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Functional outcomes following the prosthetic training phase of rehabilitation after dysvascular lower extremity amputation

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Abstract

Objective—To describe physical function outcomes and modes of physical therapy intervention for a cohort of patients with dysvascular lower extremity amputation (LEA) during the prosthetic training phase of rehabilitation.

Design—A retrospective cohort study.

Setting—Physical rehabilitation clinics at a Veterans Affairs Medical Center and a University Hospital.

Patients—Forty-two patients (38 men, 4 women, age 60.2±8.4 years) who completed outpatient physical therapy rehabilitation with prosthetic training after dysvascular LEA.

Methods—All patients underwent a prosthetic training phase of rehabilitation, with standardized outcome measures performed at initiation and discharge.

Main Outcome Measures—Performance-based physical function measures included: Two-Minute Walk (2MW), Timed-Up and Go (TUG), and 5-meter gait speed. Self-report physical function measures included: the Prosthesis Evaluation Questionnaire – Mobility Section (PEQ-MS) and the Patient-Specific Functional Scale (PSFS). Rehabilitation dose was tracked as total number of clinic visits, rehabilitation duration, and specific intervention modes.

Results—There were significant improvements in 2MW (mean±SD) [67.5±29.9 m (initial) and 103.3±45.8 m (discharge) (p<0.001)], gait speed [0.58±0.27 m/s (initial) and 0.88±0.39 m/s (discharge) (p<0.001)], TUG [34.8±21.3 s (initial) and 18.6±13.9 s (discharge) (p<0.001)], PEQ-

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MS [2.2±0.9 (initial) and 2.8±0.8 (discharge) ($p<0.001$)], and PSFS [3.2±2.0 (initial) and 5.9±2.3 (discharge) ($p<0.001$)]. Performance-based (TUG) and self-report (PEQ-MS) changes in functional mobility from initial exam to discharge had low or no correlations with rehabilitation dose measures. Number of clinic visits was 12.7±13.1 and rehabilitation duration was 13.7±16.8 weeks.

Conclusions—Significant improvements in performance-based and self-report measures of physical function occurred during the prosthetic training phase of physical rehabilitation following dysvascular major LEA. Despite improvements in function, gait speed and TUG outcomes remained below clinically important thresholds, indicating patients were limited in community ambulation and at risk for falls. Lack of moderate or higher correlation between rehabilitation dose and outcome measures may indicate need for more specific rehabilitation dose measures.

INTRODUCTION

Poor physical function outcomes are commonly reported for patients with dysvascular major lower-extremity amputation (LEA).^{1–5} Dysvascular LEA can be operationally defined as amputation resulting from severe peripheral artery disease (PAD) with critical limb ischemia or severe diabetes mellitus (DM) with dense distal neuropathy leading to a non-healing wound. Importantly, dysvascular amputations account for more than 80% of major LEA in the United States.^{6, 7} Research evidence on functional outcomes is largely based on mixed populations of patients with amputation including patients with traumatic, congenital, or cancer-related amputations. The limited amount physical function outcome data limits the knowledge needed to develop rehabilitation programs and guidelines for people following dysvascular amputation.^{8, 9}

Approximately half of patients with dysvascular transtibial amputation referred for prosthetic care are likely to not walk as their primary method of community mobility 1 year after amputation.^{2, 3, 10, 11} The ability of patients to perform tasks such as walking, sit-stand transitions, and turns is particularly limited.^{5, 12, 13} For example, Schoppen and colleagues¹² found the mean±SD time for the Timed Up-and-Go (TUG) test (which includes walking, sit-stand transitions, and turning) to be 23.8±23.0 s for a group of older adults ($n=27$) at mean time of 3.7 years after dysvascular transtibial amputation. In comparison, 13.5s is an established threshold time indicating risk of falls for older adults.¹⁴ This is a significant health care issue, considering that physical mobility and ambulation ability are key indicators of successful function for older adults.¹⁵

Much of the current research on performance-based physical function following dysvascular LEA is based on cross-sectional analyses, limiting the ability to assess expected changes during physical rehabilitation. Findings from the small number of longitudinal cohort and intervention studies indicate that rehabilitation within the first year after dysvascular LEA can help to improve physical function.^{4, 16–19} For example, Czerniecki and colleagues⁴ examined the one-year course of change in ambulatory function for 25 patients with dysvascular LEA. They found that patients made significant improvements in ambulatory function from six weeks to 12 months after LEA. However, even 12 months after amputation, ambulatory function did not return to pre-amputation level. The lack of

continued gain in physical function after rehabilitation is problematic. For example, several studies demonstrate that patients with dysvascular LEA are likely to have chronic post-rehabilitative functional deficits.^{3, 20, 21} Such unresolved functional limitations could predispose individuals to premature loss of functional independence, as well as other physical health concerns such as increased risk of falling. To advance rehabilitation practice, it is critical to better understand the course of change in both performance and self-report measures of physical mobility and ambulation function early after dysvascular LEA, during the prosthetic training phase of rehabilitation.

Therefore, the purposes of this retrospective study were to: 1) describe changes in physical mobility and ambulation function, 2) describe the documented modes of physical therapy intervention, and 3) examine correlations between change in physical mobility and physical therapy dose during the prosthetic training phase of rehabilitation for patients with unilateral dysvascular LEA.

