

Reference

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Zum Nutzen mikroprozessor-gesteuerten Prothesenkniegelenke bei eingeschränkten Außenbereichsgehern: eine aktualisierte systematische Literaturanalyse

(Benefits of Microprocessor-Controlled Prosthetic Knees for Limited Community Ambulators – Update of a Systematic Literature Review)

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Products

MPKs (C-Leg, Genium, Kenevo)

Major Findings

MPKs compared to NMPKs in limited community ambulators (MCFL-2) seven publications from 2015 to 2020 show results that favour MPKs for:

→ **Safety**

- Reduced number of stumbles and falls, and fear of stumbles and falls
- Reduced risk of falling
- Increased patient-perceived safety

→ **Function and Mobility**

- Increased walking speed (self-selected and fastest possible)
- Increased mobility on stairs, ramps and uneven terrain
- Reduced use of walking aids and wheelchairs
- Improved ability to perform complex movements (e.g. opening heavy door etc...)

→ **Subjects perception of**

- Balance
- Locomotion
- Health related Quality of Life

→ **Cost-effectiveness of MPKs in such target population**

	Hahn 2015	Wong 2015	Hahn 2016	Hasenoehrl 2017	Mileusnic 2017	Kaufman 2018	Lansade 2018
Number falls		↓↓				↓↓	○
Fear of falling	↓↓	↓↓ 11-Point NAS			↓ 10-Point NAS		
Risk of falling		↓↓ TUG		○			↓↓↓ TUG
Sense of security	↑↑		↑↑				
Patients without falls				○ number of patients	○		○
Patients without stumbles					↓↓		

↓↓↓,↑↑↑ highly statistically significant (p<0,001) Increase/Reduction; ↑↑, ↓↓ statistically significant (p<0,05) Increase/Reduction; ↑, ↓ statistical trend (0<p<0.1) towards Increase/Reduction; ○ no changes; **NAS** = Numerical analogue scale

Population	Subjects:	2249
	Previous prosthesis:	various
	Amputation causes:	Vascular (432) Trauma (1161) Other (634)
	Mean age:	ranging from 55.6 to 69.0 yrs.
	Mean time since amputation:	not reported
	MFCL:	677 subjects (30%) were AK-2/MCFL-2

Study Design **Systematic Literature Review**

Included publications: In total 7 articles, 6 of them included Kenevo, C-Leg/C-Leg Compact and/or Genium, 1 publication deals with the cost efficiency and fall prevention with C-Leg

Quality assessment: After assessing the overall relevance of the publications the quality was assessed following the Cochrane guidance as published by Hofstad et al. 2004.

Inclusion criteria:

- randomized or not-randomized comparative clinical study dealing with the fitting and results or health economic aspects of one or more MPKs in comparison to one or more NMPKs
- subjects had to have a unilateral transfemoral amputation or a knee disarticulation and the mobility grade 2 (or MFCL-2) or the aetiology of a vascular disease
- The study used and reported on quantitatively independently verifiable results of validated clinical test methods and validated questionnaires from the areas of safety, functionality and mobility as well as subjective functionality and satisfaction with the prosthesis

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 MPK vs NMPK	Reference
Safety	Falls	Number of falls reduced by 60%	Wong et al. 2015 (++) Kaufman et al. 2018 (++)
		Median number of falls reduced from 2 → 0	
		Number of falls stayed the same	Lansade et al. 2018 (0)
	Number of subjects <u>without</u> falls stayed the same	Hasenoehrl et al. 2017 (0) Mileusnic et al. 2017 (0) Lansade et al. 2018 (0)	
		Reduction of fall-related hospitalization (in patients with non-vascular amputation causes)	Kuhlmann et al. 2019
		Reduction of falls resulting in death	

Category	Outcomes	Results for MPK vs NMPK	Reference
Activity, Mobility, Activities of Daily Living (ADLs)	Stumbles	% of patients without stumbles higher with MPK vs NMPK (with Kenevo)	Mileusnic et al. 2017 (++)
	Fear of stumbles and falls	Reduction of fear of stumbles and falls	Wong et al. 2015 (++) Mileusnic et al. 2017 (+)
		Reduction of number of subjects with fear of stumbles and falls (87% in mobility grade 2)	Hahn et al. 2016 (++)
	Safety perception	Increased safety perception in 83% of subjects	Hahn und Lang 2015 (++)
		67% to 96% increased safety perception independently from MG and aetiology	Hahn et al. 2016 (++)
	TUG	Improved Timed-up-and-go-Test (TUG is associated with the risk of falls)	Lansade et al. 2018 (++, with Kenevo) Wong et al. 2015 (++) Hasenoehrl et al. 2017 (0)
	Mobility	Number of subjects who additionally use a wheelchair is reduced	Reduced use of walking aids
No reduction in walking aids used			Hasenoehrl et al. 2017 (0)
Time spent seated is reduced and increased movement during the day		Kaufman et al. 2018 (++)	
Improved ability to perform complex movements (e.g. walking backwards, overcoming obstacles without visibility)		Hahn et al. 2016 (++)	
Increased mobility grade 50% MG2 → MG3 22% MG3 → MG4		Hahn und Lang 2015 (++)	
Gait complexity stayed the same		Kaufman et al. 2018 (0)	
Gait velocity stayed the same		Hasenoehrl et al. 2017 (0)	
Walking distance in 2 min stayed the same			
AMPRO		No change in AMPRO	Hasenoehrl et al. 2017 (0)
BBS		No change in BBS	Hasenoehrl et al. 2017 (0)
Preference, Satisfaction, Quality of Life (QoL)	QUEST 2.0	Improvement in QUEST 2.0 Questionnaire (satisfaction with prosthesis)	Lansade et al. 2018 (++, with Kenevo)
	PEQ	Improvement in PEQ Score (increased satisfaction with prosthesis functionality)	Kaufman et al. 2018 (++)
	ABC	Improvement with MPK (improved sense of balance)	Wong et al. 2015 (++)

