Prosthetic fitting, use, and satisfaction following lower-limb amputation: A prospective study

Joseph B. Webster, MD;[1–2]* Kevin N. Hakimi, MD;[1–2] Rhonda M. Williams, PhD;[1–2] Aaron P. Turner, PhD;[1–2] Daniel C. Norvell, PhD;[3] Joseph M. Czerniecki, MD[1–2]

[1]*Department of Veterans Affairs Puget Sound Health Care System, Seattle, WA;* [2]*Department of Rehabilitation Medicine, University of Washington, Seattle, WA;* [3]*Spectrum Research Inc, Tacoma, WA*

Abstract—Providing a satisfactory, functional prosthesis following lower-limb amputation is a primary goal of rehabilitation. The objectives of this study were to describe the rate of successful prosthetic fitting over a 12 mo period; describe prosthetic use after amputation; and determine factors associated with greater prosthetic fitting, function, and satisfaction. The study design was a multicenter prospective cohort study of individuals undergoing their first major lower-limb amputation because of vascular disease and/or diabetes. At 4 mo, unsuccessful prosthetic fitting was significantly associated with depression, prior arterial reconstruction, diabetes, and pain in the residual limb. At 12 mo, 92% of all subjects were fit with a prosthetic limb and individuals with transfemoral amputation were significantly less likely to have a prosthesis fit. Age older than 55 yr, diagnosis of a major depressive episode, and history of renal dialysis were associated with fewer hours of prosthetic walking. Subjects who were older, had experienced a major depressive episode, and/or were diagnosed with chronic obstructive pulmonary disease had greater functional restriction. Thus, while most individuals achieve successful prosthetic fitting by 1 yr following a first major nontraumatic lower-limb amputation, a number of medical variables and psychosocial factors are associated with prosthetic fitting, utilization, and function.

Key words: ambulation, amputation, gait, prosthesis, prosthetic fitting, rehabilitation, satisfaction, transfemoral amputation, transmetatarsal amputation, transtibial amputation.

INTRODUCTION

One of the primary goals of rehabilitation following lower-limb amputation is the successful fitting of a prosthesis and use of the prosthesis to achieve functional mobility. Greater prosthesis use has been associated with higher levels of function and independence via improved self-care and mobility [1] as well as improved perceived quality of life [2–7] and employment success [8]. Satisfaction with both the functional utility and cosmetic appearance of the prosthesis is also an important outcome of prosthetic restoration. In order to maximize outcomes

following lower-limb amputation, it is essential to better appreciate the factors that affect both prosthesis use and satisfaction, particularly any modifiable factors that might be targeted in rehabilitation interventions.

Prosthesis use has been examined in several prior studies [9–11]. Two studies of transtibial (TT) and transfemoral (TF) amputees (primarily dysvascular) 1 yr after surgery found a high rate of mean daily prosthesis use; Pohjolainen et al. reported 9.3 h for women and 10.1 h for men 1 yr after surgery [9], while Gauthier-Gagnon et al. found that 75 percent of subjects wore their prosthesis ≥9 h and 20 percent wore their prosthesis 4 to 8 h [10]. These results may be skewed to reflect the typical use patterns of a younger population with fewer comorbid conditions.

Although limited, current data suggest that prosthesis use deteriorates over time in the person with dysvascular amputation [12]. A myriad of biopsychosocial factors may plausibly affect prosthesis use. Physical health factors, such as phantom-limb pain, have been shown to result in fewer hours of prosthesis use per day [13], as have dementia, end-stage renal disease (ESRD), and coronary artery disease [14]. Psychological factors such as self-efficacy, perception of symptoms, knowledge of treatment options, and balance confidence are associated with greater prosthesis use [15–16]. Lastly, social factors are important in understanding prosthesis use. Among elderly, dysvascular persons with lower-limb amputation, both the presence of a family member at home and marriage predicted the likelihood of prosthesis fitting [17]. A large study of 752 people with lower-limb amputation found that married individuals or individuals living with a partner used the prosthesis for more hours per day than people living alone [13].

The quality of rehabilitation care not only is determined by the proportion of patients who are fit with and use a prosthesis over time but also is reflected in the functional utility and satisfaction with a limb over time. For example, a number of studies have shown that, despite a high rate of prosthesis use, there is a high rate of dissatisfaction with the comfort of prostheses [18–19]. Satisfaction level has the potential to influence the amount of time that a person wears and uses a prosthesis. It may also influence other downstream outcomes such as self-confidence and self-image, such that individuals are more comfortable performing activities in the community and in the workplace with their prostheses [20–21] and may ultimately affect quality of and satisfaction with life [22]. As a result, gaining a better understanding of the variables that influence use and satisfaction with pros-

thetic limbs has the potential to affect future rehabilitation interventions, as well as prosthetic design and development.

