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Determining K-levels Following Transtibial Amputation

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Abstract

Objectives: This is a prospective feasibility study of nine subjects recruited 1-3 days following transtibial amputation, from October 2013 to October 2014. The investigators assessed the accuracy of the K-level provided by an experienced clinician 6 weeks following amputation, by comparing it to an Amputee Mobility Predictor (AMP) determined K-level at 6 weeks following amputation and the subjects' actual K-level 6 months post-operatively.

Methods: This study obtained an AMPnoPRO and Short Form-36 (SF-36) prior to prosthetic fitting on a series of consecutive patients who underwent transtibial level amputation. The main outcome measures were clinician-predicted K-levels, AMPnoPRO scores, SF-36 results 6 weeks post-amputation, and actual K-level function at 6 months post-amputation.

Results: In 7 of 9 cases, the physician predicted K level was accurate as compared to the subjects' K-level at their 6-month follow-up, whereas the AMP predicted K-level was accurate in 4 of 9 cases. Data from the SF-36 revealed marked variance in our subjects from the societal norm for physical functioning, emotional health, and social functioning.

Conclusions: The AMPnoPRO is an established, objective tool used for predicting K-levels. In comparison, predictions made by an experienced clinician were very accurate. This is the first prospective study to assess the determination of K-levels in people with lower extremity amputation before receiving their initial prosthesis.

Keywords: Amputees; Amputation; Outcome assessment (health care); Recovery of function; Rehabilitation

Introduction

A prosthesis can enhance mobility, independence, safety, and quality of life in people with lower limb amputation [1,2]. Coupling the correct prosthetic components for the appropriate level of function is one of the primary goals of the rehabilitation team [3]. Currently in the United States, Medicare and managed care providers use the Durable Medical Equipment Regional Carrier (DMERC) K-levels or Medicare's Functional Classification Level (MCFL) index to assign a level of function which determines the level of prosthetic components and consequently, the financial reimbursement a prosthetist receives for the prosthesis provided [3]. The MCFL is defined by the patient's ability to perform transfers, negotiate low-level environmental barriers such as curbs and stairs, and to vary their cadence [4]. The definitions of the MCFL classifications are outlined in Table 1 [4].

K0 - Lower extremity prosthesis functional level 0 - does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
K1 - Lower extremity prosthesis functional level 1 - 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 - Lower extremity prosthesis functional level 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.
K3 - Lower extremity prosthesis functional level 3 - has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4 - Lower extremity prosthesis functional level 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.

Table 1: Medicare Functional Classification Level (MFCL) Definitions [14].

The MCFL or "K-level" can be determined objectively using the Amputee Mobility Predictor (AMP) Assessment Tool, abbreviated AMPPRO or AMPnoPRO, reflecting whether or not the patient already has prosthesis. The AMP questionnaire was developed in 2002 to provide physicians, prosthetists and physical therapists a clinically feasible tool to objectively measure patients' functional capabilities without a prosthesis and predict their ability to ambulate with a prosthesis (Tables 2 and 3) [4].

The questionnaire uses demographic information and standardized physical tests to calculate an AMP score. The AMP consists of 21 items that evaluate ability in transfers, sitting and standing balance, and gait skills [4]. The AMP was designed to assess the specific tasks identified in the MCFL scale to objectively assign an MCFL for prosthetic prescriptions of Medicare-eligible patients.4 The AMP score is then used in conjunction with the clinician's judgement to develop an accurate Medicare Functional Classification Level (MFCL) index [5]. The AMP is used to determine functional mobility of people with all levels of unilateral lower limb amputation. A study looking at the AMP for 12 patients with bilateral transtibial amputation (AMP-B) showed significant differences existed between the AMP-B scores p<0.001 and AMP scores [6] however no modifications in scoring of the AMP are necessary for people with bilateral transtibial level amputation [6].

Alternatively, a K-level can be determined subjectively by a trained clinician. In this case, the patient's past medical history (including their previous function), their current state of health (including the state of their residual limb), their comorbidities, and their desire to ambulate are each considered to determine the anticipated K-level.

Although determining a K-level may be subjective, the 5-Level index does adequately discriminate between levels of function [3]. The AMP is the only functional assessment instrument that has demonstrated the ability to determine a K-level for people with lower limb amputation [4,7,8]. The use of outcome measures to predict K-levels is complicated by a number of factors including ease of administration and lack of scientific evidence to guide selection and interpretation [9]. A recent study reported that prosthetists do not regularly use standardized outcome measures and have limited confidence in administering them [10].

This study assessed the accuracy of K-levels determined by an experienced clinician at 6 weeks following amputation, by comparing it to an AMPnoPRO-determined K-level at 6 weeks following amputation and the subjects' actual K-level 6 months post-operatively. The Short Form–36 (SF-36), a short questionnaire surveying physical and mental health was used to determine the subjects' self-reported physical and mental function 6 weeks after amputation [11]. At our institution, patients are followed by their surgeons until their incision heals. The first visit following amputation in the amputee rehabilitation clinic occurs at 6 weeks. After completing prosthetic rehabilitation, patients typically require a second prosthesis (due to an interval volume loss) at 6 months. A second K-level (the "actual" K-level) was obtained at this time and compared to the initial K-level determined at 6 weeks following amputation.