Category	Outcomes	Results for MPK vs NMPK	Reference
		No change in sense of balance with MPK vs NMPK	Hasenoehrl et al. 2017 (0)
		Improvement in a number of perception categories: e.g., toileting	Hahn et al. 2016 (++) Hahn und Lang 2015 (++)
	SF 36	Improvement in SF-36 - PCS	Lansade et al. 2018 (+, with Kenevo)
		No change in SF-36 - PCS	Hasenoehrl et al. 2017 (0)
		Improvement in SF-36 - MCS	Lansade et al. 2018 (++, with Kenevo)
		No change in SF-36 - MCS	Hasenoehrl et al. 2017 (0)
	LCI 5	Improvement in LCI-5 (performing activities of daily living)	Mileusnic et al. 2017 (+)
		Improvement in LCI-5 results	Lansade et al. 2018 (++, with Kenevo)
	Houghton Scale	No change in Houghton Scale (perception of prosthetic use)	Hasenoehrl et al. 2017 (0)
		No change in the Houghton Scale	Wong et al. 2015 (0)
		Improvement in Houghton Scale	Mileusnic et al. 2017 (+)
	OPUS	No change in OPUS questionnaire results	Hasenoehrl et al. 2017 (0)
	Pain and Comfort	No change in pain and comfort	Mileusnic et al. 2017 (0)
	ADLs	Improved walking on level ground	Mileusnic et al. 2017 (+)
		Improved walking on uneven ground	
		Improved walking on stairs	
		Decreased fatigue	
		Increased concentration	
Health Economics	Cost	Cost per additional QALY is below the comparative value proposed by the WHO	Kuhlmann et al. 2019

MG: Mobility grade; **NAS:** Numerical analogue scale; **TUG:** Timed-up and go-Test; **ADLs:** Activities of Daily Life; **AMPPRO:** Amputee Mobility Predictor Test with Protheses; **BBS:** Berg Balance Scale; **ABC:** Activity-specific Balance Confidence Scale (Sense of balance); **OPUS:** Orthotics and Prosthetic Users' Survey (ADLs); **SF-36:** Quality of life in different aspects; **PCS:** Physical Component Score); **MCS:** Mental Component Score;**LCI-5:** Locomotor Capability Index (ADLs); **PLUS-M:** Prosthetic Limb Users' Survey of Mobility (ADLs); **PEQ:** Prosthesis Evaluation Questionnaire (Perception of the prosthesis function); **QUEST:** Quebec User Evaluation of Satisfaction with Assistive Technology (Satisfaction with Assistive Technology)

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

**Author's Conclusion
(English; translated
version)**

„The results of this updated systematic review suggest that unrestricted outdoor walkers and prosthesis users with vascular amputation etiology can significantly reduce their risk of falls, their fear of falls and the number of falls by using microprocessor-controlled prosthetic joints. Outdoor activities, which are typical for the mobility grade AK/MFCL-3, can be carried out significantly better. This is also reflected in the patients' self-perception. The specially designed components, which are tailored to the needs of this patient group, increase the probability of successful and safe fittings. Overall, the results of the present study support the position of considering the use of MPKs as standard care today for limited outdoor walkers with unilateral transfemoral amputation. Test fittings can help to identify patients who do not benefit from an MPK “ (translated Hahn et al. 2020)

**Author's Conclusion
(German; original
Version)**

“Die Ergebnisse dieser aktualisierten systematischen Übersichtsarbeit legen nahe, dass uneingeschränkte Außenbereichsgeher und Prothesennutzer mit vaskulärer Amputationsätiologie durch die Nutzung mikroprozessorgesteuerter Prothesengelenke ihr Sturzrisiko, ihre Sturzungst und die Zahl ihrer Stürze signifikant reduzieren können. Aktivitäten im Außenbereich, die eigentlich typisch für den Mobilitätsgrad AK/MFCL-3 sind können signifikant besser ausgeführt werden. Dies spiegelt sich auch in der Eigenwahrnehmung der Patienten wider. Die speziell auf die Bedürfnisse dieser Patientengruppe abgestimmten Passteile erhöhen dabei die Wahrscheinlichkeit einer erfolgreichen und sicheren Versorgung. Insgesamt stützen die Ergebnisse der vorliegenden Arbeit die Position, die Nutzung von MPKs bei eingeschränkten Außenbereichsgehern mit einseitiger Oberschenkelamputation heute als Standardversorgung zu betrachten. Testversorgungen können dazu beitragen, Patienten zu identifizieren, die nicht von einem MPK profitieren.” (Hahn et al. 2020)

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