The objectives of this study, therefore, were to (1) describe the rate of successful prosthetic fitting over a 12 mo period following dysvascular amputation and determine factors associated with successful fitting, (2) describe prosthetic use (wearing and walking) at 4 and 12 mo after amputation, and (3) determine the factors associated with greater prosthetic use and satisfaction with the prosthetic limb.

METHODS

Study Design

This study is part of a larger multisite prospective cohort study of individuals who underwent major lower-limb amputation because of vascular disease and/or diabetes. Subjects were recruited from two Department of Veterans Affairs (VA) medical centers, a university hospital, and a level I trauma center between September 2005 and December 2008. Study subjects were assessed via in-person or telephone interview at four time points: before amputation surgery (if available) and 6 wk, 4 mo, and 12 mo after amputation surgery. Subjects who were not able to be assessed prior to their amputation surgery were enrolled and assessed 6 wk after amputation. In addition to the in-person or telephone interview, data were also collected via systematic review of the medical record. All assessments and medical record reviews were performed by a trained study coordinator designated for each site.

Subjects

Individuals were screened for study participation using the following inclusion criteria: (1) aged 18 yr or older; (2) awaiting (or underwent in the last 6 wk) a first major amputation, defined as a unilateral primary transmetatarsal (TM), primary TT, or primary TF amputation or revision of a first major unilateral amputation that occurred within the last 6 wk; and (3) having diabetes or peripheral vascular disease as the primary cause of amputation. Subjects were excluded if (1) they had inadequate cognitive or language function to consent or participate defined by ≥6 errors on the Short Portable Mental Status Questionnaire (SPMSQ) or (2) they were nonambulatory before the amputation for reasons unrelated to peripheral vascular

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disease or diabetes. Of the 239 major lower-limb amputations initially identified, 136 (57%) met study criteria. Thirteen participants (5%) were excluded as a result of being unable to verify eligibility at one facility because of specific privacy standards that did not allow our study coordinator to approach them. Other reasons for ineligibility included previous contralateral major amputation (38%); dementia, failure of SPMSQ, or other disease process causing speech pathology (22%); revision of a previous major amputation >6 wk prior to enrollment (12%); nonambulatory (11%); bilateral amputation (10%); no contact information to allow for adequate follow-up (3%); and other reasons (3%). Of the 136 eligible subjects, 87 individuals (64%) consented to participate (**Figure**).

Sociodemographic and General Health Characteristics

Subject characteristics such as demographics (e.g., age, marital status, race), information about the index amputation, and health factors (e.g., body mass index [BMI], smoking and alcohol use) were assessed presurgically when possible ($n = 29$) or at 6 wk postsurgery ($n = 58$). The index level of amputation was categorized as TM, TT, or TF as reported in the medical record and confirmed during interview. The Charlson Comorbidity Index [23] was used to determine the presence of presurgical comorbid conditions. Additional comorbid conditions hypothesized to be relevant in these populations were also assessed (**Table 1**). With regard to health factors, smoking status was assessed by three standard questions from the VA Large Health Survey. Participants were considered smokers if they endorsed smoking "every day" or "some days" prior to amputation and nonsmokers if they endorsed the remaining category "does not smoke at all." A 3-item version of the Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) was used to assess alcohol consumption patterns in the past year [24]. Possible scores range from 0 to 12, with higher scores indicating greater alcohol misuse severity. Follow-up in-person or telephone interviews were performed at 4 and 12 mo after amputation.

Social Support

We assessed the degree of social support at 6 wk postsurgery using the brief version of the Modified Social Support Survey (MSSS), a measure of perceived social support developed initially as part of the Medical Outcomes Study [25] and subsequently shortened (to 5 items from 18) as part of the Multiple Sclerosis Quality of Life Inventory [26]. The 5-item version of the scale consists of the items correlating most strongly with the total MSSS score from the original 18-item version of the scale and includes items representing all four subscales on the original scale (emotional and informational support, tangible support, positive social interaction, and affectionate support). Responses are endorsed on a 5-point Likert scale. Scores are then totaled and transformed such that the possible range of scores is from 5 to 100, with higher scores representing greater support.

Major Depressive Episode

For assessing presence of a major depressive episode, we administered the Patient Health Questionnaire-9 (PHQ-9) at 4 and 12 mo postsurgery. The PHQ-9 is a well-validated self-report screening instrument designed to provide diagnoses of high prevalence psychiatric disorders based upon Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition criteria [27]. Major depressive episode is coded as present if individuals endorsed five or more of nine symptoms on "more days than not" and one of the items endorsed was either depressed mood or anhedonia.