This study aims to prospectively assess the determination of K-levels after transtibial amputation prior to prosthetic fitting using objective data, clinical assessment, and patient reported outcomes. We hypothesized that the K-levels obtained by an experienced rehabilitation physician at 6 weeks following amputation would accurately predict the subjects' "actual" K-level at 6 months, after maximal medical improvement had been achieved.

Methods

The research protocol was approved by the Institutional Review Board. Nine consecutive subjects who required transtibial level amputation and met inclusion criteria were prospectively enrolled in the study. These subjects were recruited from a tertiary care, multidisciplinary practice 1-3 days after transtibial amputation (all performed by the same surgeon) and enrolled in the study from October 2013 to October 2014. Written informed consent was obtained for all patients included in the study. The subjective, clinician-determined K-level, as well as the K-level determined by the AMPnoPRO was both recorded at 6 week following amputation at an appointment with the Physical Medicine and Rehabilitation amputee service. The "actual" K-levels were recorded at 6 months. Additional data collected included SF-36 questionnaires which were completed at the 6 week follow-up appointment.

Demographics

Initial inclusion criteria included age 18-70 years, transtibial amputation for any reason, and willingness to participate in the study. Twelve subjects met these criteria. Additional criteria required in order to remain in the study included completion of the AMP, SF-36 questionnaire and scheduled follow-up appointments. Three subjects were lost to follow up. Of the 9 subjects ultimately included in the study, there were 8 males and 1 female. Mean (range) age of the subjects was 58.6 (24-71). Reasons for amputation included infected non-healing diabetic ulcers (8 subjects) and critical limb ischemia (1 subject). Other demographic features included hypertension (8), diabetes (6), previous transmetatarsal amputation on the same limb (3) and nicotine dependence (1).

Quality of life questionnaire

General health status was assessed using the Medical Outcome Study (MOS) SF-36 (version 1). The SF-36 is a validated outcome measure to assess the burden of disease on the patient's physical as well as mental health [12,13]. Patients' scores were calculated using the RAND Scoring System as described by Hays et al. [11]. Patient data was compared to normative societal data collected in the 1992 MOS study. The MOS study collected data on 2,471 patients that were determined to be a representative selection of the population at large [12].

Amputee mobility predictor (AMP)

The AMP was developed in 2002 with the goal of providing physicians, prosthetists and physical therapists a clinically feasible tool to more objectively predict the ambulatory potential of persons with lower limb amputation [4]. The AMP uses demographic information and standardized physical tests to calculate an overall score from 0-42 for those with prosthesis (AMPPRO), or 0-38 for those who do not have prosthesis (AMPnoPRO). The AMP has been shown to have high inter- and intra-observer reliability [4]. The AMP was obtained by our senior amputee subspecialty therapist. On average it took 30 minutes to perform the AMP.

Physician predicted K-Levels

K-levels were predicted by one clinician (M.D.) with over 25 years of amputee subspecialty experience. The clinician was blinded to the results of the AMPnoPRO.

Data Analysis

Scores were compared between methods within subject by Wilcoxon signed-rank tests. Paired differences in the accuracy proportions were compared using exact binomial sign tests. The agreement of AMP-predicted and physician-predicted scores with actual K-level at 6 months was estimated with the intraclass correlation coefficient (ICC) and reported with 95% bootstrap confidence intervals. The mean SF-36 scores observed in this sample were compared to population means by one-sample t-tests. P-values <0.05 were considered statistically significant. Analysis was performed using JMP (Version 10) and R (Version 3.0.2).

Results

Participant	AMPnoPro predicted K-level at 6 weeks	Physician predicted K-level at 6 weeks	Functioning K-level at 6 months
1	1	2	1
2	1	2	3
3	1	1	1
4	2	3	3
5	1	2	2
6	3	3	3
7	1	2	2
8	2	3	3
9	2	2	2

Table 2: This table compares both AMPnoPro predicted K-levels at 6 weeks and physician predicted K-levels at 6 weeks, to actual attained K-levels as determined by the participants' functional level at their 6 month follow up appointments.

AMPnoPRO scores predicted that 5 of our subjects would function at a K1 level, 3 at a K2 level, and 1 at a K3 level. Of the 9 subjects, 3 had their actual functioning 6-month follow up K-levels accurately predicted by both their AMP score and our skilled clinician (subjects 3, 6 and 9). One of 9 had their AMP-predicted K-level and 6-month functioning K-level coincide, while their physician-predicted K-level at six weeks differed by one (subjects 1). This subject had an out-of-hospital cardiac arrest after the 6 week visit which likely skewed their functional outcome. In this case, the physician overestimated the K-level. The remaining 4 of 9 subjects had their physician-predicted K-levels at 6 weeks coincide with their actual functioning K-levels at 6 months, while their AMP-predicted K-levels differed (by one). In all 4 of these cases, the AMP test underestimated the K-level. Overall, in 7 of 9 (78%) cases, the physician predicted K-level was accurate when compared to the actual functioning K-level at 6-month follow-up, whereas the AMP predicted score was accurate in 4 of 9 (44%) cases, (p=0.38). The AMP predicted scores showed a median of 1 versus a median of 2 for the actual K-levels at 6 months (p=0.06); whereas, both the physician predicted and actual K-level showed a median score of 2 (p=1.0). The AMP predicted score showed only moderate agreement with ICC 0.45 (95% CI: 0.06-0.83) compared to the actual K-level at 6 months, while the physician predicted score showed good agreement with the actual 6 month K-level at ICC 0.80 (95% CI: 0.33-1.0).

