Reference

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Benefits of the Genium microprocessor controlled prosthetic knee on ambulation, mobility, activities of daily living and quality of life: a systematic literature review

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Products

Genium vs MPK

Major Findings

With Genium compared to standard MPKs (mostly C-Leg):

→ More physiological and symmetric gait

Prosthetic side:

Level walking - i.e. increased peak knee flexion angle in swing and stance, increased weight bearing on the prosthetic side, improved swing phase control

Stairs – i.e. up to 80% of subjects ascend stairs by using step-over-step pattern

Ramps – i.e. increased knee flexion during swing phase (toe clearance), increased weight bearing during descent

Sound side:

Reduction of loading and compensatory movements

→ Improved mobility

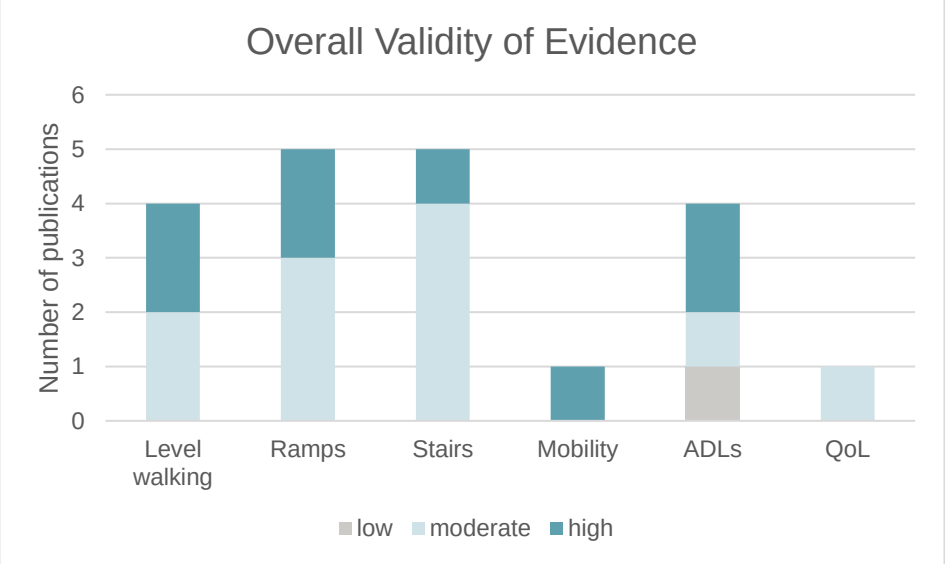
Significant improvements in Four Square Step Test, Amputee Mobility Predictor

→ Improved activities of daily living

Clinically relevant gain in safety when performing 60% of the ADLs[1].

Clinically relevant gain in difficulty when performing 53% of the ADLs[1].

→ Improved prosthesis-related quality of life

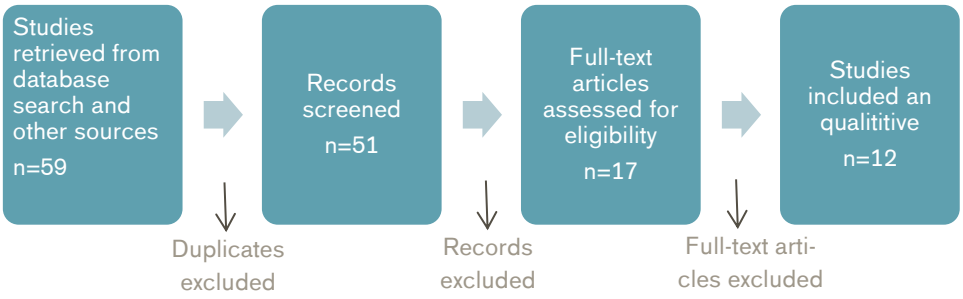


[1] patient reported outcome (questionnaire)

Population	Subjects:	961 with amputation and 5 without
	Previous prosthesis:	mostly C-Leg (in 9 publications it is comparison only to C-Leg; in Hahn et al. 2016: 77% C-Leg and 23% various mechanical knees; in Bell et al. 2016: 62% MPK (C-Leg, Rheo), 38% mechanical knee; in Aldridge Whitehead et al. 2014: 86% C-Leg, 14% mechanical knee)
	Amputation causes:	trauma, vascular disease, malignancy
	Mean age:	31.1-49.0 years (range of means across publications)
	Mean time since amputation:	10.4-17.2 years (range of means across publications)
	MFCL:	3, 4

Study Design

Systematic Literature Review



Included publications: 12 articles were included and reported primarily on active subjects (MFCL-3/4) transitioning from C-Leg to Genium.