Pain and Wound Healing

Pain in the residual limb and phantom-limb pain were measured at 4 and 12 mo after amputation using the following two questions: (1) "Do you currently experience pain in your residual limb or stump (amputated leg)?" (2) "Do you currently experience pain where your leg was (phantom-limb pain)?" To determine healing, the subject was asked at his or her 4 and 12 mo follow-up appointment, "Has your surgical wound healed?" The only responses allowed were "yes" or "no." If there was any doubt, the wound was considered not healed.

Prosthetic Use, Function, and Satisfaction

To determine prosthetic use, subjects were asked at 4 and 12 mo if they had been fitted with a prosthesis. For those who had been fitted, they were asked, "On average, how many hours per day are you wearing your prosthesis?" and "On average, how many hours per day are you walking with your prosthesis?" We measured prosthetic function and satisfaction using the Trinity Amputation and Prosthesis Experience Scales (TAPES) at 12 mo only because only half of the subjects were fitted with a prosthesis at 4 mo (vs >90% at 12 mo). The TAPES includes nine subscales measuring psychosocial outcomes, activity restriction, prosthetic satisfaction, pain, and general
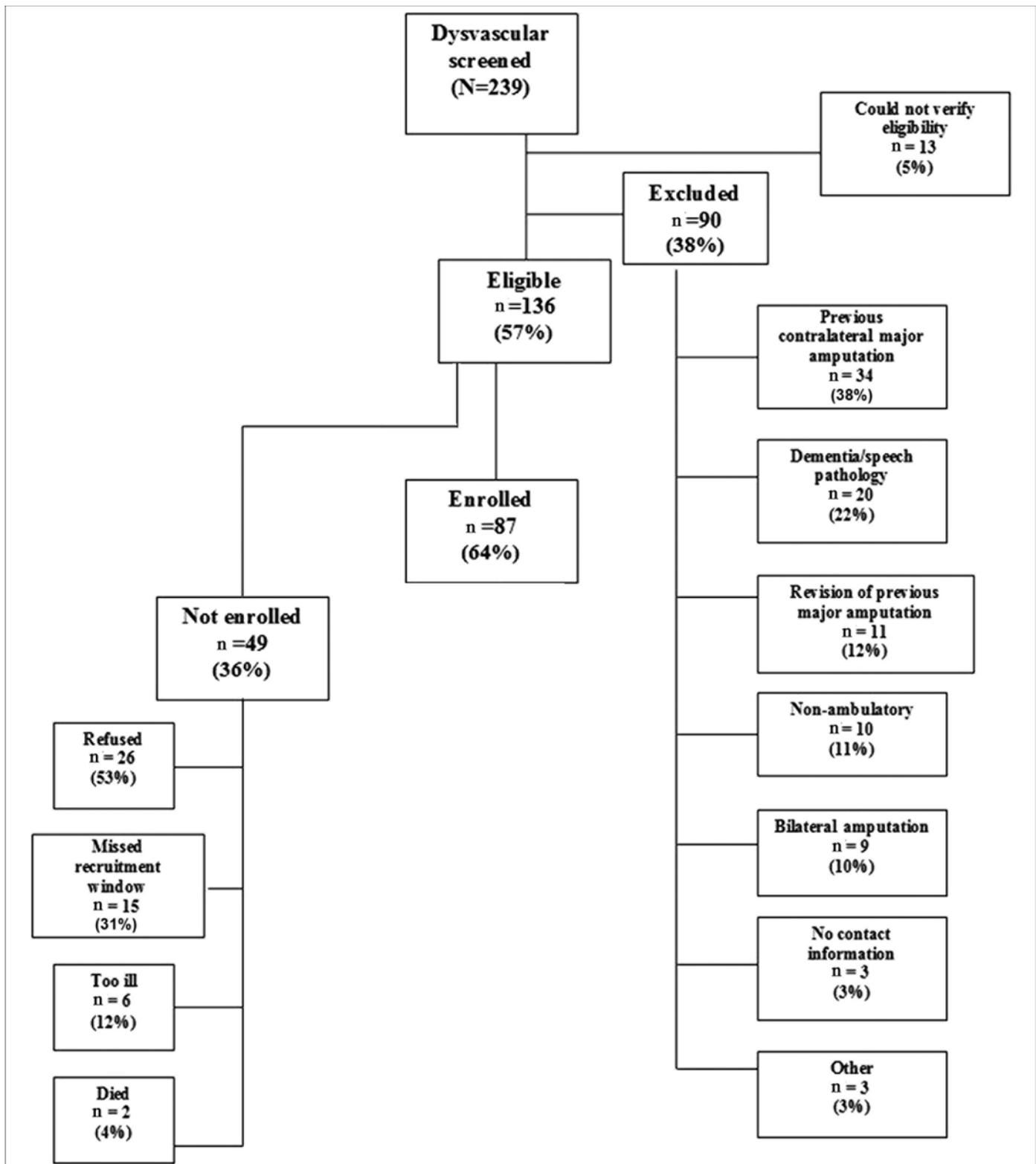
Figure.
Consort diagram depicting screening and enrollment numbers.