SF36 SCORES	Participant									Average score
	1	2	3	4	5	6	7	8	9	
Physical functioning	30	15	5	20	-	85	0	90	30	34.4
Role limitations due to physical health	100	100	100	50	100	0	100	100	100	83.3
Role limitations due to emotional problems	0	0	100	0	0	0	100	100	0	33.3
Vitality	65	65	45	45	70	77.5	30	40	80	57.5
Emotional wellbeing	76	80	64	92	86	86	56	92	88	80
Social functioning	22.5	42.5	87.5	67.5	65	100	67.5	10	87.5	61.1
Pain	77.5	80	77.5	77.5	90	90	55	42.5	90	75.5
General health perceptions	29	71	32	44	-	76	15	51	34	44

Table 3: The SF-36 scores of different categories were tabulated and compared to societal counterparts with "serious medical issues.

Data from the SF-36 revealed marked variance in our subject population from the societal norm in terms of physical functioning, emotional health, and social functioning in several areas. In each of these categories, subjects fell greater than 1 standard deviation below the mean. Mean physical function score in the subject population was 34.4 compared to a societal mean of 57.35 (higher values indicate better function), p=0.07. The mean score for role limitations secondary to emotional health in our population was 33.3, compared to the societal norm of 76.16 (p=0.02). The mean score for our subject population for social functioning was 61.1 as compared to 80.3 (p=0.06). The subjects in our study scored significantly higher as compared to their seriously ill societal counterparts with respect to their perceived role limitations secondary to physical functioning (83.3 vs. 43.92, p=0.005). Although not significantly different, subject scores

were less as compared to the societal norm scores in the category of general health (44.0 *vs.* 49.13, p=0.46) and slightly higher in the categories of vitality (57.5 *vs.* 47.79, p=0.10), emotional wellbeing (80.0 *vs.* 77.59, p=0.54), and pain (75.5 *vs.* 65.1, p=0.06) [11].

Discussion

Our data indicates that the ability of a skilled clinician to predict a patient's functioning K-level is quite accurate. In fact, our sample showed that it was more frequently accurate than the AMPnoPRO to predict the subjects' actual functioning K-levels at their 6-month follow-up.

We used the same physician to make the K-level predictions to avoid variability between different providers in this initial study. The clinician, in our study, has over 25 years of amputee subspecialty experience, which likely helped contribute to the favorable results.

There were a few notable relationships observed between the subjects' functioning K-levels at 6 months and their SF-36 scores. Among those relationships were lower physical function and general health perception scores among the two K1 subjects, and higher perceptions of emotional wellbeing among the K3 subjects. These trends seem intuitive. For example, people functioning at a K1 level are more likely to have more medical comorbidities, which is reflective of poorer general health. Additionally, by definition, K1 amputees have more impaired physical function as compared to their K2 and K3 counterparts, which can be related back to their expression of poorer physical function in the SF-36 scores. Perhaps the elevated emotional wellbeing of the K3 subjects reflects their ability to function higher on a physical level, in turn offering them more personal satisfaction and improved mood.

The strengths of this study include the prospective nature of the study and the fact that this is the first prospective study to assess the determination of K-levels in people with lower extremity amputation before receiving their initial prosthesis. This study had several limitations. We had a fairly small cohort of subjects, all from the same institution and thus may have been underpowered to demonstrate significant associations. In addition, as noted above, our clinician making the K-level predictions had over 25 years of amputee subspecialty experience, so their ability to accurately predict functioning K-levels even better than the AMPnoPRO may not be extrapolated to the general prosthetic provider.

Conclusion

The use and determination of MFCL's or "K-levels" was largely subjective and not standardized prior to the implementation of the AMP scoring system. With increasing documentation requirements for insurance approval of prescribed prosthetic components, the data obtained from an AMPnoPRO score is meant to provide objective medical justification for optimal initial prosthetic components and better guide patients' expectations through the process. Although tThe AMPnoPRO has previously been shown to be an accurate tool to assess

K-levels for participants who are medically stable with a properly fitting prosthesis. This is the first prospective study to assess the determination of K-levels for individuals receiving their initial prosthesis. Although the AMPnoPro may be of benefit for clinicians who require/prefer its use, our study demonstrates that an initial K-level determined by an experienced clinician can accurately predict prosthetic function. A study with a larger sample size N and multiple physician raters is needed to confirm our preliminary findings.

Acknowledgements

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