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Research

Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules

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KEY WORDS

Clinical prediction rule
Lower extremity
Amputation
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ABSTRACT

Questions: Can rules be developed to predict the risk of non-use of prostheses by people with lower limb amputation following discharge from rehabilitation? Are these clinical prediction rules valid? **Design**: Retrospective and prospective cohort study designs. **Participants**: Consecutive tertiary rehabilitation patients: 135 retrospective (103 males, mean age = 56 years, SD 15) and 66 prospective (58 males, mean age = 54 years, SD 16). **Method**: Medical records were audited for potential predictor variables. Retrospective participants were interviewed at a median of 1.9 years after discharge (IQR 1.4 to 2.5) and prospective participants at a median of 1.3 years (IQR 1.1 to 1.4). **Results**: Clinical prediction rules were identified at 4, 8 and 12 months after discharge, and validated. Amputation levels above transtibial and mobility-aid use were common predictors for all three time frames. At 4 months, if four out of five predictor variables were present (LR+ = 43.9, 95% CI 2.73 to 999+), the probability of non-use increased from 12 to 86% ($p < 0.001$). At 8 months, if all three predictor variables were present (LR+ = 33.9, 95% CI 2.1 to 999+), the probability of non-use increased from 15 to 86% ($p < 0.001$). At 12 months, if two out of three predictor variables were present (LR+ = 2.8, 95% CI 0.9 to 6.6), the probability of non-use increased from 17 to 36% ($p < 0.031$). **Conclusions**: These validated clinical prediction rules have implications for rehabilitation and service model development. **[Roffman CE, Buchanan J, Allison GT (2014) Predictors of non-use of prostheses by people with lower limb amputation after discharge from rehabilitation: development and validation of clinical prediction rules. *Journal of Physiotherapy* 60: 224–231]**

Introduction

Multidisciplinary rehabilitation following lower limb amputation plays an important role in restoring function for activities of daily living, work and recreation. Amputee rehabilitation service models and clinical practice guidelines for prosthetic prescription vary widely throughout the world and have been developed largely from expert consensus.[1,2] In Western Australia, patients achieve independent transfers and wheelchair mobility during inpatient rehabilitation while prosthetic gait retraining is performed as an outpatient service.[3]

Limited research exists on long-term outcomes in relation to prostheses following discharge from rehabilitation. In particular, there is a lack of quality evidence to inform clinical decisions that may impact on the continued use of prostheses following lower limb amputation.[4–9] In their literature review, Sansam et al[5] called for further investigation of predictive factors to more accurately estimate walking potential because the studies they reviewed reported different predictors; this was probably due to differences in methodology, outcome measures and definitions of prosthetic rehabilitation success.

Some studies have quantified prosthetic rehabilitation success relative to surgery-related outcomes, the duration that the prosthesis is worn as opposed to functional use, or short-term outcomes while individuals were still participating in rehabilitation; other studies have limited their analyses to cohorts with limited rehabilitation potential.[8–11] None of these quantify long-term functional prosthetic use following discharge, which is important in understanding the quality of life of these people. In general, for those with atraumatic causes of amputation there is a decline in health status following discharge and 5-year mortality as high as 77%.[9,12–14] In some cases, prosthetic gait may impair health and wellbeing through associated morbidity (eg, falls, myocardial infarction) and many individuals stop using their prosthesis within 12 months of discharge.[12,15]

Factors associated with prosthetic outcome have been considered in univariate analyses. Pre-operative factors such as comorbidities, age, pre-morbid mobility, medications, skin integrity, ethnicity, socioeconomic status, cognition and social support have been reported as being associated with outcome.[5,6,11,15–18] Weak evidence supports an association between psychological factors, self-efficacy, motivation and outcome.[5] Prosthetic outcome has also

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been associated with postoperative factors including high-level or multiple limb amputation, postoperative complications, wound healing, oedema, contractures, pain, delay to prosthesis, falls, energy cost of gait, and functional factors.[5,6,9,19–26]

Prosthetic outcome is therefore multifactorial and complex. To date, no studies have examined the factors that in combination are able to identify individuals at risk of prosthetic non-use following discharge from rehabilitation. A methodological approach of developing clinical prediction rules has been used in similar prognostic studies (eg, ankle fractures, neck pain)[27,28] and is yet to be established in the area of lower limb amputation. Clinical prediction rules are tools that assist clinicians to make evidence-based decisions and assign patients to interventions and targeted models of care using a parsimonious subset of predictor variables.[27–30] If clinical prediction rules could be generated to accurately identify individuals at risk of early prosthetic non-use, then rehabilitation teams could intervene with targeted models of care and prosthetic innovations to optimise functional outcome and allocation of healthcare resources. Therefore the research questions for this study were:

1. Can rules be developed to predict the risk of non-use of prostheses by people with lower limb amputation following discharge from rehabilitation?
2. Are these clinical prediction rules valid?

