Reference

Jayaraman C [1,2†], Mummidisetty CK [1†], Albert MV [2,3,4], Lipschutz R [1], Hoppe-Ludwig S [1], Mathur G [1], Jayaraman A [1,2*]

1 Max Näder Lab for Rehabilitation Technologies and Outcomes Research, Shirley Ryan AbilityLab, Chicago, USA. 2 Department of Physical Medicine and Rehabilitation, Northwestern University Feinberg School of Medicine, Chicago, USA. 3 Department of Computer Science and Engineering, University of North Texas, Denton, USA. 4 Department of Biomedical Engineering, Univer-sity of North Texas, Denton, USA.

Using a microprocessor knee (C-Leg) with appropriate foot transitioned individuals with dysvascular transfemoral amputations to higher performance levels: a longitudinal randomized clinical trial

Journal of NeuroEngineering and Rehabilitation *(2021) 18:88*

https//doi.org/10.1186/s12984-021-00879-3

Products

C-Leg vs NMPK

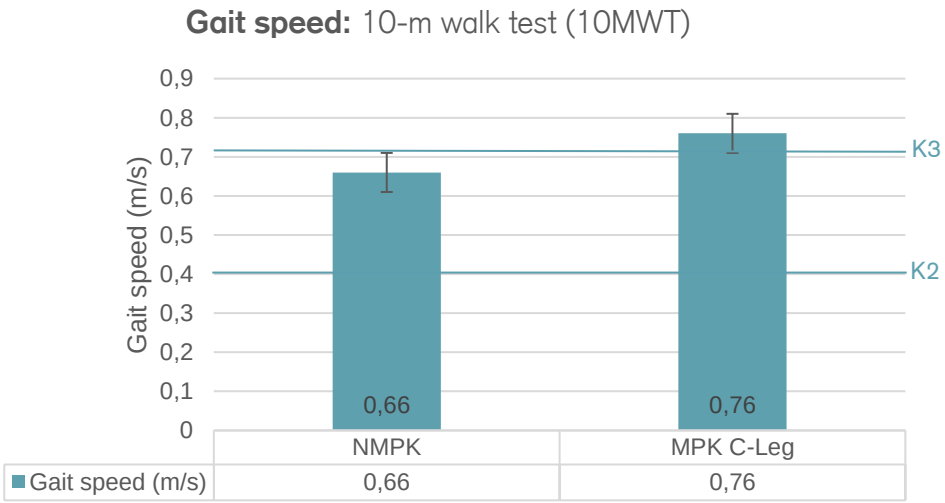
Major Findings

C-Leg compared to NMPK:

→ **50% of amputees improve gait speed related classification of Mobility Grade from K2 to K3 when using C-Leg** (p=0.008)

→ **Self-selected Gait speed increased by 0.1m/s**

Gait speed shows



→ **Participants using the MPK + 1M10 achieved higher clinical scores in balance, self-reported mobility, and fall safety**

→ **Participants using the NMPK + 1M10 showed no statistically significant improvement** (p´s>0.05)

Population

Subjects:	10 (4 males) unilateral transfemoral amputees
Previous prothesis:	currently using an NMPK
Amputation causes:	Dysvascular or diabetic unilateral transfemoral amputation
Mean age:	63.0 +/-9 years
Mean time since amputation:	5.8±8.1 years; at least 6 months or more post-prosthetic fitting
MFCL:	K2