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Table 1.
Baseline sociodemographic and general health data by amputation level.[*]

Variable	TM (*n* = 27)	TT (*n* = 52)	TF (*n* = 8)	*p*-Value[†]
Age, mean ± SD	63.0 ± 7.8	61.5 ± 9.1	62.5 ± 10.0	0.61
BMI, mean ± SD	29.8 ± 6.0	31.6 ± 7.8	34.0 ± 9.0	0.15
Married/Partner, *n* (%)	18 (67)	27 (52)	3 (43)	0.35
Race, *n* (%)				0.23
Caucasian	19 (70)	46 (88)	8 (100)	
Black	6 (22)	3 (6)	0 (0)	
Other	2 (7)	3 (6)	0 (0)	
Employment Status, *n* (%)				0.10
Not employed	27 (100)	44 (85)	6 (86)	
Employed	0 (0)	8 (15)	1 (14)	
Education Level, *n* (%)				0.85
Some High School	2 (7)	3 (6)	0 (0)	
High School Graduate	18 (67)	39 (75)	6 (86)	
College Graduate	7 (26)	10 (19)	1 (14)	
Living Status, *n* (%)				0.69
Home Alone	9 (33)	13 (25)	4 (57)	
Home with Spouse/Other	16 (59)	33 (64)	3 (43)	
SNF/Nursing Home	1 (4)	4 (8)	0 (0)	
Other	1 (4)	2 (4)	0 (0)	
Socioeconomic Status, *n* (%)				0.57
≤$25,000 income	12 (44)	24 (46)	2 (29)	
$25,001–$50,000 income	8 (30)	21 (40)	3 (43)	
>$50,000 income	7 (26)	7 (14)	2 (29)	
Charlson, *n* (%)				0.83
Low	8 (30)	9 (17)	1 (14)	
Moderate	6 (22)	16 (31)	2 (29)	
High	9 (33)	15 (29)	2 (29)	
Very High	4 (15)	12 (23)	2 (29)	
Diabetes,[‡] *n* (%)	27 (100)	44 (85)	4 (50)	0.001
Stroke,[‡] *n* (%)	5 (19)	11 (21)	1 (13)	0.84
Heart Attack,[‡] *n* (%)	9 (33)	17 (33)	3 (38)	0.97
Dialysis,[‡] *n* (%)	11 (41)	19 (37)	2 (29)	0.83
Chronic Obstructive Pulmonary Disease,[‡] *n* (%)	1 (4)	7 (13)	1 (13)	0.39
Lower-Limb Arterial Reconstruction, *n* (%)	11 (41)	19 (37)	2 (29)	0.83
Hypertension	19 (70)	33 (64)	7 (88)	0.38
Posttraumatic Stress Disorder, *n* (%)	3 (11)	8 (15)	1 (14)	0.87
Smoker, *n* (%)	5 (19)	22 (42)	5 (71)	0.02
Excessive Alcohol Consumption, mean ± SD	1.08 ± 1.9	1.81 ± 2.7	2.86 ± 4.3	0.10

[*]Incomplete numbers represent missing values.
[†]*p*-Value based on unpaired *t*-test for continuous variables and on Chi-square test for categorical variables.
[‡]Comorbidities obtained from Charlson Comorbidity Index.
BMI = body mass index, SD = standard deviation, SNF = skilled nursing facility, TF = transfemoral, TM = transmetatarsal, TT = transtibial.

health [22]. The activity restriction subscale is further divided into an athletic activity restriction, functional restriction, and social restriction—the higher the score, the higher the restriction, with scores ranging from 0 to 8. The prosthetic satisfaction subscale of the TAPES is divided further into aesthetic satisfaction (range: 4–20), weight satisfaction (range: 1–5), and functional satisfaction (range: 5–25) subscales. The aesthetic satisfaction subscale reflects contentment with cosmetic characteristics. The functional satisfaction subscale includes the areas of prosthetic usefulness, reliability, fit, comfort, and overall satisfaction. The weight satisfaction score is determined by only one question based on satisfaction with the weight of the prosthesis. Higher scores on these subscales are indicative of greater prosthetic satisfaction.

