

Reference

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Cost-effectiveness and budget impact of the microprocessor-controlled knee C-Leg in transfemoral amputees with and without diabetes mellitus

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Products

C-Leg

Major Findings

With C-Leg compared to NMPKs:

→ **C-Leg reduces the rate of fatal falls by approximately 83 %**

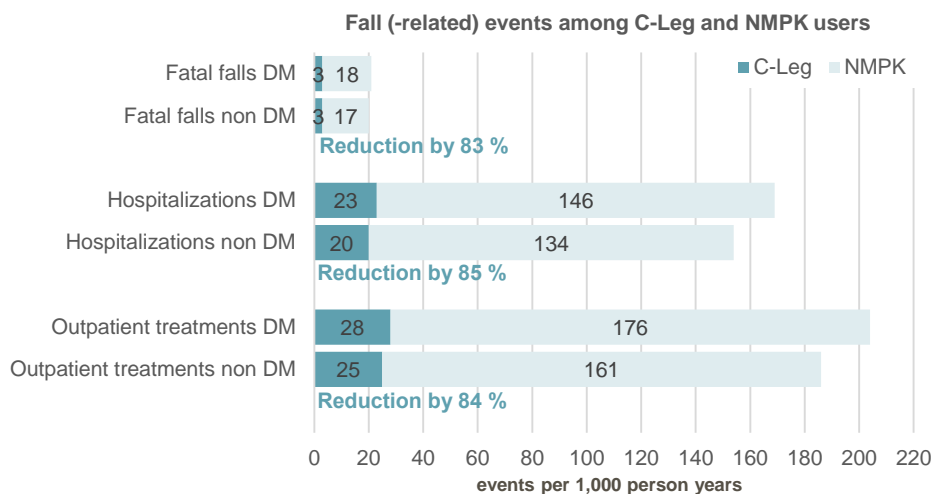
Prevention of 15 diabetes mellitus (DM) or 14 non-DM fall-related death per 1000 persons years (PY)

→ **C-Leg reduces the rate of fall-related hospitalizations by approximately 85 %**

Reduction from 134 to 20 per 1000 PY in amputees without DM and from 146 to 23 in amputees with DM

→ **C-Leg reduces the rate of outpatient treatments by approximately 84 %**

Reduction from 161 to 25 per 1000 PY in amputees without DM and from 176 to 28 in amputees with DM



→ **The use of C-Leg results in life years (LYs) gained**

On average, C-Leg users without DM gain 1.96 LYs and C-Leg users with DM 0.55 LYs

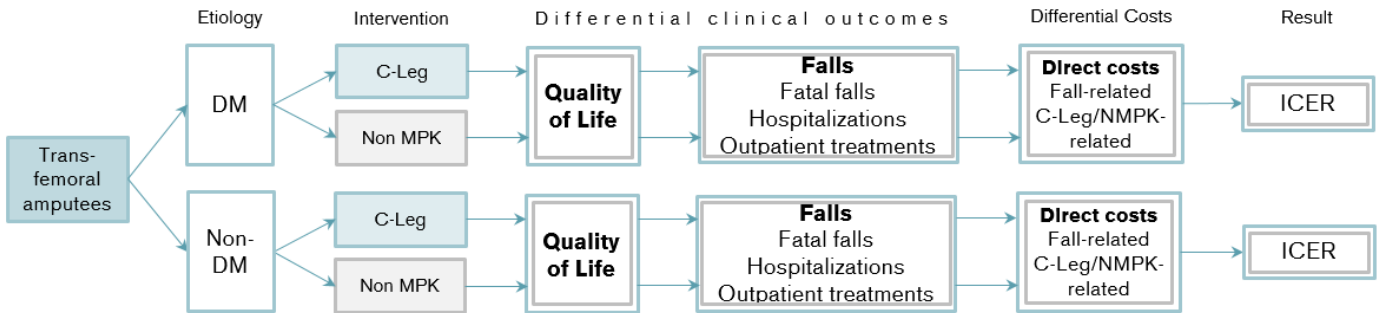
Population

Subjects:	transfemoral amputees with and without DM from the DRG statistic 2005 – 2017 of the Federal Statistic Office of Germany
Previous prosthesis:	NMPK
Amputation etiologies:	DM, in the cohort non-DM the etiology of amputation was not distinguished
Age:	40+ years, stratified 40-49, 50-59, 60-69, 70-79, 80+
Mean time since amputation:	not further defined
MFCL:	not relevant, C-Leg use indicated

