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ORIGINAL RESEARCH

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Performance-based balance tests, combined with the number of falls recalled in the past year, predicts the incidence of future falls in established unilateral transtibial prosthesis users

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Abstract

Background: Falls are common and consequential events for lower limb prosthesis (LLP) users. Currently, there are no models based on prospective falls data that clinicians can use to predict the incidence of future falls in LLP users. Assessing who is at risk for falls, and thus most likely to need and benefit from intervention, remains a challenge.
Objective: To determine whether select performance-based balance tests predict future falls in established, unilateral transtibial prosthesis users (TTPU).
Design: Multisite prospective observational study.
Setting: Research laboratory and prosthetics clinic.
Participants: Forty-five established, unilateral TTPU.
Intervention: Not applicable.
Main Outcome Measures: The number of falls reported over a prospective 6-month period. Timed Up-and-Go (TUG) and Four-Square Step Test (FSST) times, as well as Narrowing Beam Walking Test scores were recorded at baseline, along with the number of falls recalled over the past 12 months and additional potential fall-risk factors.
Results: The final negative binomial regression model, which included TUG ($P = .044$) and FSST ($P = .159$) times, as well as the number of recalled falls ($P = .009$), was significantly better than a null model at predicting the number of falls over the next 6 months ($X^2[3] = 11.6$, $P = .009$) and fit the observed fall count data ($X^2[41] = 36.12$, $P = .20$). The final model provided a significant improvement in fit to the prospective fall count data over a model with fall recall alone $X^2(1) = 4.342$, $P < .05$.
Conclusion: No combination of performance-based balance tests alone predicted the incidence of future falls in our sample of established, unilateral TTPU. Rather, a combination of the number of falls recalled over the past 12 months, along with TUG and FSST times, but not NBWT scores, was required to predict the number of "all-cause" falls over the next 6 months. The resulting predictive model may serve as a suitable method for clinicians to predict the incidence of falls in established, unilateral TTPU.

INTRODUCTION

Falls are a common[1,2] and costly[3] health care problem for lower limb prosthesis (LLP) users. The ability to identify LLP users at greatest risk for falls, and thus most likely to need and benefit from rehabilitation interventions, is essential to lower the incidence of falls in LLP users. Effective screening of fall risk in LLP users is, however, elusive because of a paucity of evidence about predictive risk factors and/or performance-based

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tests scores.[4-6] In absence of valid thresholds, indices, or models to help clinicians use such information to predict who is at risk of falling, prescription of rehabilitation interventions intended to reduce the incidence of falls by LLP users will remain a challenge.

Existing evidence to guide fall risk assessment in LLP users is largely based on retrospective or cross-sectional study designs.[2,6-15] Although suitable for identifying potential fall risk factors,[2,11,12] evaluating the degree of content and construct validity of performance-based tests,[6,8,16] or deriving initial validity indices or thresholds to discriminate LLP users with and without a history of fall(s),[7,9,10] cross-sectional study designs are unable to establish temporal relationships between balance ability or risk factor and fall status.[17] Prospective studies, where balance ability or risk factors are ascertained at baseline and future fall events are tracked over an ensuing reporting period, are needed to assess the predictive validity of risk factors and performance-based balance test scores.[4]

Evidence of predictive validity for performance-based balance tests is limited by the scope and number of studies that have investigated fall-related events in LLP users.[4,6,7] Prospective, fall-related studies in LLP users to date have identified risk factors associated with injurious falls (ie, gender and race),[18] inpatient falls (ie, age greater than 70 years),[19] and falls by acute LLP users (ie, ≥ 4 comorbidities, activity level).[20] Prospective evaluation of performance-based balance tests administered to LLP users has received even less attention. Although thresholds of ≥19 and 24 seconds on the Four Square Step Test (FSST) and Timed Up and Go (TUG), respectively, often identified acute (i.e., <6 months post amputation) unilateral transtibial prosthesis users (TTPU) at risk for multiple falls,[20] it remains unclear whether performance-based balance tests can predict future falls in established LLP users. Clinicians, therefore, have limited ability to identify LLP users most likely to need and benefit from intervention intended to reduce falls.

The primary objective of this prospective study was to assess whether performance-based balance tests could predict the number of future "all-cause" falls in a group of established unilateral TTPU (ie, falls regardless of the underlying situation, activity, environment, or fall pattern). Based on their construct and discriminant validity,[6,7] we hypothesized that Narrowing Beam Walking Test (NBWT), FSST, and TUG would predict the number of future falls in unilateral TTPU. We further hypothesized that when paired with a common clinical fall risk screening tool, the number of falls recalled over the past year, scores on these performance-based tests would improve the prediction of future falls in TTPU users compared to fall recall alone. We also sought to derive predictive regression equations (ie, models) and incidence rate ratios for those factors found to make statistically significant contributions to the prediction of future falls.

