

Reference

Sara J. Morgan PhD ^{1,2}; Janna L. Friedly ¹; Ian K. Nelson¹; Rachael E. Rosen¹; Andrew T. Humbert¹; Brian J. Hafner PhD¹

The effects of microprocessor prosthetic knee use in early rehabilitation: A pilot randomized controlled trial

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Products

MPK: C-Leg, Kenevo vs. NMPK: 3R60, Pheon

Major Findings

In new amputees, with MPK (C-Leg, Kenevo) compared to NMPK (3R60, Pheon) after 3 months of rehabilitation:

→ Higher mobility and functionality in MPK

- Participants with an MPK had significantly higher values in Prosthetic Limb Users Survey of Mobility (PLUS-M $p = 0.01$)

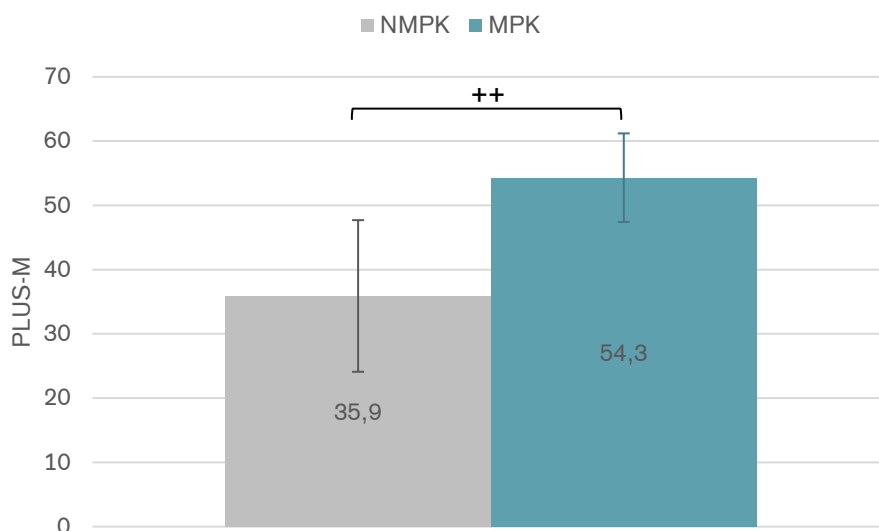


Figure 1: PLUS-M Score for NMPK and MPK users. ++ $p < 0.01$

→ Higher confidence performing activities without becoming unstable with MPK than with NMPK

- Participants with an MPK had significantly higher values in Activity-specific Balance Confidence (ABC $p = 0.01$)

→ Improved physical, social, and psychologic implications with MPK than with NMPK

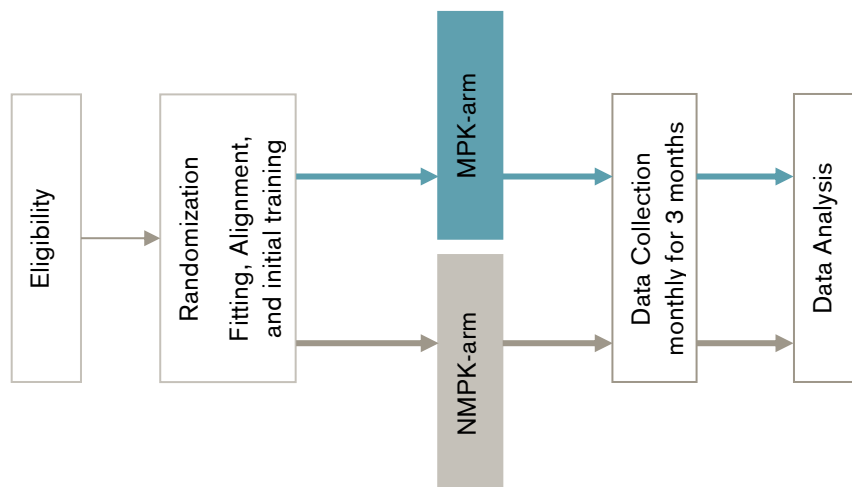
- Participants with an MPK had significantly higher values in Reintegration to Normal Living Index ($p = 0.05$)