Data Analysis

The sample is described in **Table 1**. For categorical and continuous variables, differences by amputation level were assessed using χ^2 tests and independent sample t-tests, respectively. For objective number one, rates of prosthetic fitting were computed by amputation level using Fisher exact tests because of small cell counts, especially at 4 mo. To identify factors associated with successful prosthetic fitting, we examined multivariate associations of explanatory factors with prosthetic fit (yes/no) at 4 and 12 mo using negative binomial regression to report risk differences (RD) and 95 percent confidence intervals (CIs) while controlling for amputation level. For objectives two and three, multivariate associations of explanatory factors with prosthetic use and TAPES prosthetic activity restriction and satisfaction scores were examined using forward stepwise linear regressions.

For each multivariate analysis, we initially created a model with sociodemographic variables (**Table 1**). Next, the following general health variables considered clinically important were tested for addition to the model: self-perceived health; BMI category (underweight or normal: ≤24.9, overweight: 25–29.4, obese: >29.4 kg/m^2); smoking (yes/no); alcohol consumption score measured by AUDIT-C; total burden of comorbid conditions from the Charlson Comorbidity Scale (divided into low: 0–3.0 points, moderate: 3.1–5.9 points, high: 6.0–7.9 points, and very high: ≥8.0 points); and presence of any of the following conditions: history of cerebral vascular accident, myocardial infarction, hypertension, chronic obstructive pulmonary disease (COPD), asthma, posttraumatic stress disorder, total joint replacement, diabetes, hepatitis, dialysis, meta-

static cancer (coded yes for "present" or no for "absent"). In the third step, we added the 6 wk social support score for all models and the 4 and 12 mo major depressive episode (yes/no) variable for 4 and 12 mo outcomes, respectively. In the last step, we added the level of amputation to the model and retained it for all analyses regardless of the strength of association. Explanatory variables that were associated with the outcome at a 0.05 significance level or less were kept in the model as long as they did not dramatically change the coefficients of the variables in the previous model. Variables with an association of $p < 0.05$ were considered statistically significant. Stata 9.1 (StataCorp; College Station, Texas) was used to conduct all analyses [28].

RESULTS

Baseline Characteristics

Among the 87 subjects enrolled, 4 (5%) formally withdrew, 2 were lost to follow-up (2%), and 6 (7%) passed away over the 12 mo follow-up period. Seventy-five subjects completed their 12 mo interview (86%). The majority of the 87 subjects enrolled in the study were TT (60%), followed by TM (31%) amputees. At baseline, all sociodemographic characteristics were similar except employment status and BMI, though the differences were not statistically significant (**Table 1**). With respect to baseline general health categories, the TM group contained a larger proportion of diabetic (vs peripheral vascular disease) subjects (100%) than the TT (85%) and TF groups (50%) ($p = 0.001$). The proportion of smokers increased with higher levels of amputation: 19 percent, 42 percent, and 71 percent for TM, TT, and TF amputees, respectively ($p = 0.02$). These relative baseline differences changed little for the 75 subjects who completed their 12 mo follow-up.

Rate of Successful Prosthetic Fitting and Associated Factors

At 4 mo, 53 percent of all subjects had been fit with a prosthesis ($n = 42$). Subjects with transtibial amputation had the highest rate (65%), followed by TM (37%) and TF (29%). These differences were statistically significant (Fisher exact $p = 0.03$). At 4 mo, subjects with a history of arterial reconstruction and dialysis were 19 percent (RD = −0.19; 95% CI: −0.38, −0.005, $p = 0.04$) and 26 percent (RD = −0.26; 95% CI: −0.40, −0.13, $p < 0.001$) less likely to have been fit with a prosthesis (**Table 2**). Subjects whose

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residual limb had healed by 4 mo were 45 percent more likely to have been fit with a prosthesis (RD = 0.45; 95% CI: 0.25, 0.65, $p < 0.001$). There was no statistically significant difference between TT and TM amputees; however, TF amputees were 26 percent (RD = –0.26; 95% CI: –0.39, –0.12, $p < 0.001$) less likely to have been fit with a prosthesis. At 12 mo after amputation, nearly all subjects had been fit with a prosthesis (92%); however, there was a statistically significant difference between TM (100%), TT (93%), and TF (57%) groups because of the lower rate in the TF group (Fisher exact $p = 0.006$). Because of the high rate of fitting, there was not enough power to evaluate risk factors for unsuccessful prosthetic fitting at the 12 mo time point.

