (i.e., lower IRR) identified in the bivariate analysis (i.e., ABC: 0.530, PLUS-M: 0.932) (Table 2). Consequently, four candidate predictor variables— gender, ABC scale scores, number of falls recalled in the past year, and NBWT scores—were carried forward into the development of the multivariate model.

Multivariate model development

Following model reduction, two candidate predictor variables—number of falls recalled in the past year and ABC scores—were retained in the final multivariate model ($p < .15$) (Table 3). Each step in the model reduction is presented in Table S1. A chi-square goodness-of-fit test revealed no significant differences between the observed and expected number of injurious falls over the prospective reporting period in the final model, indicating that the final model fit the prospective injurious fall count data ($\chi^{2\chi}$ (57) = 38.1, $p = .668$) (Table S1). A likelihood ratio chi-square omnibus test revealed that the final model was significantly better than a null model (i.e., one with no factors) at predicting the number of injurious falls over the next 6 months (χ^2 (2) = 8.15, $p = .017$). In the final model, the number of falls recalled over the past year was a statistically significant predictor of the number of injurious falls over the next 6 months, but ABC scores were not (number of falls recalled $p = .045$, ABC: $p = .120$). The final model predicts an increase in the expected number of injurious falls as the number of falls recalled over the past year increases, and ABC scores are held at their sample mean (number of falls in past year: IRR = 1.31, 95% CI: 1.01–1.71) (Table 3). Viewed jointly within the final model (Equation 1), the combined effect of the number of falls recalled and ABC scores on predicting the number of future injurious falls was statistically significant (Table 3).

$$\#\text{ of injurious falls over next 6 months} = exp\left((\text{-}.519 * ABC\ score) + (.271 * falls\ in\ past\ year) + .321\right)$$

TABLE 3 Final multivariate negative binomial model to predict the number of injurious falls by unilateral transtibial and transfemoral prosthesis users over the next 6 months

Final model ($ß_0 = .321$)			
Variable	**ß**	**IRR[b] (95% CI)**	***p* value[c]**
Number of falls in the past year[a]	.271	1.31 (1.01, 1.71)	.045
ABC scale score	−.519	N/A	.120

Note: Predicted # of injurious falls = exp ((−.519 * ABC score) + (.271 * Number of falls in past year) + .321).
Abbreviations: ABC, Activities-specific Balance Confidence; ß, regression coefficient; β_o, regression intercept; CI, confidence interval; IRR, incidence rate ratio.
[a]Number of falls in the past year were coded as 0, 1, 2, 3, 4, or ≥≥ 5.
[b]IRR can take values = 1 (no risk), >1 (increased risk), or << 1 (decreased risk). An IRR whose 95% confidence interval includes 1 suggests that there is no significant increase or decrease in the risk for an injurious fall.
[c]Statistical threshold was set at .15.

TABLE 4 Bivariate associations between the incidence of injurious falls and fall circumstances in the study sample of 60 unilateral transtibial and transfemoral prosthesis users

Fall circumstances	Injurious falls ($n = 29$)	Non-injurious falls ($n = 24$)	ß	OR[a] (95% CI)	*p* value[b]
Activity					
Gait	19	16	−.051	.950 (.296, 3.05)	.931
Transfer	7	5	.190	1.21 (.380, 3.85)	.748
Reaching	5	1	1.57	4.79 (.417, 55.0)	.208
Static	2	3	−.657	.519 (.131, 2.06)	.350
Surroundings					
Rough surface	10	10	−.305	1.36 (.524, 3.52)	.530
Non-level terrain	5	7	−.875	.417 (.107, 1.63)	.208
Narrow surface[c]	4	0	2.16	8.65 (0.442, 169.2)	.155
Wet surface	3	6	−1.06	.346 (.082, 1.47)	.149
Outdoor	8	10	−.629	1.88 (.699, 5.03)	.212
Crowded area	7	1	1.99	7.32 (.979, 54.7)	.053
Fall Mechanics					
Caught foot	12	11	−.181	.834 (.291, 2.40)	.736
Foot slipped	6	4	.266	1.30 (.340, 5.00)	.698
Bumped, pushed, pulled	1	1	−.197	.821 (.049, 13.8)	.891
Lateral falls	11	10	−.156	.856 (.259, 2.83)	.798
Forward falls	10	8	.051	1.05 (.428, 2.59)	.911
Backward falls	5	5	−.234	.792 (.226, 2.78)	.715
Situation					
Fatigue due to activity	16	2	2.60	13.5 (3.50, 52.3)	.001
Tired from lack of sleep	15	4	1.68	5.36 (1.22, 23.6)	.026
Rushed or in a hurry	9	7	.089	1.09 (.325, 3.68)	.886
Distracted	8	4	.644	1.91 (.465, 7.81)	.371