Methods

Participants

Inclusion criteria were: at least one recent major lower limb amputation (ie, transtibial level or above); community dwelling and ambulant prior to amputation; Medicare Functional Classification K-level 1 to 4 (from Gailey et al[24]); and had participated in and been discharged from prosthetic rehabilitation at Royal Perth Hospital, which is the state centre for amputee rehabilitation. Royal Perth Hospital rehabilitates 85% of all individuals with lower limb amputation in Western Australia.[3] Individuals with multiple limb amputations were included, as this was important for validity of the clinical prediction rules.

Participants were excluded if they were unable to communicate, did not consent, or were not prosthetic candidates (ie, K-level 0) as assessed collaboratively by the rehabilitation physician and senior physiotherapist. Reasons for K-level 0 categorisation included comorbidities, cognitive impairment, high-level amputation, multiple limb amputation, remaining limb pathology, increased body weight, mental health issues, poor motivation, no social support, poor premorbid mobility or falls history. These participants were monitored through amputee outpatient clinic but remained at K-level 0.

K-level 0 to 4 participants underwent inpatient rehabilitation to achieve independent transfers, wheelchair mobility and discharge home. K-level 1 to 4 participants received the standardised outpatient prosthetic rehabilitation service, as detailed in Appendix 1 (see eAddenda).

An independent research assistant contacted potential participants from the Amputee Physiotherapy Service database to obtain informed verbal consent for the interview. The interview process involved coordinating telephone interviews with country physiotherapists on remote community visits, Aboriginal Health workers, nurses, and the use of telehealth.

Procedure

Clinical prediction rules development

Medical records were audited for potential predictor variables and this was undertaken blind to the interviews. Box 1 outlines the predictor variable domains investigated. All potential variables were dichotomised (eg, amputation cause: atraumatic or traumatic). Receiver Operator Characteristic (ROC) curves were used to generate a threshold for dichotomous classification of continuous variables (eg, age). This was performed with an equal weighting for sensitivity and specificity. Table 1 in the eAddenda details the dichotomous variable classifications.

Medical comorbidities (including mental health issues and musculoskeletal pathology) were recorded and counted for each participant. Charlson Comorbidity Index and Combined Age Charlson Comorbidity Index were calculated from medical comorbidities data.[31]

In the present study, amputation level was classified as transtibial or above transtibial. Bilateral lower limb amputation was defined as having undergone two major lower limb amputations. Participants were classified as able to independently perform the locomotor skill or being dependent (ie, required assistance or unable to perform). Mobility aids were either used or not used, and the aid type was not statistically weighted for its level of support.

The operational definition of a successful prosthetic user was use of the prosthesis for locomotor activities (eg, transfers, standing, walking) on one or more week days. Participants were asked on which days they used their prosthesis and for one day of normal activity how long they wore the prosthesis, how many sit to stands they performed, and the duration they performed prosthetic walking and standing activities.

Prosthetic non-users did not use their prosthesis for locomotor activities on any days. Individuals who only wore their prosthesis for cosmesis were classified as non-users. Non-users were asked

Box 1. Predictor variable domains for prosthetic users and non-users investigated by this study.

Intrinsic predictor variables	Amputation predictor variables	Functional predictor variables
• gender • age • indigenous status • metropolitan versus country • accommodation at discharge: home versus residential care • medical comorbidities: diabetes type I or II, peripheral arterial disease, cardiac condition, renal failure, stroke, transient ischaemic attack, lower limb pathology • number of medical comorbidities, including mental health issues and musculoskeletal pathology	• amputation cause • amputation level • bilateral lower limb amputation • time to second lower limb amputation • time from amputation to prosthetic milestones: casting, fitting and definitive prosthesis	• mobility level achieved without a prosthesis: wheelchair mobility, transfers, hopping • independence with donning and doffing prosthesis, and monitoring prosthetic fit at discharge • mobility aid use at discharge • mobility level achieved using a prosthesis at discharge: walking indoors, outdoors, stairs, slopes, grass, gravel, uneven terrain, high-level balance activities and running