Population

Subjects:	18 Subjects (13 males, 5 female;)
Previous prosthetic knee:	None
Amputation causes:	Dysvascular 5, Trauma 6, Infection 6, Tumor 1
Mean age:	49,6 years
Time since amputation:	4-16 weeks
K-Level:	1-2: 33.3%; 3-4: 55.6%

Study Design

Randomized, controlled study with blinded assessor:



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 NMPK vs. MPK		Sig.*
		NMPK (Mean ± SD)	MPK (Mean ± SD)	
Level Walking	Six-Minute Walk Test (m)	183 ± 204	243 ± 170	0
	Timed-Up and Go: comfortable speed (s)	40.7 ± 28.4	15.9 ± 5.9	0
	Timed-Up and Go: fast speed (s)	37.6 ± 31.1	14.0 ± 6.0	0
	Average daily step count (steps/day)	972 ± 1020	2569 ± 1952	0
	Mean stride velocity (m/s)	62.8 ± 58.3	87.7 ± 34.1	0
Safety	Falls in the last month (number)	0.0 ± 0.0	0.1 ± 0.3	0
	Falls in the past 3 months (number)	1.0 ± 1.5	1.0 ± 1.3	0
Activity, Mobility, ADLs	Amputee Mobility Predictor (total score)	27.5 ± 10.1	35.9 ± 4.5	0
	Amputee Mobility Predictor single item mobility measure (0-6 scoring)	3.2 ± 1.2	4.8 ± 0.8	0

Category	Outcomes	Results for NMPK vs. MPK		Sig.*
		NMPK (Mean ± SD)	MPK (Mean ± SD)	
	PLUS-M 12-item (T-score)	35.9 ± 11.8	54.3 ± 6.9	++
	Activity-specific Balance Confidence (0–4 scoring)	1.6 ± 0.9	3.2 ± 0.8	++
	PROMIS-Physical Function 20-item (T-score)	38.6 ± 6.5	45.9 ± 8.8	+
	Return to Normal Living Index (0–100, average score)	77.3 ± 14.4	86.8 ± 18.6	++
Preference, Satisfaction, QoL	PROMIS-Anxiety 4-item (T-score)	47.4 ± 8.6	47.1 ± 9.1	0
	PROMIS-Depression 4-item (T-score)	48.0 ± 8.5	45.0 ± 6.2	0
	PROMIS-Fatigue 4-item (T-score)	49.9 ± 6.6	41.9 ± 8.9	-
	PROMIS-Sleep Disturbance 4-item (T-score)	51.1 ± 6.1	49.5 ± 7.0	0
	PROMIS-Satisfaction with Social Roles 4-item (T-score)	47.6 ± 9.2	50.6 ± 8.8	0
	PROMIS-Pain Interference 4-item (T-score)	50.2 ± 11.0	48.9 ± 7.2	0
	PROMIS-Pain Intensity 1-item (0-10, average score)	2.3 ± 3.0	2.6 ± 2.6	0

^a no difference (0), positive trend (+), negative trend (-), significant (++/--), not applicable (n.a.)

^b p value after post hoc Bonferroni correction did not significance set at p<0.05; trends set at 0.1>p>0.05 effect sizes classified by authors as small (<0.3), moderate (>0.3 and <0.5) or large(>0.5)

Author's Conclusion

"The current study assessed these important clinical outcomes for patients with recent transfemoral amputation, who are particularly susceptible to mobility restrictions and falls throughout the earliest phases of rehabilitation. Findings from the current study indicate that MPK users may improve more on overall mobility, balance confidence, independence in locomotor capabilities, and physical function in the 3-month period following their initial prosthetic fitting than NMPK users. Additional studies, such as a multicenter study that is sufficiently powered to detect differences in performance-based and self-reported measure of function, mobility, and falls are needed to verify these findings." (Morgan et al., 2024)

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