Reference	Javaraman C ^{1,2†} . Mur	nmidisetty CK ^{1†} . Albert M	AV ^{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, Chi- cago, 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, University of North Texas, Denton,						
	Using a microp	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 NeuroEngineeri https//doi.org/10.1186/s12984-0
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						
	Gait	speed: 10-m walk test ((10MWT)				
	0,9 —						
	0,8		T				
	<u>ر</u> ه 0,7		K3				
			K0				
	<u> </u>						
	0,1	0.00	0.70				
	0						
	Gait speed (m/s)	0.66	0.76				
		0,00	0,70				
	→ Participants using the MPK + 1M10 achieved higher clinical scores in bal- ance, self-reported mobility, and fall safety						
	ightarrow Participants using the NMPK + 1M10 showed no statistically significant						
	improvement (p´s>0.0	5)					
Population	Subjects:	10 (4 males) unilateral tr	ransfemoral amputees				
	Previous prothesis:	currently using an NMPK					
	Amputation causes:	Dysvascular or diabetic	unilateral transfemoral ampu-				

	tation
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 a	nd Activities					Participation			Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Metabolic Energy Consump- tion	Safety	Activity, Mobility, ADLs	Preference, Satisfac- tion, QoL	Health Eco- nomics
Category		Outcome	es	Results fo	or C-Leg				Sig.*
Level Walking		Gait spee walk test)	ed (10-m)	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 I (6-minute	Distance walk test)	[6MWT group averages in meters: MPK = 145.2 (110.3), 0 NMPK = 147.5 (112.0)] (p>0.05)			0		
Safety		Balance (Berg Ba Scale)	lance	Participant balance scores improved (BBS 44(13)) to val- ues 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)]			- + (3		
		Balance (Timed U	p and Go)	TUG (p>0.05) [TUG in seconds: MPK = 25.3 (14.1), NMPK = 29.0 (16.3)]			0		
	Fear of fa (modified ciency So	alling I Falls Effi- cale)	Significantly improved mFES scores (self-reported falls ef- ficacy) when using the mEPK C-Leg (p=0.03). [mFES: MPK = 9.33 (0.69), NMPK = 8.51 (1.03)]			!f- ++			
Activity, Mobility, ADLs		Activity (Prothesi tion Ques	s Evalua- stionnaire)	78% of participants reported higher PEQ scores while us- ing 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)]			S- ++		
		Activity (Four Sq Test)	uare Step	[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 longitudii Leg+appropria or diabetic con NMPK+foot co ments were ob (PEQ-A) when baseline condi	nal clinical trial investigated the beneft of providing an MPK C te foot in individuals with transfemoral amputation from dysva ditions at MFCL K2 level who are currently using a predicate mbination. Statistically signifcant and clinically meaningful im served in gait performance, safety, and self-reported measure using the MPK C-Leg+1M10 foot combination in comparison tion (i.e. predicate NMPK+foot)." (Jayaraman et al, 2021)	scular prove- es to their		

© 2021, Otto Bock HealthCare Products GmbH ("Otto Bock"), All Rights Reserved. This article contains copyrighted material. Wherever possible we give full recognition to the authors. We believe this constitutes a 'fair use' of any such copyrighted material according to Title 17 U.S.C. Section 107 of US Copyright Law. If you wish to use copyrighted material from this site for purposes of your own that go beyond 'fair use', you must obtain permission from the copyright owner. All trademarks, copyrights, or other intellectual property used or referenced herein are the property of their respective owners. The information presented here is in summary form only and intended to provide broad knowledge of products offered. You should consult your physician before purchasing any product(s). Otto Bock disclaims any liability related from medical decisions made based on this article summary.