
Reference

Highsmith MJ, Kahle JT, Bongiorno DR, Sutton BS, Groer S, Kaufman KR.

University of South Florida College of Medicine, School of Physical Therapy & Rehabilitation Sciences, Tampa, FL, USA.

Safety, energy efficiency, and cost efficacy of the C-Leg for transfemoral amputees: A review of the literature

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Products**C-Leg vs NMPKs vs other MPKs**

Major Findings

With C-Leg compared to NMPKs:

→ **Improved safety**

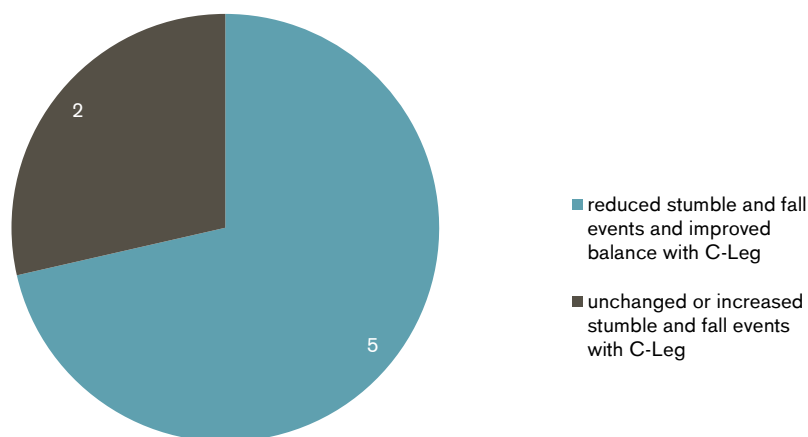
Reduced stumbles and falls
Improved safety

→ **Increased physical activity**

→ **Trend for increased energy efficiency**

→ **Cost effective and therefore worth funding**

Reduced stumble and fall events with C-Leg



7 articles discussing stumble and fall events as well as balance were reviewed. 5 of them showed reduced stumble and fall events and improved balance with C-Leg.

Population

Subjects:	440 for safety, 56 for energy efficiency, 146 for cost effectiveness
Previous prosthesis:	not reported
Amputation causes:	56% trauma, 23% others, 17% disvascular, 4.4% not reported
Mean age:	54 yrs for safety, 43 yrs for energy efficiency, 45 yrs for cost effectiveness
Mean time since amputation:	not reported
MFCL:	not reported

Study Design

Review Article:

Included publications: 7 for safety, 8 for energy efficiency, 3 for cost effectiveness.
Quality assessment: PEDro score and SIGN 50 assessment forms used for safety and energy efficiency, grading system for the assessment of methodologic quality for health economic evaluations.

Inclusion criteria: comparative study, objective/quantifiable outcome measures, C-Leg included, must address safety or energy efficiency in gait or cost effectiveness

Results

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 C-Leg	Reference
Metabolic Energy Consumption	Gas analysis at controlled walking conditions	Energy efficiency tended to be increased compared to Intelligent Prosthesis.	Chin 2006
		Energy efficiency tended to be decreased compared to Rheo Knee.	Johansson 2005
		Energy efficiency increased compared to NMPK when walking at medium and fast velocities.	Seymour 2007
		Energy efficiency increased compared to NMPK when walking at medium and slow velocities.	Schmalz 2002
	Summary	2 of 8 studies showed increased energy efficiency. 4 of 8 studies and one case report showed a trend for increased energy efficiency. 2 of these studies did show increased self-selected walking speed and increased total daily energy expenditure associated with increased physical activity.	
Safety	Safety and surrogate safety related outcomes	Reduction in number of stumbles by 59% and reduction in number of falls by 64%.	Kahle 2008
		K2 subjects: 15.8% reduction in frequency of stumbles. 4.5% reduction in frequency of uncontrolled falls. 80% reduction in number of uncontrolled falls. K3 subjects: 31% reduction in frequency of stumbles.	Hafner & Smith 2009
		Improved balance performance measured by improved composite	Kaufman 2008
	Balance and balance confidence		

Category	Outcomes	Results for C-Leg	Reference
		score.	
		Subject reported 30% increase in balance confidence measured by Activities-Specific Balance Confidence (ABC) scale.	Steven & Carson 2007
		69.8% of subjects rated “My overall balance with the prosthesis” better and 67.2% of subjects rated “I fall while wearing my prosthesis” better.	Berry 2009
		C-Leg never collapsed compared to NMPKs during all tested conditions as walking, sudden stopping, sidestepping, stepping on an object and tripping by disrupting swing extension.	Blumentritt 2009
	Summary	5 of 7 studies provide improvements in self-reported reduction in stumble and fall events and improved balance. Additional improvements in knee stability and balance confidence were reported.	
Health economics	Health economic analysis	Health system perspective incremental ratio of €3218/QALY was reported, which falls well within standard cost-effectiveness thresholds.	Brodtkorb 2008
		Productivity losses were reported as being lower.	Gerzeli 2009
		Lower productivity cost and lower housekeeping assistance cost.	Seelen 2009
	Summary	All studies found that C-Leg is the dominant prosthesis strategy providing lower social cost and positive QALY (Quality-adjusted life year) gain.	

Author’s Conclusion

“There was sufficient evidence to suggest increased efficacy of the C-Leg in the areas of safety, energy efficiency and cost when compared with other prosthetic knees for transfemoral amputees. Regarding safety, available evidence supports a grade “B” recommendation that following accommodation with a C-Leg, users will experience a reduction in stumble and fall events and have improved balance. Use of the C-Leg for the purpose of improving energy efficiency is supported by a grade “D” recommendation. However, research has shown that amputees spontaneously increase their physical activity in the free-living environment when using the C-Leg compared to a non-microprocessor controlled knee. So, energy efficiency may not be of primary relevance. Finally, evidence supports a grade “B” recommendation that the C-Leg is cost effective and worth funding. Based on standardized review criteria, methodologic quality could be improved and the risk of bias minimized with improved study design, decreased attrition, and use of double blinding for micro-

processor-controlled knee prosthetic studies. While these are worthwhile goals, the practicality of some of these methodological changes in prosthetic research is currently unrealistic. Specifically, patients recognize differing prosthetic components and the different prosthetic knees need to be aligned differently, which makes it unrealistic to conduct double-blind studies. So, given these constraints, the grades of recommendations demonstrate that the C-Leg is a clinically significant improvement for transfemoral amputees." (Highsmith et al. 2010)

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