

Functional level assessment of individuals with transtibial limb loss: Evaluation in the clinical setting versus objective community ambulatory activity

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Abstract

The functional level (K level) of prosthetic users is used to choose appropriate prosthetic components, but ratings may be highly subjective. A more objective and robust method to determine K level may be appealing. The aim of this study was to determine the relationship between K level determined in the clinic to K level based on real world ambulatory activity data collected by StepWatch. Twelve individuals with transtibial limb loss gave informed consent to participate. K level assessments performed in the clinic by a single treating prosthetist were compared with a calculated estimate based on seven days of real world ambulatory activity patterns using linear regression. There was good agreement between the two methods of determining K level with $R^2 = 0.775$ ($p < 0.001$). The calculated estimate of K level based on actual ambulatory activity in real world settings appears to be similar to the treating prosthetist's assessment of K level based on gait observation and patient responses in the clinic. Clinic-based ambulatory capacity in transtibial prosthetic users appears to correlate with real world ambulatory behavior in this small cohort. Determining functional level based on real world ambulatory activity may supplement clinic-based tests of functional capacity.

Keywords

Amputee, ambulation, gait, K-level, prosthesis

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Introduction

The United States' Medicare Functional Classification Level (MFCL) K level is a 0 to 4 point scale of functional level for those with limb loss.¹ The MFCL levels are described in Table 1. Higher K level rated individuals generally receive more technologically advanced and expensive components such as microprocessor-controlled knees and ankles, and carbon fiber “energy storage and return” prosthetic feet. In the United States, current Centers for Medicare/Medicaid Services (CMS) guidelines allow reimbursement to providers of prosthetic components if there is evidence that the individual's K level matches the prosthetic components provided. This evidence must be in the patient's medical record and noted by the evaluating physician; without this evidence of appropriate functional level, CMS may demand repayment of the reimbursement paid to the prosthetic provider for the components. The Inspector

General of Health and Human Services² has noted a 27% increase in the cost of prosthetic care for beneficiaries of CMS while the number of individuals with limb loss has dropped by 2% (2005–2009). Although the Inspector General's observation is legitimate, it was not peer-reviewed, and it does not take into account the possible mobility, quality of life, health care cost

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Table 1. Descriptions for the Medicare Functional Classification Level.¹

K level	Description
K0	Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility
K1	Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator
K2	Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator
K3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion
K4	Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete

improvements for the individuals with limb loss who received more expensive prosthetic components.

Prosthetists routinely evaluate patients' functional level, but there is no standard methodology for this assessment. The K level language is somewhat vague and each prosthetist may have a slightly different interpretation of the functional level characteristics. This brings up an important issue regarding an individual's *capacity* to perform at a high functional level during clinical tests versus high functional level *behavior* in the community. For example, Ashe et al. have shown that more than half of older community dwelling adults classified by clinic-based tests as high functional *capacity* exhibit low functional level *behavior* in the community.³ Mudge et al. have shown that clinic-based assessments of functional walking capacity show improvement after interventions for post stroke individuals, but these individuals do not demonstrate increased functional walking behavior in the community.⁴

Several clinic-based functional task test batteries have been created for those with limb loss.^{5,6} There is some published evidence that some capacity tests correlate with clinical evaluation of K level for prosthetists,⁵ but very little evidence exists that high functional capacity individuals with limb loss choose to demonstrate highly functional activity levels during typical community

behavior. The opposite might also be true; that individuals who demonstrate low functional capacity on clinic-based tests might choose to have higher levels of activity in the community. There are efforts underway to develop a new mobility instrument (questionnaire) for individuals with limb loss,⁷ but published evidence of reliability, validity and sensitivity have not yet appeared in the literature. The problem with any questionnaire assessing functional level in prosthetic users is that it will be susceptible to bias because a high score means more advanced and expensive prosthetic componentry for the prosthetic user. There is an inherent incentive to over-rate one's functional performance.

The aim of this study was to evaluate the relationship between the MFCL K level of 12 transtibial amputees determined by their treating clinical prosthetist and K level determined by a custom algorithm based on real world functional activity level from wearable sensor (StepWatch⁸) data in their typical community environment.

Methods

Twelve individuals with limb loss participated in this Institutional Review Board approved study (Table 2). The protocol was explained to each participant, and each participant signed an informed consent form. Participant recruitment was open to adults with dysvascular or traumatic causes of transtibial limb loss, including those with diabetes provided their disease was controlled and limb health was adequate on both limbs. The inclusion criteria were adults with transtibial limb loss, at least one year of successful ambulation on their prosthesis, a stable gait pattern, and fluent in English. Exclusion criteria for the study were underlying conditions that could affect gait such as chronic obstructive pulmonary disease or symptomatic cardiovascular disease.