METHODS

Study design

A two-site (University of Illinois at Chicago and University of Washington) prospective observational study was conducted to assess the predictive validity of the NBWT,[21] TUG,[22] and FSST[20] in established unilateral TTPU. Study protocols were reviewed and approved by an institutional review board at each site. All individuals provided written informed consent before participation.

Participants

Individuals with a unilateral transtibial amputation were recruited from prosthetic clinics in Chicago and Seattle using convenience sampling. To participate, individuals were required to be 18 years of age or older; have a unilateral transtibial amputation due to trauma, dysvascular complications, cancer, or infection; have a history of wearing a prosthesis for at least 1 year post amputation; be able to walk 10 m without use of a cane or walker; and be able to read, write, and speak English. Participants were excluded if they had another amputation, contralateral complications, or a neuromusculoskeletal or cardiopulmonary condition that would preclude them from completing testing procedures.

An a priori power analysis indicated that a sample of 30 LLP users (ie, 15 fallers, 15 non-fallers) would be sufficient to detect a statistically significant difference in performance-based test scores between fallers and non-fallers. To maximize the likelihood that at least 15 fallers were identified over the 6-month prospective reporting period, a conservative target of 45 TTPU was established.

Procedures

Sociodemographic, amputation, health, balance, and mobility measures were administered at baseline, along with the three performance-based balance tests. The number of falls over the ensuing 6 months was recorded during monthly telephone calls.

Measurements

Participant characterization measures

Age and gender were collected via self-report, and amputation-related characteristics and Medicare Functional Classification Level were collected via interview. The number of comorbidities was assessed using the Charlson Comorbidity Index,[23] and perceived mobility and balance confidence were assessed using the

Prosthetic Limb Users Survey of Mobility (PLUS-M)[24] and Activities-specific Balance Confidence (ABC) scale,[25,26] respectively. The ABC was administered and scored using the recommended five-point scale.[25] Comfort of the prosthesis worn by each participant was evaluated using the Socket Comfort Score.[27,28]

Performance-based tests

The TUG,[22] FSST,[20] NBWT,[21] and 10-Meter Walk Test (10MWT)[29]were administered to participants in a randomized order, determined by a random number generator, and scored according to standardized instructions (Appendix). Standardized procedures were applied to ensure conformity in test administration and scoring between study sites. The TUG, FSST, and NBWT were each included in predictive model development because they were designed or used to assess fall risk in LLP users, and have evidence of construct and discriminant validity,[6,20,30,31] as well as reliability,[32] in TTPU. The 10MWT was administered to characterize participants' self-selected walking speed but was not included in the predictive modeling owing to a lack of similar evidence demonstrating an association with falls in TTPU.

Falls assessment

The number of falls over the prior 12 months was determined at baseline by asking participants, "*In the past year have you lost your balance and landed on the ground or lower level?*"[33-35] The number of falls over the subsequent 6 months was assessed via monthly telephone interviews. At each call participants were asked, "*Since we last saw you/spoke to you on [date], have you lost your balance and landed on the ground or lower level?*"

Statistical analysis

Departures from normality among continuous variables were evaluated using the Shapiro-Wilk test.[36] Prospective falls data were summarized as the total number of falls in the sample, fall rate per person year, time to first fall, as well as the number and percentage of non-fallers, non-recurrent fallers (ie, single fall), and recurrent fallers (ie, ≥2 falls).[33] Kruskal-Wallis and Fisher's exact ($2 \times C$) tests were run to assess differences in the distributions of continuous variables and the frequency of dichotomous variables, between prospective fall categories (i.e., non-faller, non-recurrent faller, and recurrent faller) respectively. The level of significance was adjusted to $\alpha \leq .0167$ to account for multiple comparisons between the three faller categories.