Abbreviations: ß, regression coefficients; CI, confidence interval; OR, odds ratio.
[a]An OR of 1 indicates no association between dependent and independent variables. OR > or << 1 indicates a positive or negative association, respectively, and is significant if the 95% CI does not include 1.
[b]Threshold for significance set at 0.05.
[c]Haldane–Anscombe correction was performed to accommodate zero counts.

Fall circumstances associated with injurious falls

Bivariate generalized estimation equations identified two circumstances that were associated with an increased odds of a fall being injurious (Table 4). Self-reported "fatigue due to activity" at the time of the fall (OR = 13.5, 95% CI: 3.50–52.3, $p =$ .001), and "being tired from a lack of sleep" (OR = 5.36, 95% CI: 1.22–23.6, $p = .026$) were the two situations at the time of a fall that increased the odds that a fall would be injurious (Table 4). No activities, surrounding, or fall mechanics were found to be significantly associated with increased odds of a fall being injurious (Table 4).

DISCUSSION

The primary objective of this secondary analysis was to develop a model to predict the number of injurious falls an LLP user would experience over the next 6 months. We also sought to identify circumstances associated with injurious falls in established unilateral LLP users. Two predictors, balance confidence (i.e., ABC scale score) and the number of falls recalled in the past year, were retained in the final predictive model. Unique to the current study, the final predictive model is presented as a simple regression equation that clinicians can use to make quick, easy, and much needed predictions to identify unilateral transtibial and transfemoral prosthesis users at greatest risk for injurious falls. For example, an LLP user who recalls four falls in the past 12 months and has a score of 2.70 on the five-point ABC scale, would be predicted to experience 1.0 injurious falls over the next 6 months. Our results also revealed that falls when fatigued due to activity, or tired from lack of sleep, were more likely to be injurious. Future research is required to assess the external validity of the predictive injurious falls model.

The frequency of, and risk factors for, injurious falls among LLP users in this secondary analysis differed from what has been reported previously. Thirty-three percent of LLP users in the current study reported one or more injurious falls. In contrast, the historical incidence and prevalence of injurious falls in LLP users has fluctuated between 18% and 29%.[1,2,5,7] A direct comparison between the frequency of injurious falls in the current study and that reported in previous studies[1,2,5,7] is limited by differences in the length of the reporting periods (i.e., 6 vs. 12 months), as well as the number of participants. The incidence of injurious falls experienced by the 60 LLP users in the current study over 6 months cannot be compared directly to the incidence of injurious falls in samples of 41 to 435 LLP users over 12 months.[1,2,5,7] Similarly, a 6-month incidence of falls cannot simply be doubled to facilitate such a comparison. The 6-month incidence of injurious falls reported here should be interpreted in relative rather than absolute terms with respect to data from previous studies that used a 12-month reporting period.[1,2,5,7] Specifically, a direct and unbiased comparison requires presenting the number of events (i.e., injurious falls) per unit of person-time. Wong et al., the only study to describe or provide the data required to calculate the number of injurious falls per unit of person-time, reported 1.4 injurious falls per 100 person-months.[5] In contrast, LLP users in the current study reported injurious falls at a rate of 7.7 injurious falls per 100 person-months. Viewed within the context of previous research (i.e., 1.4 injurious falls per 100 person-months), the rate of injurious falls in the current study (i.e., 7.7 injurious falls per 100 person months) may be regarded as evidence that injurious falls remain as large a problem in LLP users as they have been over the past 25 years.