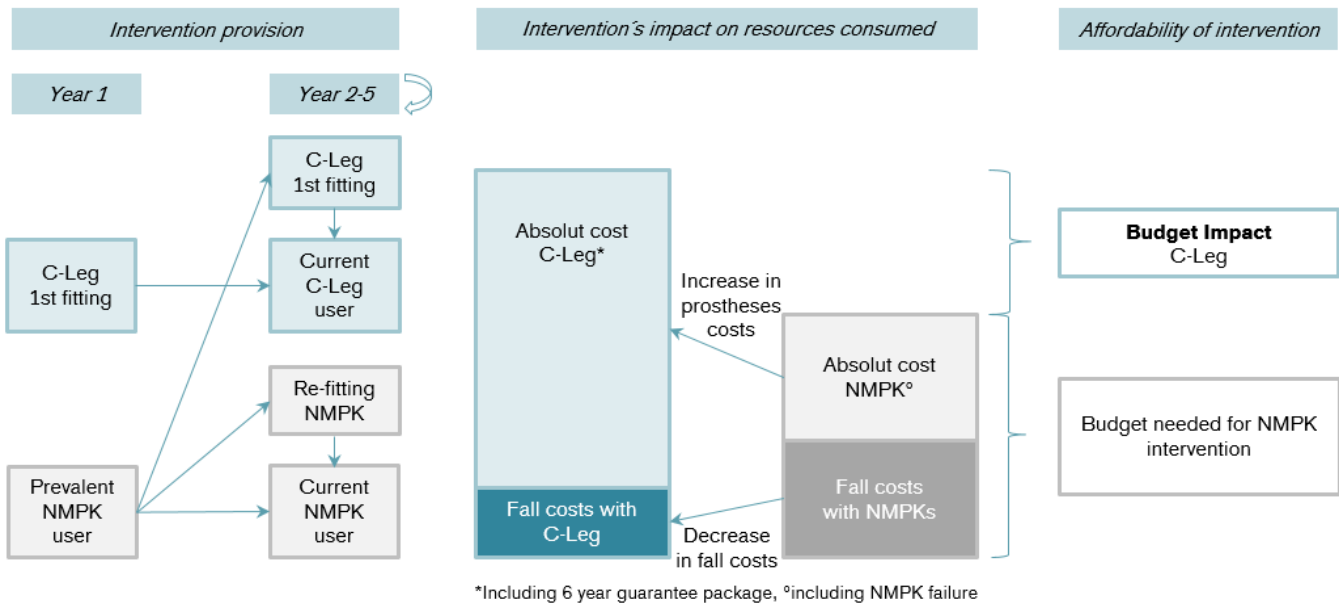
Study Design

A decision-analytic model was used to perform a **cost-effectiveness analysis** over a time horizon of **25 years** from the **payer perspective** (statutory health insurance).

Direct health care costs for hospital treatments of fall-related injuries were determined for common fall injury types (e.g. hip, femur, wrist and shoulder fractures) based on German DRGs. Direct health care costs for inpatient rehabilitation treatments were taken from the German pension insurance. Outpatient treatment costs were obtained from a German health economics study by Bleibler et al. (2014). Fatal fall costs were assumed to be equal to the costs of hospital treatments.



Furthermore, this model was used to perform a **budget impact analysis** over a time horizon of **5 years**.



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

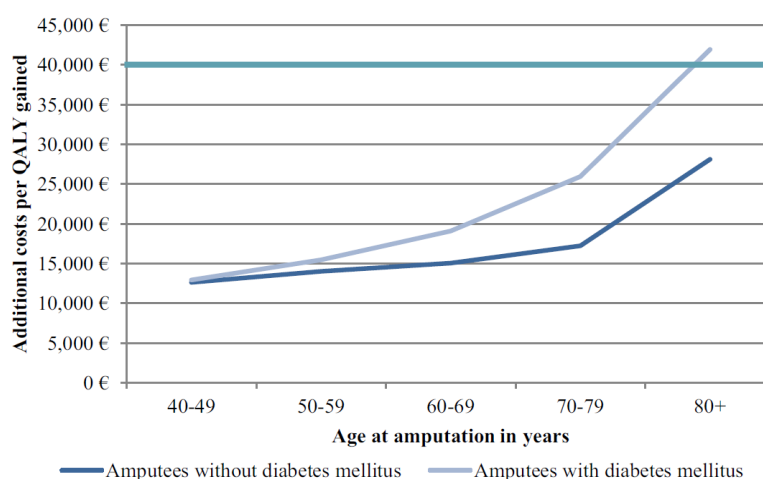
Cost-effectiveness analyses results

→ C-Leg is a likely cost-effective device from the payer perspective

Over a time horizon of 25 years, the incremental cost-effectiveness ratio (ICER) was 16,123 Euros per quality-adjusted life years gained (QALY) for amputees without DM and 20,332 Euros per QALY gained with DM.

There is moderate uncertainty and a probability of 97–99% that C-Leg is cost-effective at an ICER threshold of 40,000 Euros (\approx German GDP per capita in 2018) per QALY gained.

