INTRODUCTION: The Medicare Functional Classification Level (MFCL) is the classification system utilized by clinicians to describe the functional level of amputees. The MFCL “K-Level” is commonly determined by the clinician’s clinical judgment, patient self-report of activity, physical examination, and observation of gait. However, no standardized method exists for interpreting MFCL and patient self-report of activity may be inaccurate. The American Academy of Orthotists and Prosthetists (AAOP) stated the need to move from “subjective method of prosthetic prescription towards an objective evidence-based foundation for prosthetic practice.”

The objective of this study was to determine the most valid functional test in determining K-levels in transtibial amputees. This study evaluated the Modus CMS Functional Level Score (Modus Score), daily steps, peak cadence, six-minute walk test (6MWT), and Amputee Mobility Predictor with Prosthesis (AMPPRO).

METHOD: Following, IRB approval, subjects were recruited from the George E. Wahlen Department of Veterans Affairs Amputee Clinic. The inclusion criteria was transtibial amputation, able to walk >3 steps with prosthesis, ≥ 21 years old, ≥ 1 year post amputation, and a well-fitting functional prosthesis. Visit 1 involved obtaining consent, performing the 6MWT, performing AMPPRO, and applying the StepWatch and GPS to the prosthesis (Figure 1). The subjects wore the devices for two weeks. Absolute differences between week 1 and week 2 were used for determining repeat reliability of the real world metrics.

The Modified Clinical K-level was the functional level the VA physicians’ thought was most correct for the patient, and therefore, was the reference by which the other measures were compared. VA physicians, Bradeigh Godfrey, DO and Jeff Berdan, DO, used the number of steps in community (StepWatch and GPS), steps/day (StepWatch), peak cadence (StepWatch), and environmental barriers traversed (GPS and StepWatch) for the research subjects’ first 6-10 days, as well as their clinical expertise, to determine the Modified Clinical K-level of the subject. Drs. Godfrey and Berdan were blinded to the subject’s Modus Score, 6MWT, and AMPPRO results.

RESULTS: Data was collected on 27 subjects. Using Canonical Linear Discriminant Analysis, the Modus Score had the highest correlation to the Modified Clinical K-level, r=0.96, p<0.001 (Figure 2). The others also significantly correlated but to a lesser degree: AMPPRO (r=0.93), 6MWT (r=0.89), peak cadence (r=0.89), and daily steps (r=0.76).

Only Modus Score had no overlap in scores between K2 and K3 (Figure 1). When using basic rounding of decimal values, the Modus Score was 100% accurate in differentiating patients as K2 or lower and K3 or higher. Its overall accuracy / sensitivity was 85%. There are no standard methods of converting the other metrics to K-levels.

DISCUSSION: The Modus Score correlated the most strongly with the Modified Clinical K-level. In addition, the Modus Score had greater repeat reliability than daily steps and peak cadence indicating it has greater potential to capture clinically relevant change. The other metrics also significantly correlated with K-level but had more overlap in scores between each K-level.

CONCLUSION / CLINICAL APPLICATIONS: The Modus Score appears to be a clinically feasible tool for aiding clinicians in their functional evaluations of their patients.

REFERENCES
Geil MD et al. AAOP SSC OLC; 2010