METHODS

Study Design

A retrospective cohort study design was used to examine outcomes from two rehabilitation clinics: a Veterans Affairs Medical Center and a University Hospital. All patients underwent physical therapy during the prosthetic training phase of rehabilitation, with the same standardized outcome measures performed at prosthetic training initiation and discharge. All testing was performed in the clinics by physical therapists trained and assessed in performance of the outcome measures prior to conducting the measures with patients. The usual care intervention for the cohort was described retrospectively, based on systematic review of patient medical records. No changes were made to the intervention procedures at either clinic and length of rehabilitation was not controlled. This study was approved by the *blinded for peer-review* Institutional Review Boards.

Patients

Medical records of all patients with transfemoral or transtibial amputation within a two-year period from September 2012 to September 2014 that met the study inclusion criteria were analyzed. Inclusion criteria were: 1) physical rehabilitation that included prosthesis training for ambulation, 2) complete initial and discharge functional outcome data, 3) documented diagnosis of diabetes and/or PAD, 4) ages 40–90 years, 5) unilateral transfemoral (TFA) or transtibial (TTA) amputation (i.e., no history of amputation above the ankle on the contralateral limb), 6) fitted for and received prosthesis to allow start of prosthetic training, and 7) dysvascular etiology of amputation. Dysvascular etiology was determined by medical record confirmation that the amputation resulted from severe peripheral artery disease (PAD) with critical limb ischemia or severe diabetes mellitus (DM) with dense distal neuropathy leading to a non-healing wound, without history of lower extremity trauma or cancer. Inclusion criteria were intentionally broad to capture characteristics of diversity in the sample. While individuals were not excluded on the basis of co-morbidities, a Functional Comorbidity Index²² was used to document individual co-morbidities during chart review. The level of amputation (transfemoral or transtibial) was also documented.

Intervention

Physical therapy intervention was provided at each clinic by licensed physical therapists and documented in the medical record. Rehabilitation dose was tracked as total number of clinic visits, rehabilitation duration (weeks of intervention), and frequency of using specific intervention mode. Usual care intervention for this retrospective, descriptive study was assessed as follows: each documented intervention was assigned a mode of intervention category, based on Current Procedural Terminology (CPT) codes, including Gait/Prosthetic-Use Training, Activity Training, Therapeutic Exercise, and Self-Care Education and Training (Table 1). The frequency of each intervention mode was then calculated by determining the number of visits in which intervention within that category were used divided by the total number of visits. Descriptive characteristics recorded for each patient included: age, sex, BMI, amputation level (transtibial or transfemoral), and comorbidities (as measured with the Functional Comorbidity Index²²).

Outcome Measures

Outcome measures for this study were selected based on evidence of validity and reliability for patients with LEA. Scores from all measures were obtained at two testing points: (1) within two weeks of initiating prosthetic training during rehabilitation and (2) at discharge from physical rehabilitation. The initial test session occurring within two weeks of the initiation of prosthetic training appeared from the chart review to rely on several factors, including patient tolerance for 2-minutes of walking with the new prosthesis, participant schedules, frequency of visits, and cancellations. The average time of testing occurred within the first week, with only four participants tested between 1–2 weeks. Testing occurred at the rehabilitation clinics as a standardized component of the rehabilitation process and was performed by one of three physical therapists at each site. Procedural reliability was measured for each physical therapist prior to performing the outcome measurements in the clinic. Reliability of each tester was measured and both intra- and inter-tester reliability assessed using intraclass correlation coefficients. All testers achieved inter- and intra-tester reliability scores of >0.90 prior to implementing the outcome measure testing as the usual practice at both clinics.

Performance-based physical function measures included the Two-Minute Walk (2MW) test,²³ Timed-Up and Go (TUG),²⁴ and five-meter gait speed (gait speed).²⁵ Each of these tests are valid and reliable indicators of physical function and mobility for patients with LEA.^{12, 26–28} The 2MW was performed in a 30.5 m (200 ft.) hallway at each clinic with the total distance measured after the patients walked for two consecutive minutes (using hand-held stopwatch) at a pace dictated by the instructions to “cover the greatest distance as possible in two minutes.”²³ The TUG was performed using a standard height chair (46 cm) and a hand-held stopwatch to measure the time required by the patients to transfer from sitting to standing, walk forward 3 meters, turn, walk back to the chair, and return to sitting, as quickly as possible.²⁴ Gait speed was measured as the self-selected gait speed that the patients used during their typical daily activity (i.e., a comfortable walking pace). The distance of the hallway used for gait speed measurement was nine meters, including a two-meter acceleration zone and two-meter deceleration zone at either end of a five-meter

walkway in which walking speed was timed using a hand-held stopwatch. Use of assistive device was monitored and recorded for each performance-based test.