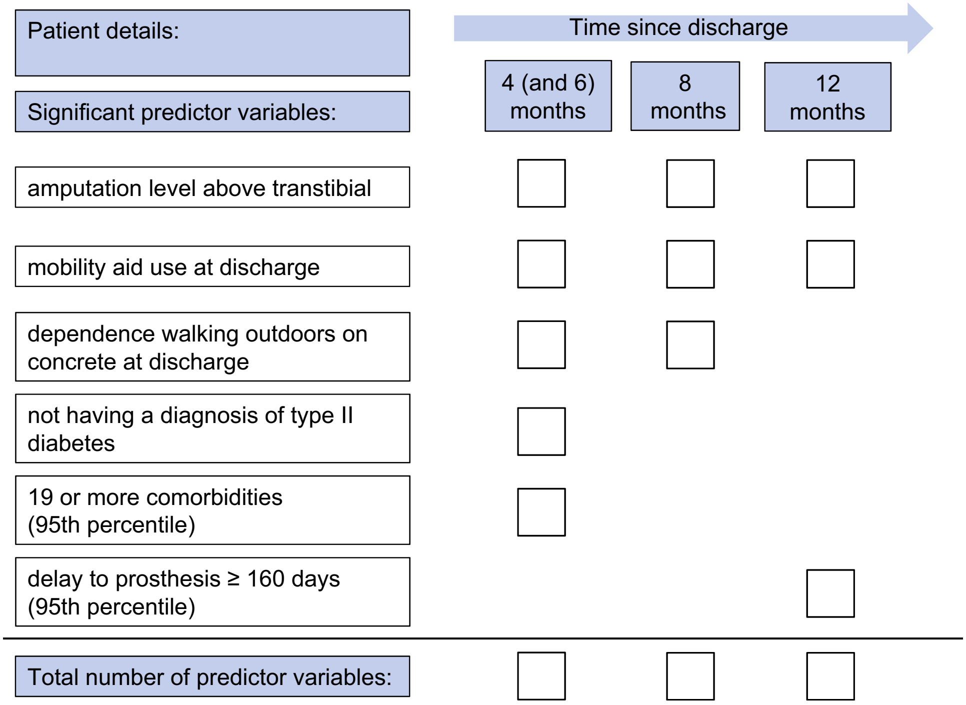

Figure 1. Validated clinical prediction rules for prosthetic non-use in individuals with lower limb amputation at 4, 8 and 12 months after discharge from rehabilitation. If the participant has the predictor variable, they score 1, which is written in the white box, and if they do not have the predictor variable, they score 0. At 4 (and 6) months, scores total out of 5, and at 8 and 12 months, scores total out of 3. Total score (below the line) is used for the risk estimates at each time point. For full details on use, see Appendix 2.

their reasons for prosthetic non-use and to recall how many months after physiotherapy discharge they stopped using their prosthesis. Important calendar events (eg, last amputee outpatient clinic, birthday, Christmas) were used as verbal prompts to assist with recall accuracy. Participants were interviewed with a previously piloted survey on their prosthetic use from 4 months onwards after discharge and re-interviewed approximately at 2-monthly intervals until data were collected for 12 months.

Clinical prediction rules validation

The procedure used for clinical prediction rules validation were the same as for the development procedure, except that data were prospectively collected during the participants' rehabilitation using a physiotherapy assessment form. This form was developed and implemented by the senior physiotherapist during clinical prediction rules development.

Statistical analyses

Clinical prediction rules development

The statistical models used in the present study are consistent with clinical prediction rules reports[27–30] and are not equivalent to a regression analysis. The primary outcome variable was prosthetic non-use at 4, 6, 8 and 12 months post-discharge. Descriptive statistics were generated.

The univariate relationship between categorical variables and prosthetic users and non-users was analysed using the chi-square test. For each of the continuous variables, ROC curves were used to determine the threshold at which specificity and sensitivity were equal to generate dichotomous classification for the univariate analyses. Univariate contingency tables were used to identify a smaller subset of variables related to prosthetic non-use that had a significance level of 10% (chi-square $p < 0.10$). This conservative significance level was selected to avoid missing critical variables. Sensitivity, specificity, and positive and negative likelihood ratios were calculated for the variables.

A backwards stepwise logistic regression model was used to reduce these variables to a set of flags or key variables that contributed to predicting non-use. To generate clinical prediction rules for the time frames, the set of variables from the regression was used to establish cumulative numbers of items present for any one individual at discharge. A list of likelihood ratios (negative and positive, 95% CI) were calculated to determine the cumulative effect of having a number of these predictors (1, 2, 3, etc) on non-use.

Clinical prediction rules validation

Prospective participants were classified as prosthetic users or non-users at 4, 6, 8 and 12 months after discharge. Descriptive statistics were generated. Participants were analysed for the absence (score = 0) or presence (score = 1) of significant clinical prediction rules variables at 4, 6, 8 and 12 months (see Figure 1, and the clinical prediction rules instructions in Appendix 2 in the eAddenda). Validity and cohort contamination effects of prosthetic use behaviours were compared by plotting pattern of non-use over time for the retrospective and prospective cohorts.

