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Effects of a Novel Microprocessor-Controlled Knee Kenevo on the Safety, Mobility, and Satisfaction of Lower-Activity Patients with Transfemoral Amputation

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Products	Kenevo				
Major Findings	With Kenevo compared to previous fitting (mostly non-microprocessor controlled knees NMPKs)				
	→ Reduced frequency of stumbles and falls				
	Subjects that never stumble increased from 8% to 50%				
	Fear of falling reduced in 50% of subjects (negative trend)				
	→ Wheelchair dependence reduced (from 87% to 37%)				
	→ Positive trend on Mobility and ADLS (Questionnaires, LCI-5, PLUS-M & Houghton scores)				
	→ Kenevo preferred by 89% of subjects				



Falls (N=12)

Stumbles and falls were evaluated by asking "how often do you stumble or fall with your current prosthesis?" at baseline measurements (with their old prosthesis) and again two months after being fit with Kenevo.

Population	Subjects:	29 (11 F) unilateral transfemoral amputees	
	Previous knee:	Polycentric (36%), brake (27%), locked (18%),	
		MPK (18%) (N=22)	
	Amputation causes:	Vascular disease (46%), infection (38%), cancer	
		(8%), trauma (8%) (N=13)	
	Mean age:	63.2 (<u>+</u> 9.5) years (N=16)	
	Mean time since amputation:	6.3 (<u>+</u> 8.9) years (N=12)	
	MFCL:	83% MFCL-2, 13% MFCL-3, 4% MFCL-1 (N=23)	

Prospective, observational study:



Demographic data and data on current prosthetic fitting was collected via questionnaire. Questions addressed topics such as pain, satisfaction and safety, together with validated clinical tests (Houghton, LCI-5, PLUS-M).

2 months after fitting, subjects returned for follow-up testing. The questions presented during baseline were again used to evaluate different aspects of Kenevo, together with questions comparing the subject's perception of Kenevo to their previous fitting.

Due to observation nature of this study, the completeness of data collected at different centres varied.

Results									
Functions and Activities					Participation				Environment
Level walking	Stairs	Ramps, Hills	Uneven (ground, c Obstacles	Cognitive demand	Metabolic Energy Consump- tion	Safety	Activity, Mobility, ADLs	Preference, Satisfac- tion, QoL	Health Economics
Ca	tegory		Outcomes		Results for I	Kenevo cor	npared to p	revious fittin	g Sig.*
Level Walking	Walkin (N=19)	Walking on level ground Better or muc (N=19)			h better (7	9%)		n.a.	
	Slow w (N=19)	Slow walking speed E (N=19)		Better or much better (74%)				n.a.	
	Normal walking speed (N=19)		l k	Better or much better (74%)			n.a.		
	Fast walking speed B (N=17)			Better or much better (59%)				n.a.	
Stairs	Stair ascent (N=16)			Equal (63%), better or much better (37%)				n.a.	
	Stair descent (N=16)			Better or much better (55%)				n.a.	
Ramps, Hills	Ramp ascent (N=19)			Better or much better (52%)				n.a.	
	Ramp descent (N=19)			Better or much better (68%)				n.a.	
	Standing on ramps (N=13)			Better or much better (69%)				n.a.	
Uneven G Obstacle (round, Course	Walkin (N=19)	g on uneven gr	ound	Better or muc	h better (6	4%)		n.a.

Category	Outcomes	Results for Kenevo compared to previous fitting	Sig.*
Cognitive Demand	Necessary concentration during walking (N=19)	Much less or less (79%)	n.a.
Metabolic Energy Consumption	Exertion during walking (N=19)	Much less or less (84%)	n.a.
Cognitive Demand Metabolic Energy Consumption Safety Activity, Mobility, Activities of Daily Living (ADLs)	Falls (N=12)	Never (72%); previous fitting (45%)	0
	Stumbles (N=12)	Never (50%); previous fitting (8%)	++
	Fear of falling (10-point scale) (N=12)	2.2; previous fitting 3.5	-
	Toe clearance in swing phase (N=16)	Better or much better (71%) than previous fitting	n.a.
	Perceived safety during walking (N=19)	Better or much better (71%) than previous fitting	n.a.
	Stability during walking (N=19)	Better or much better (71%) than previous fitting	n.a.
	Perceived safety during standing (N=18)	Better or much better (83%) than previous fitting	n.a.
	Standing stability (N=19)	Better or much better (84%) than previous fitting	n.a.
	Rising from a chair (N=19)	Better or much better (84%) than previous fitting	n.a.
Activity, Mobility, Activities of Daily Living (ADLs)	Houghton scale (N=11)	Increased score by 1.0 ± 2.0	+
	PLUS-M (N=11)	Increased score by 2.8 ± 7.2	0
	LCI-5 (N=11)	Increased score by 2.3 ± 5.2	+
Preference, Satisfaction, Quality of Life (QoL)	Pain (N=15)	No differences reported	0
	Perceived loading of the sound side (N=15)	Distinct or little load reduction felt (84%)	n.a.
	Walking comfort (N=15)	Better or much better (66%) than previous fitting	n.a.
	Standing comfort (N=15)	Better or much better (69%) than previous fitting	n.a.
	Sitting comfort (N=15)	Better or much better (42%) than previous fitting	n.a.
	Wheelchair dependence (N=11)	37%, with previous fitting: 87%	

Category	Outcomes	Results for Kenevo compared to previous fitting	Sig.*
	Satisfaction (N=19)	Very satisfied or satisfied (89%)	0
	Preference (N=19)	89% prefer Kenevo over their previous fitting	n.a.

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

Author's Conclusion "High patient satisfaction with Kenevo was observed in lower-activity individuals with transfemoral amputation. New knee functionalities designed specifically to target the safety challenges of this population seem to be effective and beneficial. The first clinical experiences collected during this observational study suggest that Kenevo offers several advantages to lower-activity persons with amputation, particularly in the areas of safety, functional mobility, preference, and satisfaction. These observations are in agreement with published evidence on effects of MPKs in limited community ambulators. Higher quality research is needed to confirm the conclusions reached in this observational study." (Mileusnic et al. 2017)

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