

Reference

Cutti AG, Lettieri E, Del Maestro M, Radelli G, Luchetti M, Verni G, Masella C.
Centro Protesi INAIL, Vigorso di Budrio, Italy.

Stratified cost-utility analysis of C-Leg versus mechanical knees: Findings from an Italian sample of transfemoral amputees

Prosthetics and Orthotics International 2016; epub.

Products

C-Leg

Major Findings

With C-Leg compared to NMPKs:

→ Quality of life improves

The quality-adjusted life years (QALYs) are ca. 10 % higher than with an NMPK

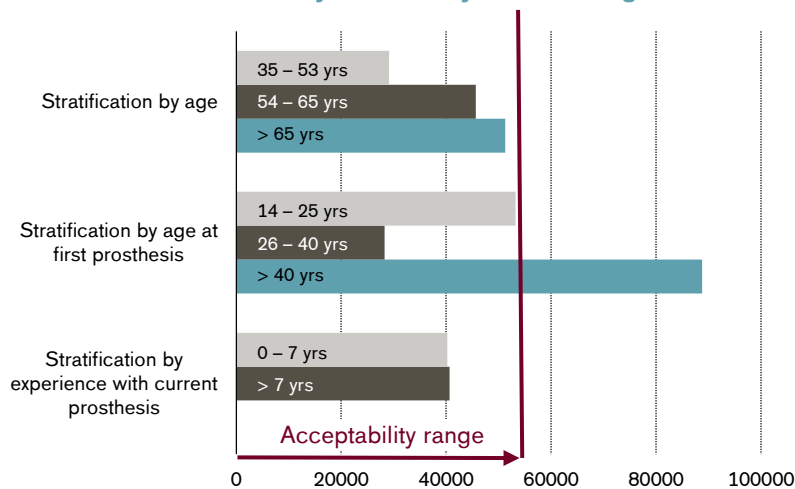
Physical mobility and the ability to perform usual activities improve significantly

Self-care, Pain, discomfort, anxiety or depression show a trend of improvement

→ Costs and gain of quality of life by C-Leg are acceptably balanced

In those receiving their first prosthesis in an age older than 40 specific attention has to be given to recognize and properly address psychosocial and psychophysical barriers.

The incremental cost-utility ratio for 5 years of C-Leg



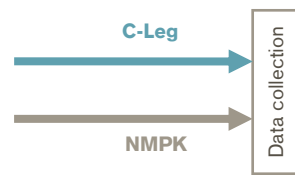
The incremental cost-utility ratio (ICUR) gives information about how much a “unit of utility improvement” costs. For subjects receiving their first prosthesis in an age older than 40 years specific attention needs to be given to psychosocial and psychophysical confounders to ensure socioeconomic acceptability.

Population

Subjects: 127 transfemoral amputees
Prosthesis: 70 C-Leg, 57 NMPKs
Amputation causes: work-related trauma
Mean age: 56.7 yrs (C-Leg), 58.5 yrs (NMPKs)
Mean age at first prosthesis: 31.5 yrs (C-Leg), 34.2 yrs (NMPKs)
MFCL: not reported

Study Design

Retrospective study:



The compared groups of C-Leg and NMPK users were statistically comparable and did not show any differences in terms of demographics, amputation and socio-economic variables.

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 C-Leg		Sig.*	
		C-Leg	NMPK		
Preference, Satisfaction, Quality of Life (QoL)	EQ-5D				
	<i>Physical mobility</i>	No problems	66%	37%	++
		Some problems	34%	63%	
	<i>Self-care</i>	No problems	87%	76%	+
		Some problem	11%	21%	
		Unable	1%	4%	
	<i>Usual activity</i>	No problems	71%	47%	++
		Some problem	27%	49%	
		Unable	1%	4%	
	<i>Pain or discomfort</i>	No pain / discomfort	29%	19%	+
		Moderate pain / discomfort	70%	77%	
		Extreme pain / discomfort	1%	4%	
	<i>Anxiety or depression</i>	Not anxious / depressed	73%	68%	+
		Moderately anxious / depressed	26%	28%	
		Extremely anxious / depressed	1%	4%	
	1-Year QALY (quality adjusted life years)	With C-Leg the calculated QALYs are 9% higher than with an NMPK. This indicates 33 days more spent in "perfect health" a year.		++	
	5-Year QALY	In 5 years with C-Leg 6 months more are spent in "perfect health".		++	

Health Economics	ICUR (Incremental cost-utility ratio)	The ICUR gives information about how much a “unit of utility improvement” costs.	
		$\frac{\text{incremental costs over 5 yrs}}{\text{incremental QALYs over 5 yrs}}$	
		In this publication a value of 54,120€/QALY was assumed as acceptability threshold.	
	<i>Stratified by age</i>	35 - 53 yrs	29,106 (under threshold)
		54 - 65 yrs	45,671 (under threshold)
		> 65 yrs	51,266 (under threshold)
	<i>Stratified by age at first prosthesis</i>	14 - 25 yrs	53,215 (under threshold)
		26 - 40 yrs	28,269 (under threshold)
		> 40 yrs	88,779 (over threshold)
		For subjects receiving their first prosthesis in an age older than 40 years specific attention needs to be given to psychosocial and psychophysical confounders to ensure socioeconomic acceptability.	
	<i>Stratified by experience with current prosthesis</i>	0 - 7 yrs	40,236 (under threshold)
		> 7 yrs	40,626 (under threshold)

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

Author's Conclusion

“Our study described an application of sCUA to support decision-making on both the adoption and the modality of provision of C-Leg, across different subgroups of patients. In particular, we showed that providers should supply C-Leg to patients receiving the first prosthesis: (1) before 40 years of age, because the higher costs are balanced by substantial improvements in QOL; (2) patients of >40 years, because of relevant and crucial improvements in mobility, but adopting interventions that address the psychosocial and psychophysical barriers affecting usual activities, self-care, pain, and anxiety/depression.” (Cutti et al., 2016)

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