The retrospective study's continuous variable thresholds were used to generate dichotomous classification of these continuous variables in the present prospective study. To validate the clinical prediction rules for each of the time frames, chi-square tests were calculated to generate a progressive list of likelihood ratios (negative and positive, 95% CI) to determine the cumulative effect of having a number (ie, 1, 2, 3 etc) of these non-use predictors. Sensitivity, specificity, positive prediction value, accuracy and balanced accuracy were calculated to define the accuracy and precision of clinical prediction rules in the prospective cohort.[32]

For both the retrospective and prospective statistical analyses, in circumstances where zero cases were present in frequency cells of the 2 x 2 contingency tables, 0.5 was added to the cell values to enable calculation of the likelihood ratios for the variables.[33] Extreme likelihood ratio upper confidence limits were truncated at 999.

Sensitivity analyses of 29 (16%) retrospective and eight (10%) prospective deceased prosthetic rehabilitation participants who could not be interviewed were performed for 4, 6, 8 and 12 months after discharge to identify the presence or absence of clinical prediction rules variables using date of death as the termination date for prosthetic use.

Results

Table 2 summarises the consecutive participants' eligibility for the study. The final response rates were 94% (n = 135) for the retrospective cohort and 97% (n = 66) for the prospective cohort. The retrospective cohort were interviewed at median = 1.9 years (IQR 1.4 to 2.5) and prospective at median 1.3 years (IQR 1.1 to 1.4) after discharge. Table 3 outlines the geographical distribution of participants, as measured by Accessibility Remoteness Index of Australia.[34]

Clinical prediction rules development interviews with the retrospective cohort were performed by telephone (n = 123), telehealth (n = 2) and in person (n = 10). Twelve interviews were performed with carer assistance due to language interpretation, hearing or intellectual disability. Clinical prediction rules validation interviews with the prospective cohort were performed by telephone (n = 47) and in person (n = 19). Carers assisted with two interviews where participants had a hearing or intellectual disability. Table 3 shows the retrospective and prospective cohort characteristics.

Clinical prediction rules development

From November 2009 until August 2011, 135 participants were interviewed; 94 (70%) were prosthetic users and 41 (30%) were non-users. At 4, 6, 8 and 12 months after discharge from rehabilitation 15 (11%), 15 (11%), 20 (15%) and 25 (19%) of participants, respectively, were non-users. As the number of prosthetic non-users and variables were identical for 4 and 6 months, these data were analysed as one time frame.

Of the 40 potential variables investigated for the univariate analysis (Box 1), a total of 16 variables were identified as being significant ($p < 0.10$) for prosthetic non-use at the 4-, 6- and 8-month timeframes, and 15 variables were significant at 12 months after discharge (Table 4, which is available in the eAddenda).

The predictor variables significant (95% CI) for prosthetic non-use after being entered into the backwards-stepwise logistic regression model are reported below. Full details, including associated accuracy statistics, are presented in Table 5.

Clinical prediction rules: 4 months

At 4 (and 6) months, the five variables that were predictive of prosthetic non-use included: amputation level above transtibial level, mobility aid use, dependence walking outdoors on concrete, very high number of comorbidities, and not having a diagnosis of type II diabetes.

Clinical prediction rules: 8 months

At 8 months, the three variables that were predictive of prosthetic non-use included: amputation level above transtibial level, mobility aid use, and dependence walking outdoors on concrete.

Clinical prediction rules: 12 months

At 12 months, the three variables that were predictive of prosthetic non-use included: amputation level above transtibial level, mobility aid use, and delay to prosthesis. The multifactorial causes of delay to prosthesis included: wound complications (n = 8), comorbidities (n = 3), orthopaedic injuries (n = 2) and deconditioning (n = 1).

Clinical prediction rules validation

From March 2011 until December 2012, 66 participants were interviewed, of whom 55 remained prosthetic users. There were eight non-users at 4 and 6 months after discharge from rehabilitation, which increased to ten at 8 months and eleven at 12 months. Similar to the retrospective cohort, prosthetic non-users and variables were identical for the 4-month and 6-month timeframes in the prospective cohort.

Survival curves (Figure 2) demonstrated a high level of concordance between the retrospective and prospective cohorts. From discharge there was rapid progression to prosthetic non-use, followed by linear decline after 1 month.

Associated accuracy statistics for having a combination of prosthetic non-use predictors (95% CI) for the clinical prediction rules time frames in the prospective cohort are reported below. Full details, including associated accuracy statistics, are presented in Table 6.