Self-Report Functional Mobility Measures

Self-report measures of physical function were the Prosthesis Evaluation Questionnaire – Mobility Section (PEQ-MS)²⁹ and the Patient Specific Functional Scale (PSFS).³⁰ The PEQ-MS has high levels of reliability and validity for measurement of functional mobility for people with LEA.^{29, 31} The PSFS, a measure that uses patient-identified problems as outcomes, has demonstrated reliability for use by people with LEA.³¹

Data Analysis

Descriptive variables were examined for the patients by using means and standard deviations for continuous variables and frequencies for categorical variables (Table 2). Descriptive variables were separated based on transtibial or transfemoral amputation. To assess the first objective, describing changes in physical mobility and ambulation function during the prosthetic training phase of outpatient physical therapy, paired *t* tests were used to compare initial and discharge values for the three performance-based (2MW, TUG, gait speed) and two self-report (PEQ-MS, PSFS) measures. The second objective, describing the documented modes of physical therapy intervention, was completed by a thorough chart review of each patient's physical therapy record. The frequency of use of each identified intervention mode (using CPT code categories) was averaged across all patients. To address the third objective, examining correlations between change in physical mobility and physical therapy dose, performance-based (TUG) and self-report (PEQ-MS) measures of physical mobility were used. Physical therapy dose was measured using total number of clinic visits, rehabilitation duration (days), and percent of visits using specific intervention mode. Pearson product-moment correlation coefficients were used to measure each bivariate relationship between change in physical mobility and rehabilitation dose. Confidence intervals (95%) were calculated for the interpretation of the Pearson product-moment correlation coefficients. Terms describing relative strength of the correlations were based on Munro's descriptive terms for strength of correlation coefficients: little, if any correlation (0.00–0.25), low (0.26–0.49), moderate (0.50–0.69), high (0.70–0.89), very high (0.90–1.00).³² Unless otherwise specified, group values are reported as mean±SD. The α level was set at 0.05 for all inferential comparisons.

RESULTS

Data from a two-year period from September 2012 to September 2014 were examined and forty-two consecutive patients (38 men, 4 women, age 60.2±8.4 years) were included who had met the inclusion/exclusion criteria. Characteristics of the patients are listed in Table 2, and are also separated by TTA and TFA. There were 31 patients with TTA and 11 with TFA. In addition, percentages of patients with comorbidities identified from the Functional Comorbidity Index are listed in Table 2. Eighty-three percent of patients had been diagnosed with diabetes (the most common comorbidity) and 36% with PAD. In addition, the mean number of comorbidities from the FCI was 4.6±1.8, with the patients with TTA having 4.6±1.8 and those with TFA having 4.8±1.9. The average time since amputation at the

baseline test session (within 2 weeks of starting prosthetic training) was 16.4 ± 13.7 weeks [25.2 ± 16.4 weeks (TFA); 13.3 ± 11.3 weeks (TTA)]. All data were examined for presence of outliers and the assumption of normality. Correlation scatterplot matrices were examined for the assumption of linearity. When the distribution of the variables was assessed for normality, some variables demonstrated skew in distribution. To confirm the results, non-parametric tests were used. In all cases, results of the parametric tests were confirmed by findings in non-parametric testing (sign test and signed rank test for physical function change scores and Spearman's rho for correlations).

Physical Function Outcomes

There were significant improvements in all physical function outcomes at the time of discharge for the entire group of patients with dysvascular LEA (Table 3). When separated into TTA and TFA groups, the mean changes in all outcomes were smaller for the TFA group. The smaller difference in mean scores across rehabilitation, along with the smaller sample size in the TFA group, resulted in only the TUG and PSFS having statistically significant improvements between initial to discharge scores. All improvements in outcomes for the TTA group were statistically significant. At the initial test point, 98% of patients used an assistive device for walking (straight cane 7.1%, wheeled or non-wheeled walker 45.2%, crutches 45.2%) compared to 62% of all patients at discharge (straight cane 9.5%, wheeled or non-wheeled walker 21.4%, crutches 31.0%).

Correlations Between Functional Mobility and Rehabilitation Dose

The number of physical therapy rehabilitation visits was 12.7 ± 13.1 and duration of rehabilitation was 13.7 ± 16.8 weeks. The number of visits and duration were slightly higher for the TFA group than the TTA group (Table 2). The frequency of use for each mode of intervention (major and sub-categories) is presented as percent of sessions used out of the total number of intervention sessions in Table 1. Correlation values between functional mobility and rehabilitation dose variables are presented in Table 4. The only statistically significant correlation was $r = -.32$ between TUG and Self-Care Education and Training, which indicated that lower TUG times (i.e., better TUG performance) had a low association with more time spent in Self-Care Education and Training during rehabilitation. No other correlation coefficient was statistically different from zero.

DISCUSSION

The primary objective of this study was to describe physical function outcomes and documented modes of physical therapy intervention for a cohort of patients with dysvascular lower extremity amputation (LEA) during the prosthetic training phase of rehabilitation. We found that the cohort had significant and clinically meaningful improvements in performance-based and self-report measures of physical mobility and ambulation function during prosthetic training following dysvascular major LEA. However, there were low or no correlations between rehabilitation dose and the functional mobility outcomes.