Negative binomial regression was used to develop predictive models and test study hypotheses. Negative binomial regression has been recognized,[37-40] and used,[41-44] as the most suitable method for analyzing fall data owing to the recurrent and dependent nature of falls in each participant, the type of data (ie, counts), the non-normal distribution (ie, Poisson), and the accompanying overdispersion of fall count data. Three predictive negative binomial regression models, a performance-based test (PB T) model, a fall recall (FR) model, and a combined performance-based test and fall recall (PB T + FR) model, were developed to determine whether performance-based tests predict future falls in unilateral TTPU, and if they improved fall prediction over fall recall alone. The initial PB T + FR model included TUG and FSST times, NBWT scores, the number of falls recalled in the past 12 months, and PLUS-M T-scores. We reduced the initial PB T + FR model by removing factors in a backward order,[45-47] preserving those variables with P values ≤.15 to ensure borderline relationships would not be overlooked.[2] These steps were repeated until a statistically significant model (i.e., omnibus test $P < .05$) was identified, which also contained factors whose contributions to predicting the incidence of future falls had P values ≤.15.[40] Similar procedures, minus the inclusion of fall recall, were followed to develop the PB T model. The FR model, which consisted of the number of falls TTPU recalled experiencing in the past 12 months and PLUS-M T-scores, was included based on the popularity of fall recall as a fall risk screening tool, and the association between mobility and falls in LLP users.[20,48] Fall risk factors previously associated with a history of falls in LLP users[4,5] including age, level of amputation[2,48] cause of amputation, and time since amputation,[2] as well as hours of prosthetic wear,[1] and number of co-morbidities[2,20] were excluded from the current analysis because of their inconsistency[1,2,9,11] and our primary focus on balance ability. Regression coefficients (β) of those factors making statistically significant contributions ($P < .05$) in each of the final models were exponentiated to calculate incidence rate ratios (IRR), and translated into the estimated number of falls associated with that factor while holding all other factors in the final models constant at their means.[49] All statistical analyses were performed using SPSS v.27 (Chicago, IL).

RESULTS

Forty-five individuals with unilateral transtibial amputation were recruited and participated in the study (Table 2). Age and PLUS-M T-scores were normally distributed (W ≥ 0.953, P ≥ .068), while the remaining amputation, demographic, mobility, and health-related characteristics were non-normally distributed (W ≤ .815, P ≤ .03) (Table 1). Thirty-eight falls were recorded over the 6-month prospective period (mean [min, max]: 1 [1,9]). The annual fall rate per participant was 1.69 falls, the median time to first prospective fall was 3 months (interquartile range: 4 months). 55% (25/45), 29% (13/45), and 16% (7/45) of study participants reported no falls, falling once, or falling at least twice, respectively. Demographic, amputation, mobility, balance, and health-related characteristics were not significantly different across non-fallers, non-recurrent fallers, and recurrent fallers (Table 1).

NBWT scores (mean ± 95% CI) (0.47 ± 0.13) were normally distributed (W ≥ .961, P ≥ .133), while TUG (8.75 ± 3.36 s) and FSST times (9.1 ± 2.3 s), as well as the number of falls in the prior 12 months, were non-normally distributed (W = .713−.910, P < .008). Kruskal-Wallis tests revealed that the distribution of performance-based test scores, and the number of falls recalled in the prior 12 months were not significantly different across participants grouped by faller status (U ≥ .823, P ≥ .148) (Table 2).

Prospective 6-month fall counts were non-normally distributed (W = .552, P ≤ .001), and overdispersed, confirming the suitability of negative binomial regression. After reduction, the final PB T + FR model retained TUG and FSST times, as well as the number of falls recalled over the past 12 months (Table S1). The PB T + FR model was not reduced any further as all a priori modeling criteria were met (i.e., omnibus test P < .05, and all remaining factors contributing to the prediction of future falls had P values ≤.15).[40] Specifically, the FSST, but not the NBWT, was retained because it met the a priori P value cut off (ie, P ≤ .15). In contrast, the final PB T model retained only PLUS-M (Table S2), while the FR model retained the number of falls recalled in the past 12 months (Table S3). Chi-squared goodness-of-fit tests revealed no significant differences between the observed and expected number of falls in the prospective period for any of the final models, implying that each model fit the prospective fall count data (FR model: $X^2[43] = 45.45$, $P = .20$; PB T model: $X^2[43] = 52.18$, $P = .10$; PB T + FR model: $X^2[41] = 36.12$, $P = .20$). Likelihood ratio chi-squared omnibus tests revealed that the final FR model and PB T + FR model were significantly better than a null model (i.e., one with no factors) at predicting the number of falls over the next 6 months, while the PB T model was not (FR model: $X^2[1] = 7.26$, $P = .007$, AIC = 111.21; PB T + FR model: $X^2[3] = 11.6$, $P = .009$, AIC = 110.87; PB T model: $X^2[1] = 3.83$, $P = .05$, AIC = 114.64). Within the final PB T + FR

TABLE 1 Characteristics of unilateral transtibial prosthesis users stratified by prospective faller category