Prosthetic Use

Among those who had been fit with a prosthesis by 4 mo after amputation, the mean time of wearing the prosthesis was 7.7 ± 4.9 h/d and the mean time of walking with the prosthesis was 3.4 ± 3.7 h/d. There was insufficient power to evaluate multiple factors associated with 4 mo wear time or walking time because of the small numbers who had been fit.

At 12 mo, the mean time of wearing was 9.3 ± 5.5 h/d and the mean time of walking was 4.3 ± 4.0 h/d. No significant difference in prosthetic walking existed at 12 mo between TT and TM; however, persons with TF amputation walked with their prosthesis more than 4 h less per day than persons with TM amputation ($\beta = -4.3$, $p = 0.046$). Subjects with higher social support scores walked with their prosthesis longer per day than those with lower scores ($\beta = 0.04$, $p = 0.03$). Subjects over the age of 55 with a diagnosis of a major depressive episode and who had had a history of

dialysis walked with their prosthesis almost 4 h ($\beta = -3.8$, $p = 0.001$), 5 h ($\beta = -4.7$, $p < 0.001$) and 4 h ($\beta = -3.7$, $p = 0.02$) less per day, respectively, controlling for other factors (**Table 3**).

Factors Associated with Prosthetic Function and Satisfaction

The TAPES divides prosthesis function into three subscales: athletic activity restriction, functional restriction, and social restriction. Activity restriction was used as a proxy for function. At 12 mo, subjects who were smokers and who had a history of stroke had greater athletic activity restriction than those without those risk factors ($\beta = -1.06$, $p = 0.02$; $\beta = -1.03$, $p = 0.04$, respectively). Subjects who were older ($\beta = -0.11$, $p = 0.003$), who had experienced a major depressive episode ($\beta = -1.9$, $p = 0.02$), and/or were diagnosed with COPD ($\beta = -2.0$, $p = 0.05$) had greater functional restriction. There was no significant difference by amputation level for any of these subscales.

At 12 mo, the mean TAPES aesthetic satisfaction score was 15.9 ± 2.9. The mean TAPES weight satisfaction score was 3.6 ± 1.1. The mean TAPES functional satisfaction score was 19.2 ± 4.2. All scores were at the upper end of the possible scoring ranges (maximum possible score for each scale: 20, 5, and 25, respectively), which suggests that, in general, subjects were satisfied with their prosthetic devices in each of the domains assessed. Among the three prosthetic satisfaction scales, only one scale was associated with an explanatory factor.

Table 2.
Multivariate results for 4 mo prosthetic fitting.

Risk Factor	RD* (95% CI)	*p*-Value
Amputation Level†		
TT	0.16 (–0.05, 0.36)	0.14
TF	–0.26 (–0.39, –0.12)	<0.001
Previous Arterial Reconstruction	–0.19 (–0.38, –0.005)	0.04
History of Dialysis	–0.26 (–0.40, –0.13)	<0.001
Healed at 4 mo	0.45 (0.25, 0.65)	<0.001

*RD generated from negative binomial regression model represent increase (or decrease if negative) in rate relative to reference category (controlling for other factors in model).
†Transmetatarsal = Reference category.
CI = confidence interval, RD = risk differences, TF = transfemoral, TT = transtibial.

Table 3.
Multivariate linear regression results for hours of prosthetic walking at 12 mo.

Risk Factor	β* (95% CI)	*p*-Value
Amputation Level†		
TT	–0.35 (–2.1, 1.4)	0.70
TF	–4.3 (–8.5, –0.07)	0.046
Age >55 yr†	–3.8 (–6.0, –1.6)	0.001
Major Depressive Episode at 12 mo (yes)‡	–4.7 (–6.9, –2.5)	<0.001
History of Dialysis	–3.7 (–6.9, –0.51)	0.02
Social Support Score§	0.04 (0.005, 0.07)	0.03

*Beta represents number of hours per day ambulating with prosthesis compared to reference category controlling for other factors in model.
†Reference categories were transmetatarsal amputation and ≤55 yr, respectively.
‡Patient Health Questionnaire-9 (depression module) presence of major depressive episode.
§Modified Social Support Survey (higher score represents higher support).
CI = confidence interval, TF = transfemoral, TT = transtibial.

Subjects with transtibial amputation exhibited less functional satisfaction than subjects with TM amputation (β = -3.6, p = 0.001). The average functional satisfaction scores for TM, TT, and TF subjects were 21.4 ± 2.6, 17.8 ± 4.6, and 18.8 ± 2.5, respectively.