The improvement in 2MW distance during rehabilitation is consistent with findings of Czerniecki and colleagues⁴ who examined change in ambulatory function across the first

year after amputation for 25 patients with dysvascular LEA. Their study used the Locomotor Capability Index³³ to assess walking ability with 14 items graded on a 5-level ordinal scale ranging from “unable to perform the activity” to “able to perform alone without aids”. The result was that significant gains in ambulatory function occurred across the 1 year following amputation, but that 1-year scores remained at low levels, compared to pre-amputation levels. Our findings regarding the 2MW distance agree with the conclusion of less than optimal outcome. For example, typical Six-Minute Walk distances for healthy older adults of ages similar to the patients in this study have been shown to be in the range of 500–600 m, which would equate to a conservative estimate of 167–200 m for 2MW, if the pace were unchanged. To be within this range of healthy older adult walk distances the discharge scores for patients with LEA in the current study would need to nearly double. In addition, 2MW distance has been shown to be chronically limited after discharge from rehabilitation after LEA, evidenced by a previous study of patients more than 2 years removed from amputation with a mean 2MW distance of 121 m.³¹

The changes seen in 2MW distances show significant improvements in walking ability across the course of rehabilitation, which are consistent with previous improvements over time reported for patients with dysvascular LEA.²⁷ The mean 2MW change of 35.8 m met the minimal detectable change for patients with LEA previously reported as 34.3 m.³¹ This minimal detectable change is an indication of the relatively high variability in the 2MW for patients with amputation (e.g., SD=45.8 m at discharge in this study) and emphasizes that the statistically significant improvement should be interpreted with caution. The mean change in 2MW distance observed in this study is large when compared to established clinically meaningful changes for the 6MW, which range for various other populations between 24–80 m.^{34–37}

Similar to the 2MW, TUG and gait speed scores also changed significantly across the prosthetic rehabilitation phase. The resulting scores are similar to previous studies. For example, Schoppen and colleagues¹² examined patients with LEA resulting from peripheral vascular disease and found that at a mean of 3.7 years after amputation, patients with transtibial and transfemoral amputations had mean TUG times of 23.8 s and 28.3 s, respectively. In terms of gait speed, the discharge speed of 0.88 m/s observed in our study is similar to cross-sectional studies, ranging from 0.50³⁸ to 1.04 m/s²⁸ seen at various time points for patients after LEA.

Also similar to the 2MW results, despite significant improvements with rehabilitation, TUG and gait speed scores remain at critically low levels at discharge. For example, the TUG has been examined in relation to falls for patients with TTA.³⁹ Dite and colleagues³⁹ examined 40 patients with unilateral TTA at hospital discharge and six month follow-up after amputation. Their finding was that patients with >2 falls in the six-month time span had 8.8s slower TUG scores compared to non-multiple fallers. In addition, they determined that a threshold score of 19s had a sensitivity of 85% and specificity of 74% in identifying multiple fallers. In our study, the mean TUG score of 18.6s is nearly at the suggested threshold score of 19s, with 26% of the TTA group and 55% of the TFA group having TUG scores above 19s at discharge. This finding indicates that despite the significant

improvements in TUG scores during rehabilitation, a large amount of patients remain at relatively high risk for falling multiple times after discharge.

The self-selected gait speed mean score of 0.88 m/s at discharge is also concerning in terms of suggested clinical threshold scores. A self-selected gait speed of <0.8m/s has been proposed as an indicator of predicted life expectancy for older adults and functional limitations.^{25, 40} In our sample at discharge, 35% (11/31) of the TTA group and 73% (8/11) of the TFA group had self-selected gait speeds below 0.8 m/s. In addition, the majority of patients (62%) continued to use an assistive device for walking at discharge.

Changes in physical function were dependent on level of amputation (TTA vs. TFA). All performance-based and self-report measures of physical function changed significantly across prosthetic training for patients with TTA, while only the TUG and PSFS were statistically improved for patients with TFA. In addition, the variability in outcome measures was generally greater for patients with TFA, compared to TTA (Table 3). The differences in functional improvements between TTA and TFA may be linked to several factors that distinguish the two groups. For example, patients with TFA initiated prosthetic training later after amputation and had a relatively larger average dose of intervention (higher number of visits and longer duration), compared to patients with TTA (Table 2). Patients with TFA also had lower mean baseline functional scores than patients with TTA. Future studies should identify the unique aspects of rehabilitation intervention and outcomes dictated by the level of dysvascular LEA.

The second objective in this study was to describe the modes of physical therapy intervention used during the prosthetic training phase for patients with dysvascular LEA. Ideal rehabilitation modes are not established for dysvascular LEA. In this study cohort, the most common documented modes of intervention were related to gait and/or prosthetic training on various surfaces. This is consistent with the phase of the intervention and the published guidelines on rehabilitation after LEA.^{41, 42} Activity training and therapeutic exercise were the second and third most frequent categories of intervention mode, with self-care education and training being the least frequent. Interestingly, the only rehabilitation mode correlated to functional mobility was Self-Care Education and Training ($r = -.32$ between TUG and Self-Care Education and Training). Although low, this correlation is consistent with the idea that self-care interventions, such as training health behaviors and self-management, are important to rehabilitation for patients with the complex medical conditions related to dysvascular LEA. In addition, the coordination of services that emphasize self-care education and training (e.g., physical therapy, occupational therapy, nursing) is an area requiring further examination for patients with dysvascular LEA.