Quality assessment: review was conducted according to the PRISMA Guidelines (Moher et al 2009) and following the recommendations of the State-of-Science Evidence Report Guidelines of the American Academy of Orthotists & Prosthetists (Hafner et al 2008). The study design was classified according to the Study Design Classification Scale. The risk of bias of the included studies was assessed in terms of 18 potential threats to internal and 8 potential threats to external validity. The included publications were used to develop the evidence statements.

Inclusion criteria: Publications comparing ambulation, mobility, ADLs and quality of life of the Genium or X2 prosthetic knee to non-microprocessor controlled knees (NMPK) or other MPK; published since 2012; published in the English language; included subjects with transfemoral amputation or knee disarticulation. (Single-case studies were excluded.)

Results

Functions and Activities							Participation			Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Three-dimensional gait analysis	Metabolic Energy Consumption	Safety	Activity, Mobility, ADLs	Preference, Satisfaction, QoL	Health Economics

Category	Outcomes	Results with Genium in comparison to (mostly***) standard MPK (C-Leg)	Reference
Level walking	Walking speed on even and uneven terrain	No significant difference.	Bellmann et al. 2012b. (0) Highsmith et al. 2014b. (0)
	Prosthetist assessed functional benefits and advanced manoeuvres	Responsiveness** in functional benefits in range of 95%-97% (i.e., symmetry, relief, attention, variable speed, effort). Responsiveness** in small steps (74.94%), walking backwards (91.28%), obstacles (75.32%).	Hahn et al. 2016. (n.a.)
	Patient perceived benefit	Responsiveness** in range of 85%–90% (obstacle, variable speed, small step, walking backwards, visual obstruction).	Hahn et al. 2016.(n.a.)
	Perceived exertion	No significant difference.	Highsmith et al. 2014b. (0)
	Biomechanical analysis	• Step length asymmetry significantly decreased. • Peak knee flexion angle significantly increased in swing, stance and during small step. • Further reduced speed dependency of maximum knee flexion angle in swing phase. • Decreased ground reaction forces at weight acceptance on the prosthetic side due to 4 degrees of pre-flexion. • Increased knee flexion moments on the prosthetic side indicating increased weight-bearing.	Lura et al. 2015. (++) Bellmann et al. 2012b. (++)
	Postural stability	No difference in postural stability.	Highsmith et al. 2014b.(0)
	Limits of stability	C-Leg offered improved control in anteriolateral Genium offered improved control in rearward direction.	Highsmith et al. 2014b.(++) (--)
Stairs	Percent of subjects ascending stairs alternatingly	In range of 64%- 80%, depending on publication.	Hahn et al. 2016.(n.a.) Bellmann et al. 2012a.(n.a.)