Four months

If four out of five predictors were present (LR+ = 43.9, 95% CI 2.73 to 999+), the probability of non-use increased from 12 to 86% ($p < 0.001$).

Eight months

If all three predictors were present (LR+ = 33.9, 95% CI 2.1 to 999+), the probability of non-use increased from 15 to 86% ($p < 0.001$).

Twelve months

If two out of three predictors were present (LR+ = 2.8, 95% CI 0.9 to 6.6), the probability of non-use increased from 17 to 36% ($p < 0.031$). Three cases of delay to prosthesis included: wound (2) and orthopaedic (1) complications.

Figures 3–5 (available in the eAddenda) illustrate the percentages of true to false positives for the clinical prediction rules time frames. This shows the clinical utility of using the clinical prediction rules for any one individual and the risk of appropriate classification.

Table 2
Summary of the consecutive retrospective and prospective cohorts.

Characteristic	Retrospective cohort	Prospective cohort
Time frame identified from Amputee Physiotherapy Service database	June 2006 to June 2009	July 2009 to July 2011
Consecutive tertiary rehabilitation patients identified from Amputee Physiotherapy Service database, n	208	99
K-level 0 participants[a], n (%)	32 (15)	11 (11)
K-level 1 to 4 participants[b], n (%)	176 (85)	88 (89)
K-level 0 deceased, n (%)	15 (47)	4 (36)
K-level 1 to 4 deceased, n (%)	29 (16)	8 (9)
Eligible participants, n	143	68
Ineligible participants, n		
excluded, minor lower limb amputation	1	2
excluded, still participating in rehabilitation	3	10
did not consent	3	0
Participants contacted, n	138	66
Unable to be contacted as they had moved interstate or overseas, n	5	2
Response rate, n (%)	135 (94)	66 (97)
Time to outpatient discharge *(d)*[c], median (IQR)	174 (103 to 314)	138 (88 to 201)

[a] Not prosthetic rehabilitation candidates.
[b] Prosthetic users at discharge.
[c] Participants participated in approximately two to three physiotherapy prosthetic gait retraining sessions per week as outpatients.

Table 3
Demographic and amputation details of prosthetic users and non-users in the retrospective and prospective cohorts.

Demographic and amputation details	Retrospective cohort		Prospective cohort	
	Users (n = 94)	Non-users (n = 41)	Users (n = 55)	Non-users (n = 11)
Gender, male, n (%)	74 (79)	29 (71)	50 (91)	8 (73)
Age at amputation, mean (SD)	55.1 (15.8)	58.3 (13.3)	55.3 (15.7)	49.5 (19.9)
Indigenous status, Aboriginal, n (%)	12 (13)	9 (22)	6 (11)	2 (18)
Accommodation after discharge from inpatient rehabilitation, n (%)				
home	91 (97)	37 (90)	55 (100)	11 (100)
residential care (hostel or nursing home)	3 (3)	4 (10)	0 (0)	0 (0)
metropolitan	56 (60)	28 (68)	34 (62)	9 (82)
country	38 (40)	13 (32)	21 (38)	2 (18)
Social support, lives with others, n (%)	77 (82)	31 (76)	42 (76)	10 (91)
Accessibility Remoteness Index of Australia[a]				
major cities of Australia (0 to 1.84)	66 (71)[a]	34 (83)	40 (73)	9 (82)
inner regional Australia (> 1.84 to 3.51)	8 (9)	0 (0)	7 (13)	0 (0)
outer regional Australia (> 3.51 to 5.80)	5 (5)	2 (5)	5 (9)	1 (9)
remote Australia (> 5.80 to 9.08)	0 (0)	2 (5)	2 (4)	0 (0)
very remote Australia (> 9.08 to 12)	14 (15)	3 (7)	1 (2)	1 (9)
Charlson Comorbidity Index, median (IQR)	2 (1 to 4)	5 (2 to 5)	2 (0 to 4)	3 (0.5 to 5)
Combined Age Charlson Comorbidity Index, median (IQR)	4 (1 to 5)	7 (3 to 7)	4 (1 to 6)	6 (1 to 7)
Comorbidities, n (%)				
diabetes type I	7 (8)	3 (7)	1 (2)	1 (9)
diabetes type II	35 (37)	19 (46)	21 (38)	6 (55)
peripheral arterial disease	44 (47)	25 (61)	30 (55)	7 (64)
cardiac condition	33 (35)	26 (63)	12 (22)	4 (36)
renal failure	13 (14)	10 (24)	5 (9)	4 (36)
stroke/transient ischaemic attack	8 (9)	5 (12)	4 (7)	0 (0)
arthritis	36 (38)	16 (39)	12 (22)	5 (45)
remaining lower limb pathology	78 (83)	36 (88)	36 (65)	11 (100)
Mental health issues, n (%)	24 (26)	8 (20)	8 (15)	5 (45)
Mild cognitive impairment, n (%)	3 (3)	4 (10)	2 (4)	1 (9)
Intellectual disability, n (%)	1 (1)	0 (0)	1 (2)	0 (0)
Substance abuse, n (%)				
drugs	7 (7)	4 (10)	2 (4)	3 (27)
alcohol	10 (11)	5 (12)	7 (13)	2 (18)
current smoker	20 (21)	14 (34)	13 (24)	4 (36)
Amputation cause, n (%)				
circulatory	18 (19)	15 (37)	16 (29)	3 (27)
infection	42 (45)	17 (41)	22 (40)	6 (55)
trauma	29 (31)	9 (22)	14 (25)	2 (18)
cancer	5 (5)	0 (0)	3 (5)	0 (0)
Amputation level, n (%)				
transtibial	78 (83)	25 (61)	50 (91)	10 (91)
knee disarticulation	4 (4)	2 (5)	1 (2)	0 (0)
transfemoral	20 (21)	28 (68)	9 (16)	5 (45)
major bilateral lower limb amputation	8 (9)	14 (34)	5 (9)	4 (36)
minor amputation of remaining limb	15 (16)	3 (7)	2 (4)	1 (9)
upper limb amputation/s	8 (9)	0 (0)	9 (16)	3 (27)