By definition, dysvascular LEA results from severe diabetes mellitus leading to a non-healing wound and/or severe peripheral artery disease with critical limb ischemia. In addition, dysvascular LEA occurs most frequently in people over the age of 55 with multiple other comorbidities.^{6, 43} For example, of Dillingham and colleagues used Medicare beneficiary data to show that older patients with amputation and diabetes have 1.6 times more comorbidities (mean number = 4) than patients with amputation who did not have diabetes.⁴³ This is consistent with our cohort, which had a mean of 4.6 comorbidities out of

the 20 assessed by the Functional Comorbidity Index.²² The poor functional outcomes seen in this cohort study, which agree with other studies examining functional outcomes after dysvascular amputation,^{1–5} are likely linked to pre-existing comorbidities and poor vascular health self-management. Indeed, the presence of vascular comorbidities that result in amputation is an indication in itself of poor patient health self-management.

The primary reason for the third objective, identifying the relationship between intervention dose and physical mobility change, was to identify intervention doses most associated with improved outcomes. The lack of significant relationships between rehabilitation dose and physical mobility outcomes in our study indicate that the current measures of dose identified from the clinical records of the given cohort, may not be sufficient. Indeed, rehabilitation guidelines for other patient populations suggest that, in general, more specific measures of intervention dose and mode are needed.^{44–47} For example, Lohse and colleagues⁴⁴ conclude that, although duration of intervention time is positively linked to functional outcomes for patients in stroke rehabilitation, a better understanding of the dose-response relationship requires measuring greater details of dose, such as active time in specific exercise, number of repetitions, and exercise intensity. It is possible that specific measures of rehabilitation dose beyond number of visits, duration, and frequency of specific interventions are related to functional outcomes after dysvascular LEA. In this study, the intensity and specific amount of time spent with specific exercises could not be consistently determined from the medical records. In addition, it is possible that the changes in physical mobility could be accounted for by factors outside of rehabilitation. Future controlled trials should address the specific effects of closely measured rehabilitation dose, while accounting for potential confounding variables (e.g., age, previous level of function, timing of intervention relative to amputation).

There are several limitations that could be improved in future studies. In this study, discharge TUG scores indicate many patients are likely at a high risk of falls, based on previously established threshold scores. However, falls were not measured. Future studies should track falls across the course of rehabilitation, to add understanding to the relationship between changes in functional outcome scores and falling. Secondly, selection criteria for participation in the prosthetic training phase of rehabilitation were not standardized or documented. While all patients had some form of inpatient rehabilitation before beginning prosthetic training, this was not consistently tracked or controlled for in this retrospective study. In addition, medical records in both settings (VA and University) did not contain consistent and/or clear data to allow determination of how patients were selected for prosthetic training. As a result, patients included in this study represent a select cohort of relatively high functioning patients who have undergone dysvascular amputation. There exists another cohort of patients, not assessed in this study, who underwent dysvascular amputation and did not participate in prosthetic training. A third limitation of a retrospective cohort study is that rehabilitation was not controlled. The usual care process at each clinic was used, which included variance in scheduling and criteria for discharge. Future studies aimed at identifying optimal interventions will require controlled intervention protocols to minimize such sources of intervention variance. Finally, the long-term functional outcomes were not measured in this study. While literature evidence suggests that patient function tends to decline, future study should examine if there are subsets of the population who: 1)

continue to improve, 2) stay at the same functional level, and 3) decline in physical function after discharge from rehabilitation.

CONCLUSION

The cohort of patients undergoing usual care physical therapy during the prosthetic training phase of rehabilitation had significant improvements in performance-based and self-report measures of physical function following dysvascular major LEA. Despite these improvements, 2MW, TUG, and gait speed means at the time of rehabilitation discharge remained below clinically important threshold scores, indicating patients remained at risk for falls and limitations in community ambulation. These findings confirm data from cross-sectional studies, but extend the understanding of the change in functional outcomes during the course of physical rehabilitation. Additionally, the absence of correlation between rehabilitation dose and physical function outcome measures indicates the need for further identification and measurement of optimal rehabilitation dose parameters.

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REFERENCES

- Schoppen T, Boonstra A, Groothoff JW, de Vries J, Goeken LN, Eisma WH. Physical, mental, and social predictors of functional outcome in unilateral lower-limb amputees. *Arch Phys Med Rehabil*. 2003; 84(6):803–811. [PubMed: 12808530]
- Davies B, Datta D. Mobility outcome following unilateral lower limb amputation. *Prosthet Orthot Int*. 2003; 27(3):186–190. [PubMed: 14727699]
- Nehler MR, Coll JR, Hiatt WR, et al. Functional outcome in a contemporary series of major lower extremity amputations. *J Vasc Surg*. 2003; 38(1):7–14. [PubMed: 12844082]
- Czerniecki JM, Turner AP, Williams RM, Hakimi KN, Norvell DC. Mobility changes in individuals with dysvascular amputation from the presurgical period to 12 months postamputation. *Arch Phys Med Rehabil*. 2012; 93(10):1766–1773. [PubMed: 22543258]
- Sansam K, O'Connor RJ, Neumann V, Bhakta B. Can simple clinical tests predict walking ability after prosthetic rehabilitation? *J Rehabil Med*. 2012; 44(11):968–974. [PubMed: 23037865]
- Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. *Arch Phys Med Rehabil*. 2008; 89(3):422–429. [PubMed: 18295618]
- Margolis DJ, Malay DS, Hoffstad OJ, et al. Incidence of Diabetic Foot Ulcer and Lower Extremity Amputation Among Medicare Beneficiaries, 2006 to 2008: Data Points #2. 2011
- Fortington LV, Geertzen JH, Bosmans JC, Dijkstra PU. Bias in amputation research; impact of subjects missed from a prospective study. *PLoS One*. 2012; 7(8):e43629. [PubMed: 22916286]
- Fortington LV, Rommers GM, Geertzen JH, Postema K, Dijkstra PU. Mobility in elderly people with a lower limb amputation: a systematic review. *J Am Med Dir Assoc*. 2012; 13(4):319–325. [PubMed: 21450239]
- Moore TJ, Barron J, Hutchinson F 3rd, Golden C, Ellis C, Humphries D. Prosthetic usage following major lower extremity amputation. *Clin Orthop Relat Res*. 1989; (238):219–224. [PubMed: 2910604]