DISCUSSION

Prosthetic fitting, use, function, and satisfaction are important rehabilitation goals following lower-limb amputation. This study prospectively examined these outcomes in a cohort of individuals who underwent lower-limb amputation secondary to peripheral vascular disease and/or diabetes. A wide range of demographic, psychosocial, and comorbid medical data were evaluated at baseline in the perioperative period, which enabled an assessment of possible contributing factors and their effect on these outcomes. This cohort of subjects was then followed for a year following amputation by utilizing a wide spectrum of objective and validated self-report outcome measures. These study design characteristics make this investigation unique compared to prior studies examining similar outcomes following dysvascular lower-limb amputation [1–11].

The study population included in this investigation is important for a number of reasons. First, only individuals with amputations secondary to peripheral vascular disease and/or diabetes were included, in contrast to several published studies that studied samples of mixed etiologies. Additionally, 31 percent of the present sample had TM-level amputations. Previous investigations have focused to a greater extent on dysvascular subject populations, which were predominantly TT and TF amputees, and their relative frequencies differed from this investigation. Historical Medicare data from 1996 reveal a lower prevalence of TM amputation and a much higher percentage of amputations at the TF level [29]. This may reflect a more recent trend where revascularization procedures are performed with the goal of salvaging a more distal amputation level [30–31]. The baseline demographic, psychosocial, and comorbid medical characteristics of the amputee populations at each major amputation level were very similar (**Table 1**). The only exceptions were a significantly higher rate of diabetes with the TM amputation and a significantly higher rate of smoking in the TF population. Lastly, the subjects included in this investigation were undergoing their first major-limb

amputation, had at least minimal ambulatory function, and had adequate cognitive function to participate in the data collection process. Using a comparatively healthy sample of amputees at baseline created an opportunity to understand prosthetic fitting, use, satisfaction, and function among a sample of individuals who were optimal candidates for prostheses. This allowed us to examine some of the less well-studied biopsychosocial influences that affect prosthesis use above and beyond the more traditional physical factors.

Prosthetic fitting and use varies across time in the amputation rehabilitation continuum [12]. In this study, prosthetic fitting was evaluated at 4 mo and 12 mo post-amputation. At 4 mo, 53 percent of participants were fit with a limb, while at 12 mo, 92 percent of subjects were fit. Based on our study findings, if early fitting of a prosthesis is a goal of the care team, a TT amputation may be preferred relative to other levels. At 4 mo, 65 percent of persons with TT amputation were fit, while only 37 percent of persons with TM amputation and 29 percent of persons with TF amputation were fit. As would be expected, residual-limb healing was a significant factor that contributed to early fitting. Additional factors that were associated with a reduced rate of prosthetic fitting at 4 mo were presence of arterial reconstruction and ESRD with dialysis at baseline. It is unclear whether the cause of the reduced rate of prosthetic fitting at 4 mo is specifically related to these factors or whether it is mediated by the effect of these factors on residual-limb healing. This investigation did not examine the effects of the rehabilitation environment or other rehabilitation treatment interventions on prosthetic use.

At 12 mo, while 92 percent of all amputees were fit with prostheses, those with TF amputation had a significantly reduced rate compared with persons with TT or TM amputation. A reduced rate of prosthesis fitting following TF amputation has been supported by other prior investigations [17]. In our study, individuals with TF amputations were also found to have a reduced walking time with a prosthesis. Hours walking with a prosthesis were also negatively affected by older age, major depressive episode, and history of dialysis from ESRD. In terms of potentially modifiable risk factors, the choice of amputation level and the treatment of depression may influence the functional use of a prosthesis. With regard to factors that may positively influence prosthesis use, greater levels of baseline social support were associated with more hours of prosthetic walking. This has not been

previously identified as an important factor and points to the potential need to build in augmented social support structures in patients that have limitations in this regard.

The TAPES outcome measures define the extent to which the amputee experiences or perceives restriction in different domains because of the use of a prosthesis. These domains include athletic activity restriction, functional restriction, and social restriction. Individuals who smoked or had concomitant underlying stroke had significantly greater athletic activity restriction. Factors that contributed to functional restriction included increasing age, depression, and COPD. End stage renal disease with dialysis approached but did not reach statistical significance. These findings emphasize the importance of specific clinical factors and their role in determining whether a prosthesis will be fit and the overall functional use of the prosthesis. Our 92 percent rate of prosthetic fitting at 1 yr is extraordinarily high relative to previously published data. The ranges of prosthetic fitting span from 36 percent [17], to 30 to 40 percent [32], to 60 percent [33]. The variability is likely related to the time period postamputation, variations in the definition of prosthetic fitting, and the patient populations. Some studies use mixed populations of dysvascular and traumatic amputations, and most typically they include the TT amputation level or higher, with varying premorbid functional status. Our study design restricted the population to dysvascular amputees with good cognitive function and at least some ambulatory mobility prior to amputation, and it included the TM amputation level. Increased age at amputation and higher level of amputation are factors that have been more consistently shown to adversely affect prosthetic fitting and use [33–36]. The role of comorbid medical conditions on functional use of a prosthetic limb is also variable, with ESRD and coronary artery disease [37] having been shown to be related to mobility outcome in some studies while not in others [33]. In our study, ESRD and COPD were shown to adversely affect differing prosthetic use outcome measures but were not consistent across all measures. The global measure of comorbid medical conditions, the Charlson Comorbidity Index, appears to be insensitive in detecting an effect on prosthetic fitting, although individual items may have greater utility. Depression emerged as one of the most meaningful clinical factors adversely affecting prosthetic use. This is interesting considering the variability in its presence in this population, as well as the variability in the results of studies that have attempted to determine its