Two factors may explain the difference in the frequency of injurious falls between the current and previous studies: how injurious falls were defined, and how they were recorded. Two of the initial studies to document injurious falls among LLP users[1,2,5,7] provided explicit definitions of injurious falls: "events resulting in a major injury (e.g., fracture) that required medical attention,"[5,7] whereas the other two did not.[1,2] Injurious falls in the current study included both minor (e.g., sprain) and major injuries (e.g., fracture). The decision to include both major and minor injuries was made to avoid excluding injuries that could be of consequence to LLP users but did not require immediate medical attention (e.g., sprain). Broadening what was considered an injurious fall likely contributed to the higher reported incidence and rate of injurious falls by LLP users in the current study. The development of a definition for injurious falls that is both clear and meaningful to key stakeholders, including LLP users (i.e., what do LLP users consider to be an injurious fall), researchers, and health insurance providers, would ensure that future research reflects what matters most about injurious falls to LLP users, and help standardize data collection across studies so that a comparison and aggregation of data between studies is possible.[41]

Methods used to ascertain the frequency of injurious falls may also have contributed to the differences between studies. Three of the four studies that have characterized injurious falls in LLP users did so using a cross-sectional study design and retrospective recall of fall events.[1,2,7] Although imposing substantially less burden, fall recall may be susceptible to memory decay and cause LLP users to under- or over-report fall events and their details.[50–52] It is possible, therefore, that LLP users in cross-sectional studies may misremember the number and/or severity of injurious falls they experienced. Owing to documented cognitive concerns noted by LLP users,[53,54] future research is necessary to better understand fall-recall accuracy and fall-related memory decay in people with lower limb amputations. In addition, cross-sectional study designs are prone to temporal limitations when interpreting associations between risk factors and falls. For example, an LLP user's balance confidence at the time of a study may be altered from what it was prior to the fall(s) that are under investigation in a retrospective study. As a result, associations between fall-risk factors and a history of falls may be confounded by the fall event(s) occurring prior to the collection of the risk factor.

Among the demographic and amputation-related characteristics previously associated with an increased risk for injurious falls by LLP users, none were associated with injurious falls in the current study. In a multivariate model that included age, gender, race, and amputation etiology, Wong et al. reported that females and people of non-White race were ∼6 and 13 times more likely than males or people of White race to experience an injurious fall in the next 12 months, respectively.[5] Similarly, Chihuri et al. reported that in addition to gender and race, amputation etiology (i.e., dysvascular) and level (i.e., transtibial) were significantly associated with a history of injurious falls.[7] The current study did not find any of these demographic or amputation-related characteristics to be significantly associated with an increased risk for injurious falls. Rather, the final multivariate model retained two different predictors of injurious falls: balance confidence and the number of falls recalled in the past year. The absence of an association between performance-based balance tests (e.g., FSST, NBWT) and injurious falls may be attributed to the fact that these balance tests do not assess injurious fall circumstances or balance strategies required to avoid or recover from a loss of balance or prevent an injury. Observed differences between the current and previous studies regarding risk factors found to be associated with injurious falls by LLP users may be due to the longitudinal (prospective) study design, the treatment of injurious falls as count data rather than a categorical variable (i.e., injury or no injury), the use of a negative binomial model to account for the recurrent and dependent nature of falls data collected, as well as the non-normal distribution and accompanying overdispersion of fall count data.[6,9,11–14,43,44]