11. Sansam K, Neumann V, O'Connor R, Bhakta B. Predicting walking ability following lower limb amputation: a systematic review of the literature. *J Rehabil Med*. 2009; 41(8):593–603. [PubMed: 19565152]
12. Schoppen T, Boonstra A, Groothoff JW, de Vries J, Goeken LN, Eisma WH. The Timed "up and go" test: reliability and validity in persons with unilateral lower limb amputation. *Arch Phys Med Rehabil*. 1999; 80(7):825–828. [PubMed: 10414769]
13. Deathe AB, Miller WC. The L test of functional mobility: measurement properties of a modified version of the timed "up & go" test designed for people with lower-limb amputations. *Phys Ther*. 2005; 85(7):626–635. [PubMed: 15982169]
14. Shumway-Cook A, Brauer S, Woollacott M. Predicting the probability for falls in community-dwelling older adults using the Timed Up & Go Test. *Phys Ther*. 2000; 80(9):896–903. [PubMed: 10960937]
15. Viccaro LJ, Perera S, Studenski SA. Is timed up and go better than gait speed in predicting health, function, and falls in older adults? *J Am Geriatr Soc*. 2011; 59(5):887–892. [PubMed: 21410448]
16. Darter BJ, Nielsen DH, Yack HJ, Janz KF. Home-based treadmill training to improve gait performance in persons with a chronic transfemoral amputation. *Arch Phys Med Rehabil*. 2013; 94(12):2440–2447. [PubMed: 23954560]
17. Darter BJ, Wilken JM. Gait training with virtual reality-based real-time feedback: improving gait performance following transfemoral amputation. *Phys Ther*. 2011; 91(9):1385–1394. [PubMed: 21757579]
18. Czerniecki JM, Turner AP, Williams RM, Hakimi KN, Norvell DC. The effect of rehabilitation in a comprehensive inpatient rehabilitation unit on mobility outcome after dysvascular lower extremity amputation. *Arch Phys Med Rehabil*. 2012; 93(8):1384–1391. [PubMed: 22465582]
19. Pauley T, Devlin M, Madan-Sharma P. A single-blind, cross-over trial of hip abductor strength training to improve Timed Up & Go performance in patients with unilateral, transfemoral amputation. *J Rehabil Med*. 2014; 46(3):264–270. [PubMed: 24363039]
20. McWhinnie DL, Gordon AC, Collin J, Gray DW, Morrison JD. Rehabilitation outcome 5 years after 100 lower-limb amputations. *Br J Surg*. 1994; 81(11):1596–1599. [PubMed: 7827880]
21. Klute GK, Berge JS, Orendurff MS, Williams RM, Czerniecki JM. Prosthetic intervention effects on activity of lower-extremity amputees. *Arch Phys Med Rehabil*. 2006; 87(5):717–722. [PubMed: 16635636]
22. Groll DL, To T, Bombardier C, Wright JG. The development of a comorbidity index with physical function as the outcome. *J Clin Epidemiol*. 2005; 58(6):595–602. [PubMed: 15878473]
23. Butland RJ, Pang J, Gross ER, Woodcock AA, Geddes DM. Two-, six-, and 12-minute walking tests in respiratory disease. *Br Med J (Clin Res Ed)*. 1982; 284(6329):1607–1608.
24. Podsiadlo D, Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc*. 1991; 39(2):142–148. [PubMed: 1991946]
25. Studenski S, Perera S, Patel K, et al. Gait speed and survival in older adults. *Jama*. 2011; 305(1): 50–58. [PubMed: 21205966]
26. Brooks D, Hunter JP, Parsons J, Livsey E, Quirt J, Devlin M. Reliability of the two-minute walk test in individuals with transtibial amputation. *Arch Phys Med Rehabil*. 2002; 83(11):1562–1565. [PubMed: 12422326]
27. Brooks D, Parsons J, Hunter JP, Devlin M, Walker J. The 2-minute walk test as a measure of functional improvement in persons with lower limb amputation. *Arch Phys Med Rehabil*. 2001; 82(10):1478–1483. [PubMed: 11588757]
28. Boonstra AM, Fidler V, Eisma WH. Walking speed of normal subjects and amputees: aspects of validity of gait analysis. *Prosthet Orthot Int*. 1993; 17(2):78–82. [PubMed: 8233772]
29. Franchignoni F, Giordano A, Ferriero G, Orlandini D, Amoresano A, Perucca L. Measuring mobility in people with lower limb amputation: Rasch analysis of the mobility section of the prosthesis evaluation questionnaire. *J Rehabil Med*. 2007; 39(2):138–144. [PubMed: 17351696]
30. Stratford PW, Gill C, Westaway M, Binkley J. Assessing disability and change on individual patients: a report of a patient specific measure. *Physiother Can*. 1995; 47:258–263.