contribution to adverse outcomes [11–12]. Atherton and Robertson identified a rate of depression of only 13.4 percent while quoting population prevalences of 3.6 percent in the general population and 10 to 15 percent in the elderly [38]. Other studies have shown an increased rate of depression, although the relative prevalence is extremely variable, ranging from 19 [7] to 28.7 percent [39] or even as high as 41.7 percent [40]. We reported a major depressive episode rate of 23 percent at 12 mo. The rates of depression depend on the diagnostic tool used, the population under study, and the time postamputation. Singh et al. showed that the rate diminished during inpatient rehabilitation and then subsequently increased postdischarge and remained elevated at 2 to 3 yr postdischarge [7]. Because of the strong and consistent association between depression and prosthetic outcome observed in our study, it is critical that rehabilitation healthcare providers be vigilant for these symptoms and perhaps specifically quantify depressive symptomatology at regular intervals so that appropriate treatment plans can be initiated to help ensure optimum outcome.

Satisfaction with a prosthetic limb is also an important consideration following amputation, and many different aspects of prosthetic-limb satisfaction might be considered. This study utilized the TAPES to assess prosthetic satisfaction in the domains of aesthetic satisfaction, weight satisfaction, and functional satisfaction. In this study, scores on these three prosthetic satisfaction subscales correlated well with scores on the general adjustment subscale of the TAPES as well as with the three activity restriction subscales. This finding supports good internal consistency of the TAPES instrument in our study. The subjects in our study reported overall moderate levels of satisfaction with their prostheses. Specifically, the level of functional satisfaction with their prosthesis at all amputation levels was rated at 19.2 ± 4.2 with a range of possible scores of 5 to 25. The aesthetic and weight subscale scores did not change over time, which is likely a reflection of the fact that these individuals kept their same prosthesis throughout the study period or that the provided prostheses were similar in weight and cosmetic appearance. The level of functional satisfaction with the prosthesis at the TM level was significantly greater than at the other major amputation levels. The focus of the majority of the literature on dysvascular amputation has been on the TT amputation level or above. This finding provides new information on potential merits of TM

amputation relative to TT or higher levels of amputation, although final evaluation of the potential value of an amputation level must be viewed in a more comprehensive way. A recent publication has shown that TT amputation may be associated with a greater likelihood of mobility success than TM amputation [41].

Several limitations with the current study are worth noting. The majority of the outcome measures utilized in this study were well-validated self-report measures. Because of the self-report nature of the measures, these data could have been biased by the subject's desire to show positive improvement. This issue is at least partially mitigated by a strong movement toward patient-reported outcomes research. The overall sample size in the study limited our ability to examine certain characteristics of specific amputation levels. This was primarily an issue in the TF amputation cohort. All interpretations relative to the TF group should be performed with caution because of the small sample size. Despite the small number of subjects with TF amputations, several of the differences noted in this population compared to those subjects with TT and TM amputation levels were statistically valid and add valuable contributions to the literature. In addition, this investigation is one of the largest prospective investigations performed to quantify outcomes and important interactions that contribute to outcome in this patient population.

CONCLUSIONS

While most individuals achieve successful prosthetic fitting by 1 yr following a first major dysvascular lower-limb amputation, individuals with TF amputations were significantly less likely to achieve prosthetic fitting success at 1 yr. TF amputation, increased age, major depressive episode, and history of dialysis were associated with significantly less prosthetic ambulation. Higher social support was associated with greater prosthetic ambulation. These findings suggest that evaluation and management of depression and promotion of social support may have a positive effect on outcome. Further study will be required to determine whether or not treatment of depression and encouragement of social support can be modified significantly enough to improve prosthetic use. Subjects in this study who achieved prosthetic fitting were overall satisfied with their prostheses.

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