Safety, Energy Efficiency, and Cost Efficacy of the C-Leg for Transfemoral Amputees: A review of the literature

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Background: There is an estimated 1.3 million person in the United States that have amputation of the lower extremity. Upper extremity aids can help TFAs attain successful ambulation but it may cause an adaptive change in their gait pattern. It is important for amputees to feel stable and safe while walking with their prosthesis. Transfemoral amputees use a prosthetic knee for ambulation and are generally available with or without microprocessor control. Microprocessor-controlled prosthetic knees (MPK) are commonly equipped with sensors to continuously detect the position, range and forces acting upon the knee throughout the stance and/or swing phases of gait and other activities. The Otto Bock C-Leg (Otto Bock; Duderstadt, Germany) is an MPK that controls stance and swing phase and adjusts to the requirements of the prosthesis wearer at a rate of fifty times per second. Such technological advancements usually come at considerable cost to the healthcare system. It is necessary to evaluate such key features of a component and their cost effectiveness.

Objectives: The purpose of this literature review was to determine a grade of recommendation regarding safety, energy efficiency during gait and cost effectiveness of the C-leg for TFAs.

Criteria for selecting studies for this review:

Types of studies: Must be a comparative study; Study used objective/quantifiable outcome measures; C-Leg MPK utilized in one arm of the trial; Must address one or more of the three key areas of interest: safety, energy efficiency in gait, cost effectiveness. Study types inclused: Case study, cross-over, Pre/Post Test, repeated measures, observational cross sectional,

Types of participants: Studies included persons with amputation from ages 25 to 65 years old on average. Amputation was caused by dyvascular, trauma, and other causes (table 1,2,3).

Types of interventions: Table 1,2,3

Types of outcome measures: Table 1,2,3

Search strategy for identification of studies: The Medline and CINAHL data bases were searched via the Ovid and EBSCO Host interfaces (respectively) on March 4, 2010.

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.

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Table I. Safety.

Study	Hafner et al. (2007)	Stevens and Carson (2007)	Kaufman et al. (2007)	Kahle et al. (2008)	Berry et al. (2009)	Blumentritt et al. (2009)	Hafner and Smith (2009)
PEDro score	4	n/a	5	4	3	4	4
Risk of bias	Moderate	n/a	Moderate	Moderate	Moderate	Moderate	Moderate
Effect size	Not enough information	n/a	Not enough information	0.8	Not enough information	Not enough information	0.2–1.4
Study design	Cross-over	Case report	Cross-over	Cross-over	Pre/post test	Repeated measures	Cross-over (re-analysis)
All study outcome measures	Walking tests, PEQ, step count, stumbles/falls, stairs/ramps, preference	Activities Specific balance Confidence scale	Balance, gait biomechanics	Walking tests, stumbles/falls, stairs (MRPP), PEQ, preference	Mixed topic survey	Gait, stumble and fall biomechanics	Walking tests, PEQ, step count, stumbles/falls, stairs/ramps, preference
Measurement method of interest	Questionnaire	Questionnaire	Motor activity and balance tests	Self-report on stumbles and falls	Questionnaire	Biomechanics of situations bearing the risk of falling	Questionnaire
Results of outcome measures of interest with statistical significance†	($p < 0.05$) Reduced frequency: Stumbles (19%), semi-controlled falls (12%), and falls (5%)	Activities Specific balance Confidence scale Balance efficacy increased 30%†	($p < 0.01$) Balance-improved	($p \leq 0.03$) Decreased number of stumbles (59%) and decreased number of falls (64%)	($p < 0.0001$) 2 fall related questions "better": "My overall balance with the prosthesis" (69.8%) "I fall while wearing my prosthesis" (67.2%)	No statistical analysis reported	($p \leq 0.05$) Reduced stumble frequency: K2 (15.8%), K3 (31%) Reduced number of falls: K2 (80%) Reduced falls frequency: K2 (4.5%)
Sample							
Total *n*	17	1	15	19	368	3	17
Dysvascular PVD and/or DM	1	0	1	7	88	0	1
Trauma	10	1	7	12	185	2	10
Other	6	0	7	0	95	1	6
Age††	48 ± 16 (21–77)	30	42 ± 9 (26–57)	51 ± 19 (22–83)	55 ± NR (15–85)	25, 42, 43	48 ± 16 (21–77)
Accommodation time on C-Leg	1–33 weeks	9 days. 6-month follow-up.	10–39 weeks	90 days	6–9 months	30 min*	1–33 weeks

†Statistically significant outcomes related to improvement with the C-Leg. Statistical significance and effect size not applicable (n/a) for case studies. ††Mean Age in years ± SD (not reported [NR]) (Range); unless listed individually. *C-Leg preferred knee.