	Non-fallers (n = 25)	Non-recurrent fallers (n = 13)	Recurrent fallers (n = 7)	
		# of participants (%)		P value
Etiology				
Dysvascular	12 (27%)	3 (7%)	5 (11%)	.100[a]
Non-dysvascular	13 (29%)	10 (22%)	2 (4%)	
MFCL				
K1 and K2	6 (13%)	3 (8%)	2 (4%)	.961[a]
K3 and K4	19 (42%)	10 (22%)	5 (11%)	
Gender				
Male	20 (44%)	8 (19%)	5 (11%)	.471[a]
Female	5 (11%)	5 (11%)	2 (4%)	
		Mean (95% CI)		
Time since amputation (years)	13.1 (8.4, 17.8)	19.6 (8.7, 30.5)	6.6 (2.3, 10.8)	.195[b]
Prosthesis use (hours/day)	14.5 (13.2, 15.7)	14.2 (12.5, 16.0)	11.5 (6.0, 17.0)	.536[b]
PLUS-M (T-score)	58.0 (55.1, 60.9)	57.1 (52.6, 61.6)	54.5 (47.4, 61.5)	.490[b]
10MWT (time, s)	8.3 (7.6, 9.0)	8.8 (7.7, 9.9)	8.5 (7.3, 9.8)	.564[b]
ABC Scale (0-4)	3.15 (2.83, 3.46)	3.07 (2.65, 3.50)	2.78 (2.01, 3.55)	.462[b]
Age (years)	53.4 (46.2, 60.5)	56.6 (46.7, 66.5)	55.7 (43.3, 68.2)	.895[b]
CCI	0 (0, 2)	1 (0, 2)	1 (0, 2)	.599[b]
SCS	8.2 (7.5, 8.8)	7.5 (6.4, 8.7)	6.1 (5.0-8.5)	.062[b]

Abbreviations: 10MWT, 10 Meter Walk Test; ABC, Activities-specific Balance Confidence scale; CI, confidence interval; CCI, Charlson Comorbidity Index; IQR, interquartile range; MFCL, Medicare Functional Classification Level; PLUS-M, Prosthetic Limb Users Survey of Mobility; SCS, Socket Comfort Score.
[a]Chi-square tests run to compare categorical variables between prospective fall categories.
[b]Kruskal-Wallis tests run to compare continuous variables across prospective fall categories.

TABLE 2 Performance-based tests scores among transtibial prosthesis users stratified by prospective faller category

	All Participants n = 45		Faller status based on 6-month prospective period			
			Non-faller n = 25	Non-recurrent faller n = 13	Recurrent faller n = 7	
	Mean (95% CI)	10th, 90th percentile	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	*P* value
NBWT score, /1.0	.47 (.40, .53)	.22, .77	.49 (.40, .58)	.43 (.30, .56)	.47 (.34, .60)	.663
FSST time, s	9.1 (8.0, 10.3)	5.2, 14.0	9.1 (7.2, 11.0)	9.4 (8.0, 10.7)	8.6 (5.7, 11.6)	.477
TUG time, s	9.8 (9.2, 10.4)	7.5, 13.5	9.4 (8.5, 10.3)	10.3 (9.2, 11.3)	10.4 (8.3, 12.4)	.148
# Falls prior 12 months	1.27 (.56, 1.97)	0, 3	.96 (.48, 1.44)	.62 (.22, 1.01)	3.57 (1.21, 8.34)	.590

Abbreviations: CI, confidence interval; FSST, Four Square Step Test; NBWT, Narrowing Beam Walking Test; TUG, Timed Up and Go.

TABLE 3 Negative binomial regression models to predict falls in unilateral transtibial prosthesis users

Performance-based test plus fall recall (PB T + FR) final model (βo = −2.90)			
Variable	ß	IRR (95% CI)	*P* value
Number falls recalled	0.202	1.22 (1.05, 1.42)	.009
TUG	0.370	1.45 (1.01, 2.07)	.044
FSST	−0.154	0.86 (0.69, 1.06)	.149
Predicted # falls = exp [(0.202)(number falls recalled) + (0.370)*(TUG) + (−0.154)*(FSST) − 2.90)]*			
Performance-based test (PB T) final model (βo = 3.37)			
Variable	ß	IRR (95% CI)	*P* value
PLUS-M T-score	−.064	0.94 (0.88, 1.00)	.058
Predicted # falls = exp [(−0.064)(PLUS-M T-score) + 3.37)]*			
Fall recall (FR) final model (βo = −0.54)			
Variable	ß	IRR (95% CI)	*P* value
Number falls recalled	.175	1.19 (1.04, 1.37)	.014
Predicted # falls = exp [(0.175)(number falls recalled) – 0.54)]*			