Category	Outcomes	Results with Genium in comparison to (mostly***) standard MPK (C-Leg)	Reference
	Prosthetist assessed advanced manoeuvres	Responsiveness** in stairs down (70.52%), stairs up alternatingly (32.81%), descent (66–70%).	Hahn et al. 2016. (n.a.)
	Patient perceived benefit	Responsiveness** 65% on stairs down, 90% on stairs up alternatingly	Hahn et al. 2016. (n.a.)
	Stair Assessment Index	The median score improved during ascent from 5 or 6 (depending on study) to 11.	Aldridge Whitehead et al. 2014. (++) Highsmith et al. 2016b.(++)
		The mean score significantly improved by 9%.	Highsmith et al. 2016b.(++)
	Time to ambulate stairs	Stair ascent and descent completion time did not differ significantly.	Highsmith et al. 2016b. (0)
	Biomechanical analysis	• More physiological increase in knee and hip range of motion on the prosthetic side and decrease of compensations on the sound side (due to step-over-step ascent). • Reduced contralateral knee extension power and increased ankle joint power during step-over-step.	Aldridge Whitehead et al. 2014. (++) Bellmann et al. 2012a.(++) Bellmann et al. 2012b. (++)
Ramps	Prosthetist assessed advanced manoeuvres	Responsiveness** 70.86% for ramp descent and 74.53% for ramp ascent	Hahn et al. 2016. (n.a.)
	Patient perceived benefit	Responsiveness** in range of 85–95%	Hahn et al. 2016. (n.a.)
	Biomechanical analysis	• Significantly increased peak knee flexion in swing phase (improved toe clearance). • Significantly increased flexion at initial contact and weight bearing during descent and unloading of sounds side. • Increased prosthetic limb step length. • Reduction of knee moment asymmetry, variance in peak knee flexion moments.	Lura et al. 2015 (++) Bellmann et al. 2012b (++) Bell et al. 2016 (++) Highsmith et al. 2016a(++)
	Standing on slopes	Significantly increased loading on prosthetic side, reduced hip moments on the prosthetic side, reduction in hip compensation and postural sway.	Bellmann et al. 2012b. (++)
	Hill Assessment Index	No difference.	Bell et al. 2016. (0)
	Self-selected walking speed	Either no change or significantly increased.	Highsmith et al. 2016a (0); Bell et al. 2016. (++)
	Four Square Step Test	Mean time significantly decreased (improved) by 1.1 sec with Genium.	Highsmith et al. 2016b(++)

Category	Outcomes	Results with Genium in comparison to (mostly***) standard MPK (C-Leg)	Reference
Activity, Mobility, Activities of Daily Living (ADLs)	Amputee Mobility Predictor	Significantly improved median score by 2 points with Genium.	Highsmith et al. 2016b(++)
	Step activity derived functional level (K-level)	Significantly improved median score by 0.2 points.	Highsmith et al. 2016b(++)
	Prosthetist assessed advanced manoeuvres	Responsiveness** in range of 72%–82%.	Hahn et al. 2016.(n.a.)
	Patient perceived benefit	Responsiveness** in range of 80%–90%.	Hahn et al. 2016.(n.a.)
	Continuous Scale – Physical Functional Performance (CSPFP10),	Total score significantly improved with Genium by 7.4%.	Highsmith et al. 2016c.(++)
	ADLs questionnaire	: • Clinically relevant gain in safety with 27 out of 45 of ADLs (60%) and • Clinically relevant decrease in difficulty with 24 out of 45 ADLs (53%). • Improvements in the ADLs related to family and social life, mobility and transportation.	Highsmith et al. 2016b.(n.a.) Kannenberg et al. 2013(n.a.).
Preference, Satisfaction, Quality of Life (QoL)	Prosthetic Evaluation Questionnaire (PEQ)	Significantly improved: Perceived Response, Social Burden, Utility, and Well-Being. Positive trend: Appearance and Sounds. No difference: Ambulation, Frustration and Residual Limb Health	Highsmith et al. 2014c. (++) (+) (0)

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
**Responsiveness: percentage of subjects showing 'clear' or 'very clear' benefit with Genium.
*** mostly C-Leg was used at baseline. Please refer to 'Previous prosthesis' section.

Author's Conclusion

"Most of the reviewed evidence reports on active, community ambulating transfemoral amputees transitioning from C-Leg to Genium. The quality of the evidence is predominantly moderate and high showing improvements in outcomes when compared to conventional MPKs and NMPKs. Accommodation with and use of Genium resulted in more physiological gait during level walking, ramp and stair ambulation, as well as reduced loading and compensatory mechanisms of the sounds side. More symmetrical gait and more physiological, evenly distributed loading of sound and prosthetic sides could perhaps contribute to reducing the long-term risks of secondary physical complications in prosthetic users (i.e., osteoarthritis, osteoporosis). Mobility and functional levels were both significantly improved, while positive effects on performance in and safety of activities of daily living were demonstrated by both performance-based and patient-reported outcome measures. Significant improvements in quality of life, as measured by the PEQ, were also reported. At this time, it is unclear if results are generalizable beyond unilaterally involved, community ambulators with TFA." (Mileusnic et al. 2021)

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