#### Reference

Shane R. Wurdeman<sup>1</sup>, Brian J. Hafner<sup>2</sup>, Andrew Sawers<sup>3</sup>, Dwiesha L. England<sup>1</sup>, Russell L Lundstrom<sup>4</sup>, and Andreas HJ Kannenberg<sup>4</sup>

ASsessing Clinical outcomes with microprocEssor kNee uTilization in a K2 population (ASCENT K2): randomized controlled trial results for above-knee prosthesis users over age 65.

#### **Products**

## C-Leg 4 and Kenevo

#### **Major Findings**

After 1 year following Kenevo fitting compared to NMPK condition:

# → 21% reduction in Fear of Falling Related Avoidance Behaviour (FFABQ) Average decrease of 5.7 points (p<0.001) in the Kenevo group, but no significant change in the NMPK group.

## → 20% improvement in 10 Meter (10MWT) walking speed

Average increase of +0.08 m/s (p=0.001) in the Kenevo group, but no significant change in the NPMK group.

## → 24% improvement in Timed Up and Go (TUG) time

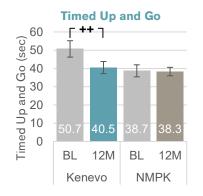
Timed up and go (TUG) time reduced by  $10.1 \sec \pm 3.3 \sec (p = .001)$  in the Kenevo group, but no significant change in the NMPK group.

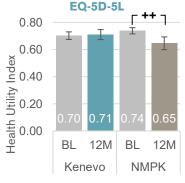
## → 52% fewer falls in 12 months

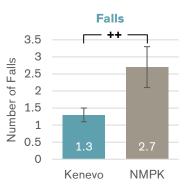
Kenevo:  $1.3 \pm 0.2$  falls, NMPK:  $2.7 \pm 0.6$  falls (p=0.015)

## → Kenevo preserved quality of life

Health Related Quality of Life (QoL)from EQ-5D-5L did not significantly change in the Kenevo group (+1%, p=0.42), but decreased by a significant 12% in the NMPK group, with an average change in Health Utility Index (HUI) of -0.092 (p=0.021) after 1 year.







++ statistically significant (p< 0.05)

#### **Population**

Subjects: 107 (31 female) K2 ambulators

Randomization: MPK: 54, NMPK: 53

Underlying conditions: Participants had 3 chronic conditions on average at

baseline:

Hypertension: 65%,

Peripheral vascular disease: 41%,

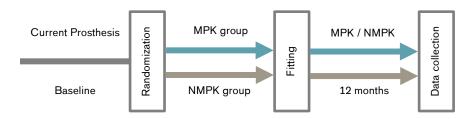
Obese: 40%, Diabetes: 39%, Arthritis: 37%) 73.7 ± 5.6 yrs Transfemoral: 97%,

Mean age: Amputation level:

Bilateral: 3%

## **Study Design**

Prospective, randomized control (NMPK) parallel design:



NOTE: Primary outcomes were evaluated at 12 months, with intermittent check-ins.

## **Results**

Functions and Activities								Participation	Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Metabolic Energy Consump- tion		Activity, Mobility, ADLs		Health Eco- nomics

Category	Outcomes	Results for Kenevo vs. NMPK	Sig.*	
Level Walking	Fast Walking Speed (FWS) measured by the 10-meter Walk Test.	20% improvement in walking speed in the Kenevo group. Average increase of +0.08 m/s (p=0.001) in the MPK group, but no significant change in the NPMK group.		
	Timed up and Go (TUG)	24% improvement in Timed Up and Go (TUG) time in the Kenevo group. Average decrease of 10 seconds (p=0.001), but no significant change in the NPMK group.	++	
	2-minute walk test (2MWT)	Both MPK and NMPK had increases in 2MWT distance, Kenevo: increased 10.71 ± 1.97 m vs NMPK: increased 7.88 ± 1.84 m (p<0.001)	0	
Safety	Fear of Falling Avoidance Behaviour Questionnaire (FFABQ)	<b>21% reduction in the Kenevo group,</b> average decrease of 5.7 points (p<0.001), but no significant change in the NMPK group	++	
	Falls	52% fewer falls in 12 months, Kenevo: 1.3 $\pm$ 0.2 vs NMPK: 2.7 $\pm$ 0.6, p = 0.015		
	Near Falls	70% fewer near falls in 12 months, Kenevo: 1.7 ± 0.4 vs NMPK: 5.7 ± 1.1, p < 0.001		
	Total fall events	67% fewer Total fall events in 12 months, Kenevo: 2.7 ± 0.4 vs NMPK: 8.3 ± 1.5, p < 0.001	++	
Activity, Mobility, ADLs	Activity-specific Balance Confidence (ABC)	No significant difference in patient-perceived balance confidence	0	

Category	Outcomes	Results for Kenevo vs. NMPK		
		Kenevo: 30.4% ± 1.7 vs NMPK: 25.9% ± 1.1		
Health Economics	EQ-5D-5L QoL Health Utility Index	No significant change in Health Related Quality of Life in the Kenevo group (+1%, p=0.42), but <b>significant 12% decrease in Quality of Life in the NMPK group,</b> with average change in Health Utility Index (HUI) of -0.092 (p=0.021) in 1 year.		
	PROMIS PROPr HR-QoL	No significant difference in Health-Related Quality of Life (HR-QoL) as measured by PROMIS PROPr Kenevo: $0.325 \pm 0.033$ vs NMPK: $0.340 \pm 0.032$		

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

effect sizes classified by authors as small (<0.3), moderate (>0.3 and <0.5) or large(>0.5)

#### **Author's Conclusion**

"The clinical trial demonstrated that MPKs significantly improve clinical outcomes for older adults with above-knee amputations classified as limited community ambulators. Participants using MPKs reported lower levels of activity avoidance due to fear of falling and experienced a notable reduction in the number of falls, near-falls, and combined fall events compared to those using NMPKs. While the MPK group maintained HR-QoL through the trial, the NMPK group experienced a significant decline, highlighting the potential for MPKs to sustain or enhance HR-QoL in this population. Despite limitations, the results of this clinical trial confirm that benefits of MPKs reported among younger limited community ambulators also extend to older, less functional individuals with above-knee amputations. Findings from this randomized controlled trial also suggest that wider adoption of MPKs could enhance safety and HR-QoL in this rather impaired clinical population." (Wurdeman et al., 2025)

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b p value after post hoc Bonferroni correction did not significance set at p<0.05; trends set at 0.1>p>0.05