Abbreviations: ß, regression coefficient; βo, regression intercept; FSST, Four Square Step Test; IRR, incidence rate ratio; PLUS-M, Prosthetic Limb Users Survey of Mobility; TUG, Timed Up and Go.

model, TUG times and fall recall, but not FSST times, were statistically significant predictors for the number of falls over the 6-month prospective period (TUG: *P* = .044; fall recall: *P* = .009) (Table 3). In the final FR model, the number of falls recalled in the past year was also a statistically significant predictor of the number of falls over the subsequent 6 months (fall history: *P* = .014) (Table 3). A likelihood ratio test revealed that the PB T + FR model provided a significant improvement in fit to the prospective fall count data over the FR model $X^2(1) = 4.342$, $P < .05$.

For both the final FR and PB T + FR models, the modeled relationship predicts an increase in the expected number of future falls as the number of falls recalled over the past 12 months increases, and all other factors are held at their sample means (Figure 1A,B). Similarly, an increase in TUG time within the PB T + FR model, holding all other factors at their sample means, predicts an increase in the number of future falls (Figure 1C). A TUG time greater than 10.97 s was associated with 1 or more falls in the next 6 months (Figure 1C). Predicted falls increased sharply as the TUG score increases beyond 11.5 s. For example, an increase in TUG time from 7.51 to 13.46 s (10th to 90th sample percentile), when FSST time and fall history were held at their means, results in a predicted increase of 2.25 falls over the next 6 months (Figure 1C). Viewed jointly within the final PB T + FR model (Equation 1), the combined effect of the number of falls recalled, TUG times, and FSST times on predicting the number of future falls was statistically significant (Table 3).

$$\text{falls over the next 6 months} = \exp\left[(0.202)*(\text{falls recalled past year}) + (0.370)*(\text{TUG time}) + (-0.154)*(\text{FSST time}) - 2.90\right] \quad (1)$$

DISCUSSION

The objective of this study was to test the hypothesis that a combination of performance-based balance tests

