FUNCTIONAL LEVEL ASSESSMENT USING WEARABLE SENSOR DATA: EXPERIENCED GAIT EXPERTS VERSUS A CALCULATED ESTIMATE

Michael S. Orendurff, Teri Rosenbaum-Chou, Toshiki Kobayashi and David Boone
Orthocare Innovations, Mountlake Terrace, WA, USA
morendurff@orthocareinnovations.com

INTRODUCTION

Establishing functional levels for individuals with limb loss is necessary for selecting appropriate prosthetic components, for evaluating the effect of interventions, and for rationalizing reimbursement from payers. Currently, the Medicare Functional Classification System (MFCL) “K level” is the dominant system in use, and certain prosthetic components are only reimbursed for K3 level ambulators or above. There has been some debate as to the repeatability and accuracy of the K level method, primarily due to the short time period the individual’s gait level is assessed, and the subjective recall of daily activity level by prosthetic users[1].

CLINICAL SIGNIFICANCE

Creating a valid and repeatable method of determining the functional level of individuals with limb loss would be valuable for improving selection of appropriate prosthetic components and for rationalizing payer reimbursement.

METHODS

Seven individuals with expertise in observational and computerized gait analysis rated the functional level of 65 anonymous transtibial amputees using a 4 level ordinal scale. Based solely on a strides-per-minute graphical display across 24 hours for 5-7 days, the seven gait experts rated each amputee’s functional as K1, K2, K3, K4; these seven experts never saw the individuals walk. The strides-per-minute data were recorded using a StepWatch Activity Monitor (Orthocare Innovations, Mountlake Terrace, WA). These seven experts’ ratings were averaged, and taken as the gold standard of functional level. The strides-per-minute data of each amputee were also used in an algorithm designed to objectively apply the written requirements of the MFCS K levels with calculations to estimate potential to ambulate (highest step rate achieved in one minute), ambulatory requirement (energy expenditure based on total daily steps[2]) and cadence variability (low : med : high step rate ratio [low <15 vs. med 16-40 vs. high >40 steps/min ]). Using these criteria, each amputee’s functional level was rated on a 0 to 4 interval scale. These two measures, the expert’s rating of K level and the calculated functional level were compared using simple linear regression.

RESULTS

The simple linear regression comparing the calculation of functional level to the experts rating of K level resulted in a significant relationship ($p < 0.001$) with a $R^2$ of 0.799 (see figure 1.). The slope was slightly less steep than perfect agreement ($y = x$). The linear
equation was \( y = 0.8322x + 0.2588 \). This formula produced excellent agreement in the middle of the functional range, but high-level ambulators were slightly under-rated, and low-level ambulators were slightly over-rated. From this small sample it appeared that the rating of K2 had the greatest variance both across expert raters and across calculated values.

**DISCUSSION**

There was good overall agreement between expert rating of K level and the calculated functional level, with the resulting regression equation accounting for nearly 80% of the variance. Although an effort was made to select individuals with a full range of functional levels, K1 level ambulators appear under-represented in this sample. This calls into question the validity of the equation at very low functional levels. Examining individual data revealed that prosthetic users achieved higher functional levels through several different means: some were moderately active all day long whereas others engaged in 30-40 minute periods of high activity (exercise), but had very low activity for the remainder of the day. Some individuals had very high potential to ambulate, and adequate cadence variability but did not ever demonstrate sustained ambulation (3+ min), suggesting that perhaps their prosthetic componetry were limiting their ability to ambulate. This objective method might be used to convince a payer to provide a more advanced component if a functional level improvement could be demonstrated in community ambulation patterns after fitting. Kahle, et al have shown that some K2 ambulators became K3 ambulators when fit with a C-Leg[3].

These data suggest that 5-7 days observing ambulatory activities in the community for objective signs of functional performance might be a more accurate system of rating individuals with limb loss than observing them for short time in a clinic setting.

**REFERENCES**


**DISCLOSURE STATEMENT**

Michael Orendurff, Teri Rosenbaum-Chou, Toshiki Kobayashi, and David Boone are employees of Orthocare Innovations, makers of the StepWatch Activity Monitor, the Galileo Clinical Outcomes Assessment System and the Galileo Functional Level Assessment System.