

Reference

Lansade C, Vicaut E, Paysant J, Ménager D, Cristina MC, Braatz F, Domayer S, Pérennou D, Chiesa G.

Institut Robert-Merle d'Aubigné (Valenton, France), Lariboisière Hospital (Lariboisière, France), Institut régional de médecine physique et de réadaptation (Nancy, France), Pôle Saint-Hélier (Rennes, France), Hôpital Sud, CHU de Grenoble (Echirolles, France), Universitätsmedizin Göttingen (Göttingen, Germany), Sonderkrankenanstalt Zicksee (Zicksee, Austria).

Mobility and satisfaction with a microprocessor-controlled knee in moderately active amputees: A multi-centric randomized crossover trial.

Annals of Physical and Rehabilitation Medicine (2018) – in press

Products

Kenevo

Major Findings

With Kenevo compared to NMPK:

→ Risk of falling reduced

Timed Up and Go (TUG) test: clinically and statistically significant reduction of 12.9% ($p=0.001$)*

Number of falls during last 30 days of observation:

6 falls with NMPK (4 related to NMPK), 1 fall with Kenevo (none related to Kenevo; difference in falls did not reach statistical significance)*

→ Mobility significantly increased

Locomotor Capability Index (LCI-5) global mean increased by 7.4% ($p=0.006$)*

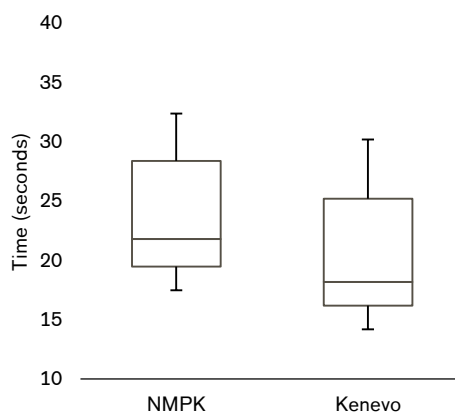
→ Satisfaction and domains of quality of life significantly increased

QUEST 2.0 score increased by 15.2% ($p=0.002$)*

Significant increase in the SF-36 domains mental component score ($p=0.01$), physical activity ($p=0.04$), limitations related to physical health ($p=0.005$), mental health ($p=0.009$) and limitations related to mental health ($p=0.04$).*

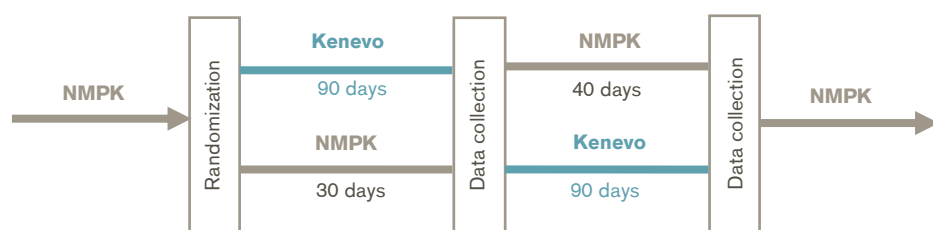
* Based on Intent-to-Treat (ITT) Analysis

Clinically and statistically significant reduction in Timed Up and Go Test



Population	Subjects:	33 unilateral transfemoral, 2 unilateral knee disarticulated amputees
	Previous prosthesis:	NMPK
	Amputation causes:	57% vascular, 11% diabetic vascular, 23% trauma, 11% tumour, 9% infection
	Mean age:	65.6 ± 10.1 years
	Mean time since amputation:	61.4 ± 85.5 months

Study Design Interventional randomized cross-over study:



Data was analyzed both by intent-to treat (ITT) with the population mentioned above (for ITT analysis n=30 after 5 participants decided not to continue study or did not qualify for first assessment) as well as per-protocol (PP, n=27 after 3 participants were not able to use the prosthesis as described in the protocol).

Results

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

Category	Outcomes	Results for Kenevo	Sig.*
Safety	TUG (Timed Up and Go Test) (ITT)	Participants needed 12.9% less time to complete the TUG test.	++
	TUG (Timed Up and Go Test) (PP)	Participants needed 16% less time to complete the TUG test.	++
	Number of falls (ITT)	Total number of falls during last 30 days of observation: 6 falls with NMPKs, 1 fall with Kenevo. Falls related to the knee: 4 with NMPK, 0 with Kenevo.	0
	Number of falls (PP)	Total number of falls during last 30 days of observation: 3 falls with NMPKs, 1 fall with Kenevo. Falls related to the knee: 2 with NMPK, 0 with Kenevo.	0
Activity, Mobility, Activities of Daily Living (ADLs)	LCI-5 (Locomotor Capability Index)(ITT)	The LCI-5 score was increased by 7.4%. Basic activities score: + 8.2%	++ ++
		Advanced activities score: + 6.6%	0
	LCI-5 (Locomotor Capability Index)(PP)	The LCI-5 score was increased by 5.6%. Basic activities score: + 6.3%	++ ++
		Advanced activities score: + 4.4%	0

Category	Outcomes	Results for Kenevo	Sig.*
	Number of walking aids (ITT, PP)	The number of walking aids needed did not change significantly.	0
Preference, Satisfaction, Quality of Life (QoL)	QUEST 2.0 (Quebec User Evaluation of Satisfaction with assistive Technology) (ITT)	Global score significantly increased by 15.2%. Technology score: + 15.5% Service score: + 8.2%	++ ++ ++
	QUEST 2.0 (Quebec User Evaluation of Satisfaction with assistive Technology) (PP)	Global score significantly increased by 17%. Technology score: + 13.3% Service score: + 4%	++ ++ ++
	SF-36 (ITT)	All subscores of SF-36 increased, indicating a higher quality of life. The changes in the domains mental component score (+11.3%) physical activity (+14.2%), limitations related to physical health (+35.7%), mental health (+17.1%) and limitations related to mental health (25%) were significant.	+ ++
	SF-36 (PP)	All subscores of SF-36 increased, indicating a higher quality of life. The changes in the domains mental component score (+11.5%), limitations related to physical health (+33.4%) and mental health (+16.7%) were significant.	+ ++

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

Author's Conclusion

“Recent studies suggested that MPKs could be useful for amputees with moderate activity level. We compared the efficiency of a MPK (Kenevo, Otto Bock) and NMPKs for these individuals in a multi-centric randomized crossover study, which provided a high level of evidence. Dynamic balance and functional mobility were improved with the MPK, as were satisfaction and quality of life on the MCS of the SF-36v2. The incidence of falls did not differ with use of the 2 devices. Thus, all individuals with transfemoral amputation or knee disarticulation, regardless of their mobility grade, can be provided with appropriate prostheses . [...] In conclusion, MPKs explicitly tailored to the specific needs of this vulnerable population should be considered a viable therapeutic option to increase mobility and participation. Once other MPKs dedicated to moderately active persons are available on the market, comparisons with the Kenevo will be necessary for clinicians and health authorities to provide accurate recommendations and guidelines in the choice of the device.”

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