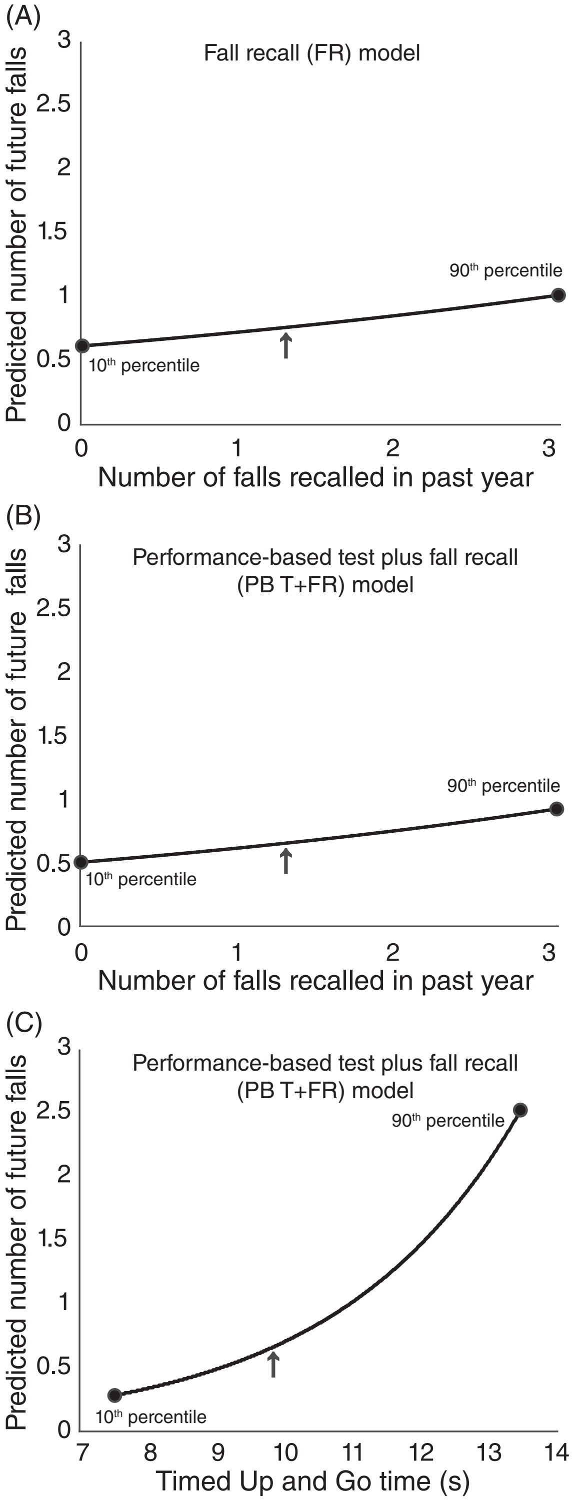

FIGURE 1 Estimated relationship between clinical measures and the predicted number of falls for unilateral transtibial prosthesis users in the next 6 months. Each plot displays the predicted number of falls over the next 6 months (y-axis) at different levels of the clinical predictor (x-axis) while holding the remaining variables in the model at their sample mean. Predicted number of falls are plotted for values of the clinical predictors that made a significant contribution in each of the final regression models. A: number of falls recalled in past 12 months (fall recall model); B: number of falls recalled in past 12 months (performance-based test plus fall recall model); C: TUG time (performance-based test plus fall recall model) between the 10th and 90th percentile of the sample. Sample mean is indicated by arrow

could predict the number of future falls in established unilateral TTPU. Results failed to support the primary hypothesis. No combination of performance-based tests included in this study (i.e., the PB T model) could alone predict the number of falls over the next 6 months in established unilateral TTPU. Rather, a combination of FSST and TUG times, along with the number of falls recalled over the prior 12 months (i.e., PB T + FR model*)* was required to accurately predict the number of future falls. Further, and in support of the secondary study hypothesis, the PB T + FR model provided a significantly better fit to the prospective falls data than the FR model, suggesting that the addition of performance-based test scores to fall recall improved the prediction of future falls over fall recall alone. Consequently, the common clinical practice of using fall recall to screen for fall risk in TTPU would appear to be significantly improved when combined with TUG and FSST scores. Given the ease with which fall recall, FSST, and TUG times can be collected, the resulting predictive model may serve as a suitable method for clinicians to predict the number of falls established unilateral TTPU may experience over the next 6 months. The accompanying IRR and estimated relationship curves provide researchers with indices and visualizations to understand the theoretical association between the studied factors and future falls in established unilateral TTPU. This is the first study, to our knowledge, to examine whether performance-based balance tests can predict future falls in established unilateral TTPU.

The current results provide new clinical insight into the assessment of fall risk in established unilateral TTPU. Consistent with our findings, Dite et al reported that TUG times identified unilateral TTPU at risk for falls.[20] The two studies differ however in sample composition, analysis of fall events, as well as their clinical application and interpretation. Dite et al focused on older, but recent TTPU (i.e., ≤6 months post amputation), where as the current study concentrated on established and slightly younger TTPU. Between the two studies, it could be inferred that the TUG has broad appeal to predict "all-cause" falls in unilateral TTPU regardless of time since amputation and possibly age. Dite et al treated falls as a categorical binary outcome (i.e., multiple faller or non-multiple faller), while the current study treated falls as counts, yielding a continuous outcome (i.e., number of falls in the next 6 months). Furthermore, Dite et al studied the predictive validity of the TUG independent of other potentially confounding variables, while it was part of a multivariate predictive model in the current study. Therefore, where Dite et al offered a discrete cut-off threshold of ≥19 s on the TUG as a means for clinicians to make a binary determination of whether a unilateral TTPU is at risk for multiple falls or not in the next 6 months, the PB T + FR model in the current study enables clinicians to more specifically predict the *number* of expected falls over the ensuing 6 months. By administering the TUG and

FSST, and asking about the number of falls recalled over the past year, clinicans can use the PB T + FR model (i.e., Equation 1) to make predictions about the number of fall(s) that might be expected in the next 6 months for individual unilateral TTPU. For example, an established, unilateral TTPU with a 11.8 s TUG time, a 9.7 s FSST time, and who recalls having fallen twice in the past year, would be predicted to fall 1.46 times over the next 6 months.