[a] n = 93. One person was excluded from this retrospective analysis because he moved overseas after discharge. All other retrospective analyses used n = 94.

There were no significant associations between having a number of clinical prediction rules variables for the time frames and cessation of prosthetic use due to death, based on 29 deceased participants from the retrospective cohort ($p = 0.164$) and eight deceased participants from the prospective cohort ($p = 0.170$).

Discussion

Few studies have examined factors at the time of discharge in order to determine prosthetic use into the future. This is the first study to propose and validate clinical prediction rules for timelines

Table 5
Associated accuracy statistics with 95% CI for having a combination of predictor variables at 4 (and 6), 8 and 12 months for the retrospective cohort.

Predictors present for clinical prediction rules time frames (n)	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	Probability of prosthetic non-use (%)	*p*-value
4 (and 6) months						
1	0.97 (0.74 to 1.00)	0.16 (0.13 to 0.16)	1.20 (0.85 to 1.19)	0.20 (0.0 to 2.04)	13	0.183
2	0.97 (0.72 to 1.00)	0.52 (0.48 to 0.52)	2.00 (1.40 to 2.09)	0.06 (0.0 to 0.57)	21	< 0.001
3	0.80 (0.53 to 0.95)	0.75 (0.72 to 0.77)	3.20 (1.87 to 4.08)	0.27 (0.07 to 0.65)	29	< 0.001
4	0.27 (0.10 to 0.33)	0.99 (0.97 to 1.00)	32.00 (3.61 to 748)	0.74 (0.67 to 0.92)	80	< 0.001
5	0.03 (0.00 to 0.06)	0.99 (0.99 to 1.00)	7.80 (0.00 to 999+)	0.97 (0.94 to 1.01)	0	0.223
8 months						
1	0.98 (0.78 to 1.00)	0.43 (0.39 to 0.43)	1.70 (1.29 to 1.76)	0.06 (0.00 to 0.55)	23	0.001
2	0.90 (0.69 to 0.98)	0.74 (0.70 to 0.75)	3.50 (2.31 to 3.98)	0.14 (0.02 to 0.44)	38	< 0.001
3	0.15 (0.04 to 0.26)	0.97 (0.96 to 0.99)	5.80 (0.96 to 34.30)	0.87 (0.75 to 1.00)	50	0.013
12 months						
1	0.96 (0.79 to 0.99)	0.42 (0.38 to 0.43)	1.70 (1.28 to 1.74)	0.10 (0.01 to 0.55)	27	< 0.001
2	0.72 (0.53 to 0.86)	0.76 (0.72 to 0.80)	3.05 (1.88 to 4.25)	0.37 (0.17 to 0.66)	41	< 0.001
3	0.24 (0.12 to 0.28)	0.99 (0.96 to 1.00)	26.40 (3.40 to 580.00)	0.77 (0.72 to 0.91)	86	< 0.001