Almost the entire cohort is below the ICER threshold of 40,000 Euros, while the increase in ICER values is accelerated in patients 70+ years old, and more pronounced in patients with DM.



(Figure adapted from Kuhlmann et al. 2020)

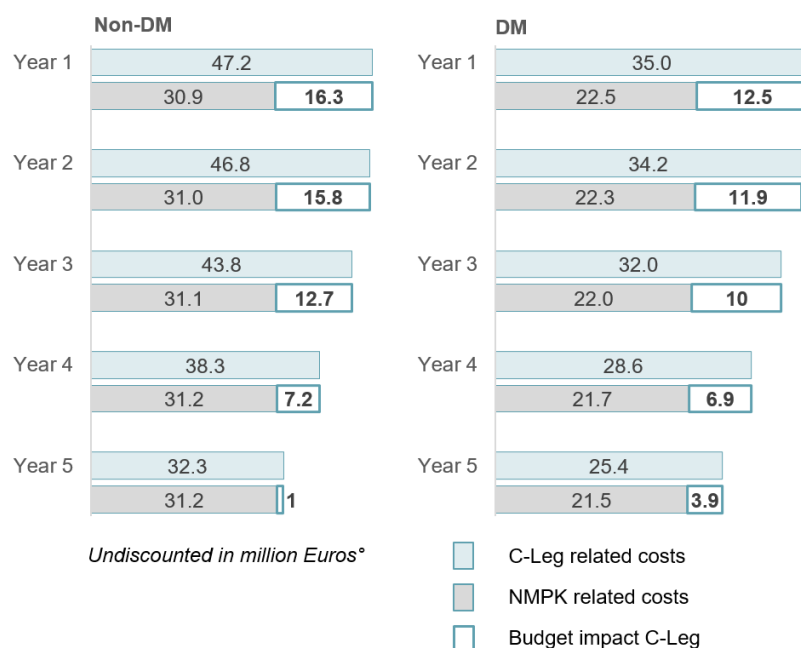
Category	Outcomes	Results for C-Leg compared to NMPKs	Sig.*
Cost-effectiveness analysis (discounted by 3%)	QALYs gained	Non DM: 1.74 DM: 0.92	n.a.
	Additional costs (in Euros)	Non DM: 27,976 DM: 18,660	n.a.
	ICER (in Euros)	Non DM: 16,123 DM: 20,332	n.a.
Probabilistic sensitivity analysis	At an ICER threshold of		n.a.
	- 40,000 Euros/ QALY gained, probabilities that C-Leg is cost-effective were 99% in non-DM and 97% in DM cohort		
	- 20,000 Euros/ QALY gained, probabilities that C-Leg is cost-effective were 70% and 44%, respectively		
	- 20,000 Euros/ QALY gained, probabilities that C-Leg is cost-effective were 59% for both patient groups combined		

Category	Outcomes	Results for C-Leg compared to NMPKs	Sig.*
	ICER ranges (in Euros)	Q _{0.025} –Q _{0.975} intervals non DM: 8,098 to 32,631 Q _{0.025} –Q _{0.975} intervals DM: 9,465 to 40,721	
	Univariate and multivariate sensitivity analysis	Input parameters with highest impact on cost-effectiveness are: - Effects of falling - Proportion of medical falls - C-Leg price	n.a.

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

Budget impact analyses results

→ Over the period of 5 years (2020-2024), a diminishing effect in the size of the annual budget impact of C-Leg in comparison to NMPKs is observed.



° assumption that all new prosthesis users received C-Leg and that 50% of NMPK users whose prostheses were worn out switched to C-Leg

Category	Outcomes	Results for C-Leg compared to NMPKs	Sig.*
Budget impact analysis (undiscounted)	Total (in million Euros)	Difference non DM: 53.0° Difference DM: 45.2°	n.a. n.a.
	Probabilistic sensitivity analysis (in million Euros)	Q _{0.025} –Q _{0.975} intervals non DM: 27.5 to 70.0 Q _{0.025} –Q _{0.975} intervals DM: 30.1 to 58.1	n.a. n.a.
	Univariate and multivariate sensitivity analysis	Input parameters with highest impact on the budget impact are: - Cost parameters: price of C-Leg, hospitalization costs - Effects of falling - Proportion of medical falls - NMPK survival time	n.a.

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

Author's Conclusion

Citation by Kuhlmann et.al 2020:

"The results of our study suggest that the C-Leg provides substantial additional benefits and is very likely to be cost-effective in transfemoral amputees with and without DM from the perspective of the German SHI when adopting an ICER threshold of around 40,000 Euro per QALY gained. For patients without DM and for both patient groups combined, C-Leg may also be cost-effective at a threshold of 20,000 Euro per QALY saved."

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