The current results also provide researchers with indices and visualizations to understand relationships between potential fall risk factors and future falls in unilateral TTPU. Exponentiating the TUG regression coefficient (β) in the PB T + FR model (i.e., β: .370) to express it as an incidence rate ratio (i.e., IRR: 1.45) indicates that for every one unit increase in TUG (i.e., 1 s), there is a compounding 1.45 times or 45% increase in the likelihood of a fall over the next 6 months when holding all other factors in the model at their sample mean. For example, a unilateral TTPU with a TUG score of 12.25 s would have a 45% greater likelihood of falling in the next 6 months compared a unilateral TTPU with a TUG score of 11.25 s, and a 110% greater likelihood of falling in the next 6 months compared to a unilateral TTPU with a TUG score of 10.25 s, all other factors being equal. In contrast, the IRR for fall history, in either the FR model (i.e., 1.19) or the PB T + FR model (i.e., 1.22), indicates that for every additional fall in the past year, there is a compounding 19% or 22% increase in the likelihood of another fall over the next 6 months, respectively. For example, a unilateral TTPU reporting one fall in the past year would have a 19% likelihood of falling in the next 6 months, whereas a history of two falls in the past year would increase the likelihood that they would fall again in the next 6 months to 1.42, or 42%. These differences in the compounding rates at which fall risk are expressed for TUG times and fall history are reflected in the slopes of their respective estimated relationship curves (Figure 1). The steeper slope of the TUG curve, dictated by the larger IRR, suggests that fall risk is more susceptible to a change in TUG time than fall history, providing additional support to the secondary hypothesis that performance-based tests improve fall risk assessment in unilateral TTPU over fall history alone.

The effectiveness of the TUG as a measure of fall risk among TTPU in both the current prospective and earlier retrospective studies[6,7] may be due the range of tasks included in the TUG (i.e., standing up, walking, turning, and sitting down). Where previous retrospective studies found the NBWT, FSST, and TUG to each successfully discriminate between LLP users with and without a history of falls,[6,7] the TUG was the only one to serve as a statistically significantly predictor of future falls in the current study. By including a range of tasks, the TUG may be better suited to assessing risk of "all-cause falls." In contrast, the NBWT and FSST focus on specific aspects of balance control, which may make them better suited for predicting specific types of falls. The NBWT for example, assesses medial-lateral control of the center-of-mass,[21] and may therefore be better suited to predict the incidence of lateral falls attributed to intrinsic sources of center-of-mass instability, such as in older transtibial prosthesis users.[50] Additional research is warranted to determine whether specific performance-based tests are better suited to predict specific types of falls versus "all-cause" falls in LLP users.[50,51]

Study limitations

The results of this study should be interpreted and applied in light of several limitations. First, the sample was slightly skewed towards younger, and non-dysvascular TTPU who had been using a prosthesis for at least 1 year.[52-55] Additional research is required to determine if these results extend to older, transfemoral, dysvascular, bilateral, and acute LLP users (ie, <1 year post amputation). Additionally, while the use of an assistive device (e.g., cane, walker) was not permitted during testing, participants may have used one to perform activities in their daily lives.

Next, fall recall, used to ascertain fall history, may be susceptible to memory decay over time, and cause LLP users to either under- or over-report falls.[56,57] The accuracy of recall does not, however, affect whether the number of falls *recalled* in the past year can serve as a predictor future falls. Specially, regardless of its accuracy, fall recall was a significant contributor to our predictive model. Additionally, querying LLP users about the number of falls they recall over the past year, as a way to estimate future fall risk, is consistent with how this information would be collected in clinical practice. We also selected a longer 1-year recall period, because it has been shown to minimize fall recall decay compared to shorter timeframes (i.e., 3-6 month) in older adults.[58,59] Future research examining fall recall accuracy in LLP users is recommended.

We did not measure or control for each participant's amount of physical activity. Physical activity levels (e.g., number of steps, non-sedentary time) may have therefore influenced prospective fall counts by increasing opportunity for a fall. Methods for collecting fall data in the current study were however based on a consensus statement that recommends against adjusting for physical activity when presenting and analyzing fall data.[33] Nonetheless, measures of activity and participation should be considered and explored in future studies as ways to assess fall risk and/or stratify study samples.

Additional fall risk factors in LLP users including strength,[11] protective stepping ability,[60] number of medications,[13] and sense of vibration[12] may improve model performance. The current study only evaluated three performance-based tests. Future research to assess the predictive validity of additional performance-based tests that have proven useful in other clinical populations (e.g., Functional Reach Test, Fullerton Advanced Balance Scale)[61,62] is warranted.

This study sought to predict "all-cause" falls, regardless of severity. The prediction of injurious falls is an important next step,[3,18,63] likely to require additional factors beyond performance-based test scores (eg, strength, endurance, reaction time, etc), as well as a longer prospective reporting period to ensure a sufficient number of injurious falls are recorded. Furthermore, the ability of specific balance tests to predict the risk of specific types of falls (e.g., forward vs. backward falls; falls with or without a prosthesis) remains unknown, yet may provide important details that facilitate the prescription of interventions to reduce falls. Finally, additional research to validate the efficacy of the PB T + FR model in an independent sample of unilateral TTPU is recommended.