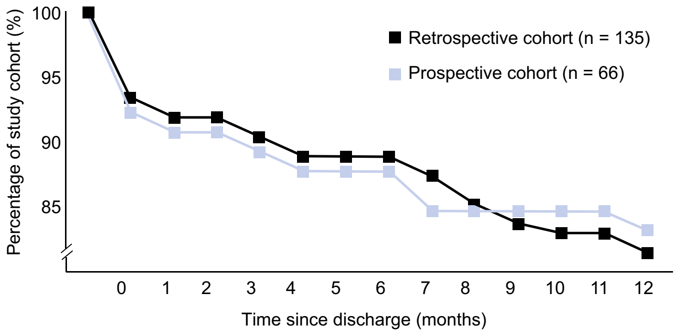

Figure 2. A survival curve for the proportion of individuals using prostheses for every month in the year following hospital discharge. Note: The retrospective and prospective cohorts show similar patterns and rates of prosthetic non-use.

of 4, 8 and 12 months post-discharge that use statistical optimisation modelling to select a parsimonious set of variables from the rehabilitation model of care, which predict increased likelihood of prosthetic non-use. Previous research has examined univariate associations with poor outcomes.[5] In the present study, a much wider range of perioperative and demographic factors were examined and confirmed that a large number of factors are significantly associated with prosthetic non-use. These were grouped into intrinsic, amputation and functional domains. The major point of difference from surgical studies[12,21,35] was that causative factors for amputation were not associated with non-use.

The key point of this research, however, was that multivariate predictive models were used to determine a predictive model of outcome at four time points. Three clinical prediction rules were derived and validated, as the results for the 4-month and 6-month outcomes were identical. These results validate that a subgroup of early prosthetic non-users exist and can be targeted. The high level of concordance between retrospective and prospective prosthetic non-use survival curves demonstrates that there was no substantial change in clinical practice (contamination) during the validation study. These findings call for development of a model of care that optimises outcome for these individuals. Rehabilitation may focus on optimising transfers, wheelchair mobility, physical fitness and mental wellbeing rather than prosthetic gait.

The present study found that having a very high number of comorbidities was significantly predictive of prosthetic non-use at 4 months, but not at later time periods. This was an interesting finding, as depending on how effectively comorbidities are managed they may become worse with age.[32] However, this finding suggests that if prosthetic use can be sustained for the first 4 months post-discharge in the presence of this disease burden, then such systemic conditions may not be highly related to non-use at a later time. The Charlson Comorbidity Index for both cohorts indicates that non-users were at greater risk of mortality from comorbid disease than users.[32]

Validated predictors for prosthetic non-use common to all three clinical prediction rules were amputation level above transtibial and mobility aid use. High amputation level has been associated in the literature with poor prosthetic outcome.[11,36] From a functional perspective, the transtibial prosthesis can be used to facilitate transfers, while the transfemoral prosthesis is only of functional assistance when an individual is standing or walking. This may result in some activities being performed with greater efficiency from a wheelchair or using assistive equipment (eg, individuals with transfemoral amputation may self-propel a commode rather than walking to the shower).

Mobility aid use at discharge is more common in individuals who premorbidly used aids, are frail, deconditioned, have remaining limb pathology (eg, claudication, osteoarthritis), and high or multiple limb amputation.[37,38] Mobility aids reduce functionality of gait by limiting capacity to carry objects, however, use may be necessary to prevent falls.[37,38] As mobility aid use is a predictor of non-use, future research may investigate interventional strategies (eg, mobility aid type, back pack use, prosthetic componentry) that potentially improve functionality of gait.

At 4 months and 8 months after discharge, dependence walking outdoors on concrete was a significant predictor of prosthetic non-use. Validation of this predictor with early prosthetic non-use is important, as many locomotor activities require the ability to walk outdoors on concrete (eg, shopping). Poor prosthetic outcome has been associated with indoors-only ambulation.[11,24]

Similar to the literature,[5] the present study validated a critical time frame in which gait retraining needs to occur, because at 12 months, a delay of >160 days was predictive of non-use. Wound complications were the commonest delay in both cohorts. Delays to walking generally result in prolonged wheelchair sitting and reduced physical activity. Rehabilitation programs may not provide the exercise intensity to overcome deconditioning or prevent complications (eg, joint contracture, muscle weakness) that limit walking capacity. Furthermore, individuals with severe comorbidities and frailty may adversely or not respond to exercise intervention.

Although the proportion of non-users of prostheses is relatively small, these people are difficult to identify; therefore, these clinical prediction rules will assist clinical decisions during rehabilitation and primary healthcare planning following discharge. The validated clinical prediction rules for 4 and 8 months had positive likelihood ratios of 43.9 and 33.9, respectively. These values are consistent with the interpretation that positive likelihood ratios of >5 are clinically significant.[28,39,40] In contrast, the 12-month clinical prediction rules were statistically significant for non-use ($p = 0.031$) but did not possess the predictive magnitude of the other clinical prediction rules. To improve the

Table 6
Associated accuracy statistics with 95% confidence intervals for having a combination of predictor variables at 4 (and 6), 8 and 12 months for the prospective cohort.