31. Resnik L, Borgia M. Reliability of outcome measures for people with lower-limb amputations: distinguishing true change from statistical error. *Phys Ther.* 2011; 91(4):555–565. [PubMed: 21310896]
32. Munro, BH.; Page, EB. *Statistical Methods for Health Care Research.* 2nd ed. ed.. Philadelphia, PA: Lippincott Co; 1993.
33. Franchignoni F, Orlandini D, Ferriero G, Moscato TA. Reliability, validity, and responsiveness of the locomotor capabilities index in adults with lower-limb amputation undergoing prosthetic training. *Arch Phys Med Rehabil.* 2004; 85(5):743–748. [PubMed: 15129398]
34. Henricson E, Abresch R, Han JJ, et al. The 6-minute walk test and person-reported outcomes in boys with duchenne muscular dystrophy and typically developing controls: longitudinal comparisons and clinically-meaningful changes over one year. *PLoS Curr.* 2013; 5
35. Wise RA, Brown CD. Minimal clinically important differences in the six-minute walk test and the incremental shuttle walking test. *COPD.* 2005; 2(1):125–129. [PubMed: 17136972]
36. du Bois RM, Weycker D, Albera C, et al. Six-minute-walk test in idiopathic pulmonary fibrosis: test validation and minimal clinically important difference. *Am J Respir Crit Care Med.* 2011; 183(9):1231–1237. [PubMed: 21131468]
37. Learmonth YC, Dlugonski DD, Pilutti LA, Sandroff BM, Motl RW. The reliability, precision and clinically meaningful change of walking assessments in multiple sclerosis. *Mult Scler.* 2013; 19(13):1784–1791. [PubMed: 23587605]
38. Collin C, Wade DT, Cochrane GM. Functional outcome of lower limb amputees with peripheral vascular disease. *Clin Rehabil.* 1992; 6:13–21.
39. Dite W, Connor HJ, Curtis HC. Clinical identification of multiple fall risk early after unilateral transtibial amputation. *Arch Phys Med Rehabil.* 2007; 88(1):109–114. [PubMed: 17207685]
40. Abellan van Kan G, Rolland Y, Andrieu S, et al. Gait speed at usual pace as a predictor of adverse outcomes in community-dwelling older people an International Academy on Nutrition and Aging (IANA) Task Force. *J Nutr Health Aging.* 2009; 13(10):881–889. [PubMed: 19924348]
41. Esquenazi A, DiGiacomo R. Rehabilitation after amputation. *J Am Podiatr Med Assoc.* 2001; 91(1):13–22. [PubMed: 11196327]
42. VA/DoD Clinical Practice Guideline for Rehabilitation of Lower Limb Amputation: Department of Veterans Affairs & Department of Defense. 2008
43. Dillingham TR, Pezzin LE, Shore AD. Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations. *Arch Phys Med Rehabil.* 2005; 86(3):480–486. [PubMed: 15759232]
44. Lohse KR, Lang CE, Boyd LA. Is more better? Using metadata to explore dose-response relationships in stroke rehabilitation. *Stroke.* 2014; 45(7):2053–2058. [PubMed: 24867924]
45. Kwakkel G, van Peppen R, Wagenaar RC, et al. Effects of augmented exercise therapy time after stroke: a meta-analysis. *Stroke.* 2004; 35(11):2529–2539. [PubMed: 15472114]
46. Pozzi F, Snyder-Mackler L, Zeni J. Physical exercise after knee arthroplasty: a systematic review of controlled trials. *Eur J Phys Rehabil Med.* 2013; 49(6):877–892. [PubMed: 24172642]
47. Beaupre LA, Binder EF, Cameron ID, et al. Maximising functional recovery following hip fracture in frail seniors. *Best Pract Res Clin Rheumatol.* 2013; 27(6):771–788. [PubMed: 24836335]

Table 1

Classification for mode of intervention

Intervention Mode	Frequency (%)
Gait/Prosthetic-Use Training	85
Level Ground Walking	62
Parallel Bar Walking	35
Weight-Shifting Standing	28
Un-level Ground Walking	27
Marching/Stepping Level Ground	18
Standing Tolerance	2
Treadmill Walking	1
Activity Training	77
Stairs and/or Steps	46
Supine/Sit/Stand Transitions	36
Balance and/or Proprioception	28
Wheelchair Mobility	8
Therapeutic Exercise	73
Strengthening	52
Cardiovascular / Endurance	49
Stretching	42
Trunk Stabilization	39
Self-Care Education & Training	48
Donning & Doffing Prosthesis	21
Wound Care & Prevention	20
Residual Limb Wrapping	16
Family/Caregiver Education	4
Prosthetic Wear Schedules	3
Fall Prevention Education	1

* Data shown are % of sessions the mode of intervention was used out of total number of intervention sessions.