The results from the present study pertain to a 6-month timeframe and should not be extrapolated beyond this timeframe. It is unknown whether model predictions retain their accuracy over a longer period. Future research that tests the durability of model predictions is needed to determine the time interval between testing sessions that maximizes fall prediction accuracy.

CONCLUSION

The primary objective of this study was to determine whether select performance-based balance tests could predict future falls in established, unilateral TTPU. Using a prospective design to develop a predictive model, this study found that the combination of TUG and FSST times, plus the number of falls recalled over the past year could predict the number of falls over the next 6 months. Additional prospective studies are required to validate the proposed model, and evaluate additional fall-risk factors and performance-based tests. Given the limited options available to predict falls in established TTPU, the predictive model from the current study may serve as a suitable method for clinicians to predict the number of falls over the next 6 months in this clinical population.

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PRIOR PUBLICATION
The work described in this manuscript has not been previously published, nor is it under consideration for publication elsewhere.

INSTITUTIONAL REVIEW
All study procedures were reviewed and approved by University of Illinois at Chicago and University of Washington institutional review boards.

CLINICAL TRIALS REGISTRATION
Not applicable.

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SUPPORTING INFORMATION

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

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APPENDIX

Timed Up and Go (TUG) Protocol

Explanation to participant: The objective of this test is to rise from the chair, walk around the cone, back to the chair and sit down. You should walk at your normal speed. I will time you while you perform the test.

Demonstration: Demonstrate the test once.

Test instructions: Start the test sitting with your back against the back of the chair and your arms resting on the armrests. When I say go, please stand up and walk around the cone, walk back to the chair, and sit down again. Please walk at your normal speed.

Practice: Administer one practice trial that is not timed.

Administration: Administer the test twice. Begin timing when you say go. Stop timing when the participants' buttocks touch the chair.

Scoring: Select the faster of the two timed trials as the TUG score.

Four Square Step Test (FSST) Protocol

Explanation to participant: The objective of this test is to step over the canes in a specific sequence as quickly as possible. I will time you while you perform this test.

Demonstration: Demonstrate the test one time. Demonstrate starting in square 1 and stepping in squares 2, 3, 4, 1, 4, 3, 2, and 1.

Test instructions: When I say go, please step in the sequence I demonstrated. Try to complete the sequence as fast as possible without touching the canes. Both feet must make contact with the floor in each square. Face forward during the entire sequence.

Practice: Administer one practice trial that is not timed.

Administration: Administer the test twice. Begin timing when the first foot contacts square 2. Stop timing when the last foot contacts square 1. Repeat the trial if the participant does not complete the sequence, loses balance, or contact a cane.

Scoring: Select the faster of the two timed trials as the FSST score.

Narrowing Beam Walking Test (NBWT) Protocol

Explanation to participant: The goal of this test is to walk as far as possible along the beam. Speed is not being evaluated. Begin the test by standing with one foot on the wide end of the beam and the other foot on the ground to the side. You may choose which foot to put on the beam and which to put on the ground. Please cross both your arms across your chest.

Demonstration: Demonstrate the test one time.

Test instructions: When I say go, please walk along the beam as far as you can. Please walk at a comfortable speed. Remember to keep your arms crossed over your chest as you walk. Once you move your arms away from your body or step off the beam, I will ask you to stop.

Practice: Do not administer a practice trial.

Administration: Administer the test 5 times. Stop the trial when a participant: walks the length of the beam, steps off the beam, or moves their arms away from their body.

Scoring: Average the distances walked during trials 3 through 5, and divide by 22. This creates the normalized distance walked. The average is divided by 22 not 24 (the total length of the beam), because participants already have one foot on the beam to begin.

10 Meter Walk Test (10MWT) Protocol

Explanation to participant: The goal of this test is to walk a short distance at your preferred comfortable walking speed. I will time you while you perform this test.

Demonstration: Demonstrate the test one time.

Test instructions: When I say "go," please walk at your normal, comfortable pace until I say stop.

Practice: Administer one practice trial.

Administration: Prepare a 14-m walkway in a hallway or other unobstructed area. Place lines at 0, 2, 12, and 14 m. Have the participant start in a standing position on the 0-meter line. Inform them that, on the word “go,” they are to walk at a comfortable speed until you say “stop.” Begin timing when the participant crosses the 2-m line. Stop timing when the participant crosses the 12-m line. Inform the participant to stop when they cross the 14-meter line. Repeat the test two times.

Scoring: Select the faster of the two timed trials as the TUG score.