

# SELECTION AND ASSESSMENT OF A SET OF OUTCOME MEASURES FOR ELECTRONICALLY CONTROLLED KNEE USERS

Andrea G. Cutti<sup>1</sup>, Caterina Guida<sup>1</sup>, Stefano Bandoli<sup>1</sup>, Claudia Marchese<sup>1</sup>, Michele Ferraro<sup>1</sup>, Arianna Di Bernardo<sup>1</sup>, Periche Randi<sup>1</sup>, Mirco Branchini<sup>2</sup>, Rosario Vallone<sup>1</sup>, Amedeo Amoresano<sup>1</sup>, Gennaro Verni<sup>1</sup>

<sup>1</sup> Centro Protesi INAIL, Italy

<sup>2</sup> Policlinico Sant'Orsola Malpighi, Italy

E-mail: ag.cutti@inail.it;

## INTRODUCTION

Electronically controlled knees have the potential to improve the mobility and quality of life of transfemoral amputees if patients are involved in a tailored rehabilitation program [1]. To understand if the personalized care has been successful, it is essential to evaluate its outcome, both with functional tests and clinical questionnaires. Instruments for K3-K4 users should:

- 1) not suffer from ceiling effect;
- 2) have a smallest detectable change (SDD) between raters as low as possible;
- 3) be little or non-correlated, to ensure they are capturing different constructs;
- 4) be able to correctly classify subjects with different characteristics.

The aim of this work was to start answering these questions, considering a set of outcome measures, that were selected by 5 physical therapists during a 1-year internal course on evidence-based physical therapy: PLUS-M [2], AMP [3], L-TEST, 6 Minutes walking test (6MWT) [4], and 4-SQUARE [5].

## METHODS

Since PLUS-M (12 questions) and AMP were developed in English, a back-translation approach was followed to produce an Italian version. Before study begun, both instruments were tested on a group of 5 pilot subjects and 5 physical therapists. Then 11 male unilateral transfemoral amputees were recruited (mean age 45±7, weight 76±9, 6 smokers), after signing an informed consent: 4 after completing the transition from a mechanical to an electronic knee (group 1, G1), and 7 experienced electronic knee users (group 2, G2). All subjects completed all outcome measures once. Ten completed the functional tests twice within the next working day to minimize the within-patient variability. Repeated tests were administered by two different PTs.

PLUS-M and AMP scores were checked for ceiling effects. SDD (90%) was computed for all functional tests. Cross-correlation among instruments was calculated. Since the experience of subjects in G1 and G2 was known to be different, scores of G1 and G2 were statistically compared within each instrument to understand which outcome measure was able to highlight the dissimilarity.

## RESULTS

The mean values was 50.7±5.7 for PLUS-M (ceiling: 71.4), and 43.7±1.2 for AMP (ceiling: 47). The SDD (including bias) was 0.6 pts, 2.9 seconds, 1.3 seconds and 62.0 meters for AMP, L-TEST, 4-SQUARE and 6MWT, respectively.

Table 1 reports the correlation matrix among outcomes.

The rank-sum test was close to statistical significance only for PLUS-M (p=0.07), while the p-values for AMP, L-TEST, 4-SQUARE and 6MWT were 0.98, 0.32, 0.79 and 1, respectively.

	PLUS-M	AMP	L-TEST	4_SQUARE	6MWT
PLUS-M	1,00				
AMP	0,03	1,00			
L-TEST	-0,38	-0,42	1,00		
4_SQUARE	-0,24	-0,34	0,53	1,00	
6MWT	0,29	0,04	-0,60	-0,75	1,00

Figure 1 – Correlation matrix among outcome scores.

## CONCLUSION

PLUS-M and AMP did not show any ceiling effect, but for AMP all subjects scored between 42 and 45. The AMP had an almost null SDD, smaller than what reported in [6]. L-test SDD was also smaller than the value reported in [7], while 6MWT SDD was higher [6]. No SDD reference values was found for 4-SQUARE. The analysis of correlation suggests that PLUS-M and AMP address different constructs: both outcomes should be administered. The correlation between 6MWT and AMP could not be confirmed. 6MWT, L-TEST and 4-SQUARE were most correlated. PLUS-M results for G1 and G2 were close to statistical significance.

## SIGNIFICANCE

Results suggest that PLUS-M and AMP do not suffer from ceiling effects, AMP is reliable between rater, and the two instruments measure different constructs. 6MWT seems a good addition too, based on the low correlation with AMP; however, this conclusion is different from the literature. All results will need confirmations on a wider group of patients.

## REFERENCES

1. Cutti et al, Prosthet Orthot Int, 2016
2. Hafner et al, Arch Phys Med Rehab, 2017
3. Gailey et al, Arch Phys Med Rehab, 2002
4. BACPAR toolkit
5. Whitney et al, Arch Phys Med Rehab, 2007
6. Resnik et al, Physical Therapy, 2011
7. Deathe et al, Physical Therapy, 2005

## DISCLOURE

None.