Study Design

Prospective longitudinal crossover Randomized Controlled Trial

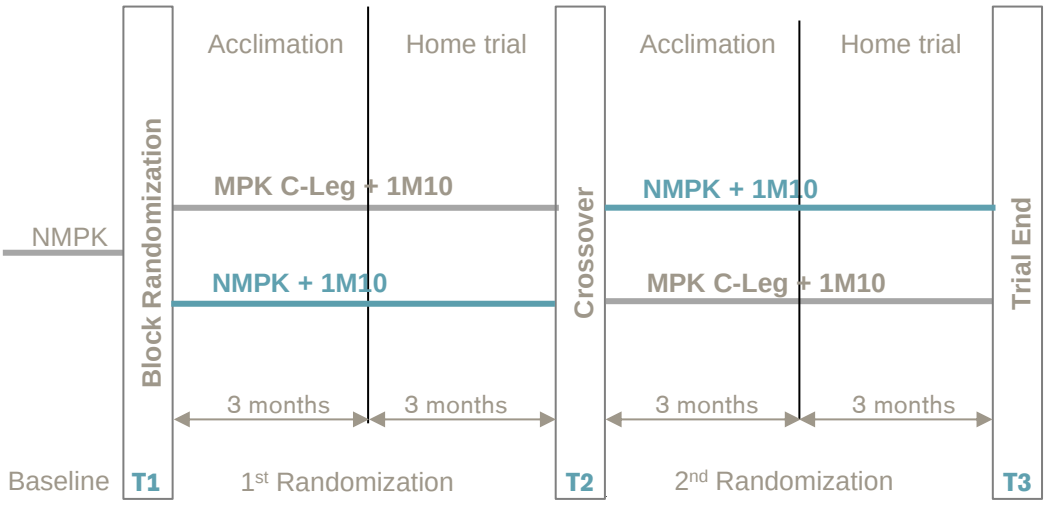


Figure: Clinical trial design schematic and outcome assessment time points (T1, T2, and T3). Randomization to NMPK + 1M10 acclimation and trial period followed by a crossover to MPK + 1M10 acclimation and trial period (or vice versa).

Results

Functions and Activities						Participation			Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Metabolic Energy Consumption	Safety	Activity, Mobility, ADLs	Preference, Satisfaction, QoL	Health Economics

Category	Outcomes	Results for C-Leg	Sig.*
Level Walking	Gait speed (10-m walk test)	0.1 m/s (p=0.009) improvement in MPK group, 66% transition above K3 level (K3=0.88±0.39 m/s) [10MWT: MPK = 0.76 (0.28) m/s, NMPK = 0.66 (0.29) m/s]	++
	Walking Distance (6-minute walk test)	[6MWT group averages in meters: MPK = 145.2 (110.3), NMPK = 147.5 (112.0)] (p>0.05)	0
Safety	Balance (Berg Balance Scale)	Participant balance scores improved (BBS 44(13)) to values within range of scores achieved by individuals with K3 functional level (BBS ≥50.5/56) (p>0.05). [BERG: MPK = 44 (13), NMPK = 39 (15)]	+
	Balance (Timed Up and Go)	TUG (p>0.05) [TUG in seconds: MPK = 25.3 (14.1), NMPK = 29.0 (16.3)]	0
	Fear of falling (modified Falls Efficiency Scale)	Significantly improved mFES scores (self-reported falls efficacy) when using the mEPK C-Leg (p=0.03). [mFES: MPK = 9.33 (0.69), NMPK = 8.51 (1.03)]	++
Activity, Mobility, ADLs	Activity (Prothesis Evaluation Questionnaire)	78% of participants reported higher PEQ scores while using MPK (ability walk on different terrain and surfaces). These improved scores matched K3 MFCL performance level when using MPK C-Leg (p=0.008). [PEQ-A: MPK = 81.92 (18.74)]	++
	Activity (Four Square Step Test)	[FSST: MPK = 16.8 (11.2), NMPK = 19.6 (12.4)], (p>0.05).	0

Category	Outcomes	Results for C-Leg	Sig.*
	Mobility (Amputee Mobility Predictor)	For both interventions clinically meaningful improvement was observed in group mean AmpPro scores. However, not high enough to match K3 level (p=0.008). [AMPPro: MPK = 36 (5), NMPK = 35(6)]	++

Author's Conclusion

"This longitudinal clinical trial investigated the beneft of providing an MPK C-Leg+appropriate foot in individuals with transfemoral amputation from dysvascular or diabetic conditions at MFCL K2 level who are currently using a predicate NMPK+foot combination. Statistically signifcant and clinically meaningful improvements were observed in gait performance, safety, and self-reported measures (PEQ-A) when using the MPK C-Leg+1M10 foot combination in comparison to their baseline condition (i.e. predicate NMPK+foot)." (Jayaraman et al, 2021)