Each participant's K level was determined by a single treating prosthetist in the clinic setting by the typical method of gait observation and questioning the participants about habitual walking behavior, environmental barriers and community ambulation challenges. After collecting these K level rating data in the clinic, each participant was fitted with a StepWatch Activity Monitor on their prosthesis (proximal to the prosthetic foot) to record their ambulatory activity over a seven day period in the community. The StepWatch records step counts of amputees with 99.6% accuracy,⁸ and is especially accurate at slow walking speeds when other monitors under-count steps.⁹ StepWatch has demonstrated high accuracy in step counts for a wide range of gait pathologies including post-stroke,^{10,11} multiple sclerosis and Parkinson's disease,¹² cerebral palsy,¹³⁻¹⁷ Duchene muscular dystrophy,¹⁸⁻²⁰ intermittent claudication,²¹⁻²⁵ and many others.²⁶⁻³⁷

Table 2. Demographic data of study participants with K level determined by the prosthetist and using the calculated K level based on seven days of real world ambulation.

Participant	Age (years old)	Body mass (kg)	Body height (m)	Prosthetist K level	Calculated K level	K level difference	Gender	Limb loss side
1	68	70	1.68	2	3	1	F	R
2	69	57	1.57	2	2.9	0.9	M	L
3	55	73	1.7	2	3.1	1.1	M	R
4	41	110	1.96	3	3.7	0.7	M	L
5	74	75	1.78	3	3.3	0.3	M	R
6	65	91	1.83	3	3.3	0.3	M	L
7	58	86	1.78	3	3.5	0.5	M	L
8	53	99	1.88	3	4	1	M	L
9	66	78	1.73	3	3.4	0.4	M	L
10	49	75	1.75	4	4.2	0.2	M	R
11	39	111	1.91	4	3.9	-0.1	M	R
12	47	61	1.7	4	4.6	0.6	M	L
Mean	57	82	1.77	3	3.6	0.6		
SD	12	18	0.11	0.7	0.5	0.4		
Range	41-74	57-111	1.57-1.96	2-4	2.9-4.6	-0.1-1.1		

F: female; M: male; R: right; L: left

The data from the StepWatch was downloaded and a custom algorithm was utilized to determine each individual's K level. This algorithm had four total components that used both community activity data (StepWatch data – three components) and clinically determined K level (clinician's judgment – one component) for calculation. These four components were averaged to determine the final calculated K level estimate; therefore the StepWatch data contributed 75% of the calculated score and the clinician's judgment contributed 25% to the final calculated K level estimate. The calculated K level ranged from 0.0 to 4.9 point scale similar to the K level score. Participants were considered within a K level until they achieved the next whole number rating; a 2.9 is still a K2 ambulator (no rounding for the calculated value).

Three parameters, which contributed 75% to the calculated K level, were extracted from the StepWatch community activity data that were mathematical analogs of the descriptions of the K level attributes in the original HCFA1 document: 1) the average step rate from 60 of each participant's most active non-contiguous minutes of activity was calculated for each of the seven days. Essentially this estimate is the average of the fastest, densest (most steps per minute) short term walking the individual can perform during community ambulation. This portion of the algorithm is intended to emulate the "potential to ambulate" section of the MFCL description (for example, "MFLC-2—Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven

surfaces. Typical of the limited community ambulator.")¹ 2) The ratio of Low:Medium:High step rates was calculated (Low 0-15 steps/min; Medium 16-40 steps/min; High >40 steps/min) for each of the seven days. Primarily this evaluates the ability of the individual to walk at different cadences during community ambulation. This portion of the algorithm is intended to emulate the "cadence variability" section of the MFCL description (for example, "MFLC-3—Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.")¹ 3) The total number of daily steps was used to estimate energy expenditure for each of the seven days based on an equation ($EE_{total} (kcal) = 2.033 \text{ kcal} \cdot \text{kg}^{-1} \cdot \text{weight (kg)} + 0.368 \text{ kcal} \cdot \text{steps} - 86.1 \text{ kcal}$) developed by Foster et al.³⁶ This estimates the metabolic cost of walking in the community. This portion of the algorithm is intended to emulate the "energy level" section of the MFCL description (for example, "MFLC-4—Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete.")¹

Each of these StepWatch components (1) rating of average step rate for 60 non-contiguous minutes; 2) rating of Low:Medium:High step rate ratios; 3) rating of energy expenditure based on total daily steps) uses steps per minute data in different ways and

the calculated values are mapped to a 0.0 to 4.9 point scale for each. This results in individual K levels for “potential to ambulate”, “cadence variability” and “energy level”, all on 0.0 to 4.9 point scales. The fourth component comes from the K level judged by the clinical prosthetist. Together these four components make up the calculated K level score by averaging them. To evaluate the concurrent validity, simple linear regression was utilized to determine the correlation between the prosthetist’s clinical judgment of K level and the K level determined by the algorithm.

Results

All participants completed the study and were rated by the prosthetists after seven days of community ambulation. The prosthetist rated three participants as K level 2, six participants as K level 3, and three participants as K level 4. The linear regression revealed a significant relationship between the prosthetist’s K level rating and the calculated K level ($p < 0.001$) with an R^2 of 0.775. The calculated K level was consistently slightly higher than the prosthetist’s rating for all but one individual, with the mean difference 0.6 K levels, the standard deviation 0.4 K levels and a range of -0.1 to $+1.1$ difference between the prosthetist’s K level and the calculated K level. The relationship between the two K level methods is shown in Figure 1.