Fall-related circumstances have been studied previously among LLP users for descriptive and classification purposes.[2,7,16,17] In this study, several circumstances associated with increased odds of a fall being injurious were identified. None of the fall circumstances most frequently reported in previous studies (e.g., walking, catching the prosthetic foot, incorrect body weight shift)[2,7,16,17] were found to be associated with an increased odds of a fall being injurious in the current study. It would appear therefore, that the circumstances most frequently associated with all falls are not the same as those that are the most likely to result in a fall being injurious. Falls that occurred when LLP users reported "being tired from lack of sleep" or "fatigued due to activity" were 5 and 15 times more likely to be injurious, respectively. Fatigue due to activity has been associated with increased risk of falls[55] and greater instability in older adults,[56,57] as well as people with multiple sclerosis.[58] The impact of activity-related fatigue on falls and balance performance might be explained by its deleterious effect on muscle strength,[59] proprioception and sensation,[60,61] or gait.[62] For example, in older adults, activity-based fatigue resulted in lower foot clearance and a decrease in obstacle-crossing performance.[63] Circumstances found to be associated with an increased odds of a fall being injurious may help design and develop performance-based tests that can be administered to improve risk assessments for injurious falls in LLP users. For example, based on the circumstance "fatigue due to activity," a performance test that assesses balance ability after a fatiguing protocol may help identify LLP users at greater risk for injurious falls.

Interpretation and application of the results of this study should be done in consideration of several limitations. First, both minor and major injuries were included and analyzed in this study. Although the incidence of minor and major injuries may require and warrant separate prediction models in a larger study, their inclusion herein addressed a limitation of previous work, namely that minor injuries may affect prosthetic function and should therefore be considered in any predictions.[5] It is also possible that a major injury resulting from a fall could confound the number of falls experienced by LLP users by reducing their activity level, and thus opportunity or exposure to fall-related situations. Minor injuries may similarly alter activity patterns of LLP users to avoid a more severe injury in the future. Although it has not been historically recommended,[22] it might be suitable to adjust the frequency of fall events for physical activity or step count.[64] Second, predictions made with the final multivariate model are limited to a 6-month period. It is unknown if the same model would retain its predictive accuracy over longer or shorter periods. Future research is warranted to establish the optimal interval of time between evaluations, and over which, fall prediction accuracy is maximized. Third, sample composition may limit the generalizability of the proposed model. The study sample was slightly skewed toward non-dysvascular, more experienced, otherwise healthy transtibial prosthesis users with above-average perceived mobility. Consequently, the proposed model may not generalize to older, less-experienced bilateral LLP users, who have lower perceived mobility, additional comorbidities, and routinely use an assistive device to ambulate. Additional research with a larger sample that includes these additional amputation, demographic, health, and mobility-related characteristics is required to discern the external validity and generalizability of the predictive model. Fourth, backward stepwise regression may produce an unstable selection of variables or result in biased outputs that may affect model prediction. Several precautions, including testing for collinearity and confounding variables, were used to minimize the limitations of the chosen approach. Alternative regression methods, which capitalize on larger sample sizes, should be considered in future research to strength the validity of predictive models (e.g., cross-validation). Furthermore, although falls included multiple circumstances, the odds that a fall would be injurious were estimated by associations with individual circumstances rather than any observed combination of circumstances. As a result, those falls with more circumstances were represented with greater frequency, potentially confounding how the circumstances of a fall interact to increase the odds of an injury. Finally, because this was a secondary analysis, several variables that have been reported to be associated with balance ability or fall history (e.g., muscle strength, number of medications, or sensation)[65–67] were not included in this study. Furthermore, an analysis of minor versus major injuries was not performed due to the limited sample size. The inclusion of such variables and consideration for the severity of injury in future research may serve to improve model function.

CONCLUSION

The combined effect of number of falls recalled in the past year and balance confidence was found to predict the number of injurious falls over the next 6 months in established, unilateral LLP users who were largely of non-dysvascular etiology, above average perceived mobility, and otherwise healthy. Among fall circumstances, being fatigued due to activity or tired from lack of sleep at the time of a fall increased the odds of a fall being injurious. The results of this study may help clinicians identify LLP users at risk for injurious falls, and thus in need of suitable intervention. Additional research with a larger sample and an expanded set of risk factors (e.g., pain, reaction time, strength) as well as participant characteristics (e.g., greater number of comorbidities) is needed to assess the external validity and test the generalizability of the proposed prediction model to the wider LLP user population.

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DISCLOSURE

The authors declare no competing interest.

INSTITUTIONAL REVIEW

All study procedures were reviewed and approved by University of Illinois at Chicago and University of Washington institutional review boards. All participants provided written informed consent prior to participation.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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