Predictors present for CPR time frames (n)	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio	Probability of prosthetic non-use (%)	Accuracy (%)	Balanced accuracy (%)	*p*
4 (and 6) months								
1	0.94 (0.61 to 1.0)	0.14 (0.09 to 0.15)	1.09 (0.67 to 1.17)	0.43 (0 to 4.40)	14	24	54	0.519
2	0.93 (0.53 to 1.0)	0.66 (0.61 to 0.67)	2.8 (1.36 to 3.03)	0.10 (0 to 0.77)	26	69	80	0.002
3	0.50 (0.19 to 0.81)	0.86 (0.82 to 0.90)	3.6 (1.02 to 8.5)	0.58 (0.21 to 0.99)	33	82	68	0.013
4	0.38 (0.12 to 0.44)	0.99 (0.96 to 1.0)	43.9 (2.73 to 999+)	0.63 (0.56 to 0.92)	86	92	68	< 0.001
5	0.06 (0 to 0.12)	0.99 (0.98 to 1.0)	6.9 (0 to 999+)	0.95 (0.88 to 1.0)	50	87	52	0.259
8 months								
1	0.90 (0.57 to 0.99)	0.50 (0.44 to 0.52)	1.8 (1.0 to 2.06)	0.20 (0.01 to 0.98)	24	56	70	0.019
2	0.70 (0.38 to 0.91)	0.82 (0.76 to 0.86)	3.9 (1.6 to 6.5)	0.37 (0.10 to 0.81)	41	80	76	0.001
3	0.30 (0.09 to 0.35)	0.99 (0.96 to 1.0)	33.9 (2.1 to 999+)	0.71 (0.65 to 0.95)	86	89	65	< 0.001
12 months								
1	0.91 (0.60 to 0.99)	0.51 (0.45 to 0.53)	1.85 (1.08 to 2.1)	0.18 (0.009 to 0.9)	27	58	71	0.011
2	0.46 (0.19 to 0.72)	0.84 (0.78 to 0.89)	2.8 (0.9 to 6.6)	0.65 (0.31 to 1.03)	36	77	65	0.031
3	0.09 (0.005 to 0.14)	0.99 (0.97 to 1.0)	10.1 (0.19 to 999+)	0.92 (0.86 to 1.02)	67	84	54	0.095

clinical utility of the 12-month clinical prediction rules, future research may incorporate a follow-up assessment at 6-months post-discharge.

Amputation rate has been reported as being 38 times greater in Aboriginals who have diabetes.[41] In the present study, indigenous status, geographical isolation from health services and having diabetes were not predictive of prosthetic non-use. Environmental conditions in Aboriginal communities, where the terrain is rough, sociocultural factors and service model strategies such as telehealth may have contributed to sustained prosthetic use.

The present research had some potential limitations. The prosthetic-use interview relied on participant recall. Missing data is a potential issue for retrospective research; however, a strength of the present study was that it had minimal missing data. Mortality rate was high within the review period for the retrospective (16%) and prospective (10%) cohorts; however, the sensitivity analyses demonstrated that the deceased sub-groups did not bias clinical prediction rules development or validation. Although further validation could be undertaken at other rehabilitation centres, the use of the prospective cohort in the present study validates the use of these clinical prediction rules by health professionals.

In conclusion, this is the first study to integrate rehabilitation variables into a parsimonious set of predictors that are significant for prosthetic non-use at 4, 8 and 12 months after discharge, and validate these clinical prediction rules. The research has validated that a sub-group of early prosthetic non-users exists, and highlights a need to separate causative factors for amputation that impact on surgical outcome, from those related to prosthetic non-use. These validated clinical prediction rules may guide clinical reasoning and rehabilitation service development.

What is already known on this topic: Long-term functional use of a prosthesis following discharge from hospital is important for quality of life for lower limb amputees.
What this study adds: Clinical prediction rules can provide valid data to help identify people who are at risk of discontinuing use of their prosthesis in the year following discharge from hospital after lower limb amputation. Different predictors contribute to these clinical prediction rules, depending on the time frame considered (4, 8 or 12 months). Amputation above the transtibial level and use of a mobility aid were predictors that were common to the clinical prediction rules for all three time frames.

eAddenda: Figures 3, 4 and 5, Tables 1 and 4, and Appendices 1 and 2 can be found online at doi:10.1016/j.jphys.2014.09.003

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