Discussion

This study aimed to evaluate the correlation between the K level for 12 adults with transtibial limb loss determined by their clinical prosthetist and the K level determined by the calculated estimate from their daily ambulatory behavior. There was good agreement between the two methods of determining K level with $R^2 = 0.775$ ($p < 0.001$) and a very strong positive correlation ($R = 0.88$). The calculation tended to rate the participant’s K level slightly higher than the prosthetist, but by definition the decimal portion of the calculated K level is truncated. The calculated method also has greater resolution than the single integer value for K levels given by the prosthetist. It could be that some individuals were given K2 rating for example when they were actually a very high K2, but not quite a K3 in the opinion of the prosthetist. The lack of an additional significant figure in the prosthetist K level adds a certain level of inaccuracy that may have altered the observed linear relationship between functional level measures.

It should be noted that the MFCL K levels have no published evidence of reliability or construct validity, and have only been accepted by clinicians and researchers because of reimbursement policies in the United

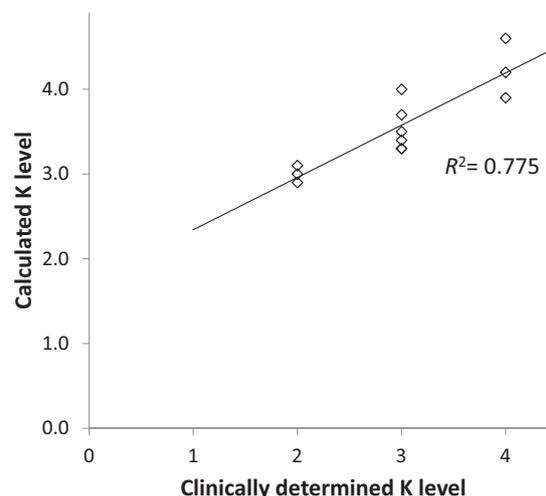


Figure 1. K level rating of 12 transtibial amputees by a single treating prosthetist using usual clinical methods and calculated by the algorithm from StepWatch data in their community setting.

States. For many prosthetists, the key feature that distinguishes a K3 ambulator from a K2 ambulator is cadence variability. It is implicit in the description that individuals who have multiple walking speeds will exhibit cadence variability, be more functional community ambulators and deserve more expensive and high-performance prosthetic components such as carbon fiber “energy storage and return” feet or microprocessor-controlled knees.

These data also show that there is some variability between clinic-based estimate of *capacity* and real world *behavior*, but there is still a fairly high relationship between the two for this small cohort of participants. One confounding effect is that individuals may have been limited in their community behavior by the very prosthetic components provided based on their clinical K level assessment, creating a self-fulfilling cycle of component, capacity and behavior. Previous work has demonstrated that some K2 individuals can become K3 individuals if given a microprocessor-controlled knee.³⁸ Additional carefully controlled studies with larger numbers of subjects are needed to determine if specific prosthetic components can increase or decrease performance on clinic-based tests of capacity or alter real world functional behavior.

This initial study on the concurrent validity of the calculated K level algorithm compared with typically derived clinician impression of K level focused only on transtibial prosthesis users, and additional work is needed for individuals with other levels of limb loss. Also, quantifying steps may not be as informative as other metrics that relate to mobility and health of prosthetic users. Objectively quantifying the loads applied to the prosthetic and contralateral limb during ambulation may provide a more direct link between

prosthetic component performance, individual functional performance and limb loss comorbidities such as osteoarthritis, obesity, diabetes, cardiovascular disease, and stroke. Systems that remotely monitor forces and loads during ambulation in the community may provide early intervention opportunities to halt medical problems before they progress to the point that only expensive interventions are effective. Work in this area quantifying the moment impulse during the gait of prosthetic users appears to hold some promise for understanding limb and joint loading in these individuals.³⁹ By quantifying the loading dose perhaps more effective interventions could be developed and monitored for lower limb prosthetic users.

Although this study was conducted in North America and the K levels were created by the United States CMS, K levels have become the de-facto functional level in several international locations, including the Netherlands,^{6,40,41} Canada,⁴² and Germany.⁴³ There seems to be a general consensus that expensive, higher performance prosthetic components should be provided to those who will utilize the added performance of these more expensive components.

Conclusion

This study sought to relate clinic-based assessments of K level with a calculated functional level estimate based on ambulation in real world settings for transtibial amputees. There was good agreement between the two methods of determining K level with $R^2=0.775$ ($p < 0.001$). Determining functional level based on real world ambulatory activity may supplement clinic-based tests of functional capacity and increase objectiveness in K level assessment.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: MO, TK, and DB work or worked for Orthocare Innovations, the manufacturers of the sensor worn by the participants in this study, and the developers of the algorithm used to determine K level from community activity data.

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