Table 2

Participant characteristics by amputation level*

Variable	TTA (n=31)	TFA (n=11)	Total (n=42)
Age (y)	59.7±8.6	61.6±8.2	60.2±8.4
BMI (kg/m ²)	27.5±6.7	26.3±5.3	27.2±6.3
Sex (n (%) male)	28 (90.3)	10 (90.9)	38 (90.5)
Time Since Amputation (weeks)	13.3±11.3	25.2±16.4	16.4±13.7
Prosthetic Training Duration (weeks)	11.6±11.3	19.7±27.1	13.7±16.8
Physical Therapy Visits (n)	10.8±8.8	18.1±20.6	12.7±13.1
Comorbidities			
Diabetes (Type II)	27 (87.1)	8 (72.7)	35 (83.3)
Hypertension	20 (64.5)	9 (81.8)	29 (69.0)
Peripheral Artery Disease	8 (25.8)	7 (63.6)	15 (35.7)
Congestive Heart Failure	6 (19.4)	6 (54.5)	12 (28.6)
Obesity (BMI >30)	8 (25.8)	3 (27.3)	11 (26.2)
Visual Impairment	9 (29.0)	2 (18.2)	11 (26.2)
Arthritis (OA or RA)	7 (22.6)	2 (18.2)	9 (21.4)
Gastrointestinal Disease	8 (25.8)	1 (9.1)	9 (21.4)
Heart Attack (MI)	7 (22.6)	2 (18.2)	9 (21.4)
Degenerative Disc Disease	5 (16.1)	2 (27.3)	7 (16.7)
Depression	6 (19.4)	1 (9.1)	7 (16.7)
Hearing Impairment	6 (19.4)	1 (9.1)	7 (16.7)
Stroke (CVA)	5 (16.1)	1 (9.1)	6 (14.3)
Anxiety or Panic Disorder	2 (6.5)	3 (27.3)	5 (11.9)
Asthma	3 (9.7)	0 (0.0)	3 (7.1)
COPD or Emphysema	0 (0.0)	3 (27.3)	3 (7.1)

Abbreviations: TTA, transtibial amputation; TFA, transfemoral amputation; BMI, body mass index; OA, osteoarthritis; RA, rheumatoid arthritis; MI, myocardial infarct; CVA, cerebral vascular accident; COPD, chronic obstructive pulmonary disease.

* Data shown are means ± SD or n (%) unless otherwise stated.

Table 3

Between time point comparison of physical function outcomes*

Variable	Initial	Discharge	p-value [†]
Total Lower Extremity Amputation (n=42)			
Performance-Based			
2MW (m)	67.5 ± 29.9	103.3 ± 45.8	<0.001
TUG (s)	34.8 ± 21.3	18.6 ± 13.9	<0.001
Gait Speed (m/s)	0.58 ± 0.27	0.88 ± 0.39	<0.001
Self-Report			
PEQ-MS (score 0–4)	2.2 ± 0.9	2.8 ± 0.8	<0.001
PSFS (score 0–10)	3.2 ± 2.0	5.9 ± 2.3	<0.001
Transtibial Amputation (n=31)			
Performance-Based			
2MW (m)	71.0 ± 30.9	113.7 ± 41.5	<0.001
TUG (s)	34.3 ± 22.1	15.6 ± 9.2	<0.001
Gait Speed (m/s)	0.61 ± 0.27	0.96 ± 0.36	<0.001
Self-Report			
PEQ-MS (score 0–4)	2.1 ± 1.0	2.9 ± 0.8	<0.001
PSFS (score 0–10)	3.5 ± 2.0	6.4 ± 1.9	<0.001
Transfemoral Amputation (n=11)			
Performance-Based			
2MW (m)	57.6 ± 25.6	73.9 ± 46.6	0.09
TUG (s)	36.3 ± 20.0	27.2 ± 20.8	0.04
Gait Speed (m/s)	0.50 ± 0.25	0.65 ± 0.40	0.06
Self-Report			
PEQ-MS (score 0–4)	2.3 ± 0.6	2.5 ± 0.6	0.20
PSFS (score 0–10)	2.4 ± 1.6	4.6 ± 2.8	0.001

Abbreviations: 2MW, Two-Minute Walk; TUG, Timed-Up and Go; PEQ-MS, Prosthesis Evaluation Questionnaire-Mobility Scale; PSFS, Patient-Specific Functional Scale.

* Data shown are means ± SD unless otherwise stated.

[†] p-value denotes comparison of change from initial to discharge.

Table 4

Pearson product-moment correlations between functional mobility and rehabilitation dose measures *

Variable	TUG	PEQ-MS
Number of Rehabilitation Sessions	.01 (–.29 to .31)	.01 (–.29 to .31)
Rehabilitation Duration	.11 (–.38 to .22)	.06 (–.24 to .37)
Gait/Prosthetic-Use Training	–.28 (–.54 to .03)	.16 (–.15 to .44)
Activity Training	–.17 (–.45 to .14)	.16 (–.15 to .44)
Therapeutic Exercise	.25 (–.06 to .51)	.00 (–.30 to .30)
Self-Care Education & Training	–.32 [‡] (–.57 to –.02)	–.06 (–.36 to .25)

Abbreviations: TUG, Timed-Up and Go; PEQ-MS, Prosthesis Evaluation Questionnaire-Mobility Scale.

* Data shown are *r* values (95% CI).[‡]Correlation is significant at 0.05 level (2-tailed).