Table II. Energy efficiency.

Study	Schmalz et al. (2002)	Perry et al. (2004)	Johansson et al. (2005)	Orendurff et al. (2006)	Chin et al. (2006)	Seymour et al. (2007)	Kaufman et al. (2008)	Highsmith et al. (2009)
PEDro score	5	n/a	6	4	5	3	5	n/a
Risk of bias	Moderate	n/a	Low	Moderate	Moderate	Moderate	Moderate	n/a
Effect size	0.8	n/a	Not enough information	Not enough information	Not enough information	0.9–1.8	Not enough information	n/a
Study design	Pre/post test	Case report	Repeated measures	Cross-over	Pre/post test	Pre/post test	Cross-over	Case report
All study outcome measures	Energy efficiency: Expired gas, heart rate	Energy efficiency: Expired gas, heart rate. Gait biomechanics	Energy efficiency: Expired gas, heart rate. Gait biomechanics	Energy efficiency: Expired gas, heart rate, walking speed	Energy efficiency: Expired gas, heart rate	Energy efficiency: Expired gas, heart rate, obstacle course, walking speed, SF-36	Energy efficiency: Expired gas and doubly labeled water, heart rate	Heart rate, walking speed, Physiological cost index
Speed control method	Treadmill	Over ground/ self-paced	Over ground/ self-paced	Timing lights	Walking meter	Treadmill	Treadmill/free living	Over ground/ Self-paced
Prosthetic alignment method	LASAR posture device	Experienced prosthetist	Experienced prosthetist	Experienced prosthetist	Experienced prosthetist	Not reported	LASAR posture device	Experienced prosthetist
Results of outcome measures of interest with statistical significance†	($p < 0.05$) 6–7% Increased energy efficiency at medium and slow walking speeds	184% Reduction of normal oxygen cost†	None	None	None	($p < 0.05$) Increased energy efficiency @ typical (6.4%) and fast (7%) pace walking	($p \leq 0.04$) Increased energy expenditure: Total daily (8%) Physical activity (6%)	20.2% Reduced post-activity heart rate†
Sample								
Total *n*	6	1	8	8	4	13	15	1
Dysvascular PVD and/or DM	0	0	2	Not reported	0	0	1	1
Trauma	6	0	3	Not reported	3	Not reported	7	0
Other	0	1	3	Not reported	1	13	7	0
Age††	37 ± 9 (27–53)	≈ 28	44 ± 8 (29–54)	49 ± 10 (NR)	24 ± 8 (NR)	46 ± 13 (30–75)	42 ± 9 (26–57)	82
Accommodation time on C-Leg	Not reported	≈ 8 months	10 h*	3 months	Not reported**	2–44 months***	10–39 weeks	90 days

†Statistically significant outcomes related to improvement with the C-Leg. Statistical significance and effect size not applicable for case studies. ††Mean age in years ± SD (range or not reported [NR]); unless listed individually. *Four subjects routinely used the C-Leg. Remaining four subjects given 10 h to accommodate to the C-Leg. **Chin et al. stated "After changing from the IP to C-Leg, the subjects were allowed to practice walking to familiarize themselves with it." p75. ***C-Leg was preferred knee for all subjects.

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Table III. Cost effectiveness.

Study	Brodtkorb et al. (2008)	Gerzeli et al. (2009)	Seelen et al. (2009)
Grading score (0 = extremely poor, 100 = excellent)	82	91	81
Study setting	Sweden	Italy	The Netherlands
Effect size for total cost and effectiveness	Not enough information	Not enough information	1.3 (utility for new and experiences users) 1.5 (utility for new users only) −0.2 (total costs for new and experienced users) 0.2 (total costs for new users only)
Study design	Observational, cross sectional, Markov modeling (hypothetical cohort)	Observational, cross sectional	Observational, cross sectional
Type of economic evaluation (utility weight if used)	Cost-utility (EuroQol (EQ) Visual Analog Scale)	Cost-utility (EQ-5D)	Cost-consequences (SF-6D)
Study perspective	Healthcare system	Healthcare system and societal	Patient, healthcare system and societal
Comparison	C-Leg versus NMPK	C-Leg versus NMPK	C-Leg versus NMPK
Time horizon	8 Years	5 Years	1 Year
Sensitivity analysis	Probabilistic	1-way on discount rate only	1-way (sub-group analysis)
Incremental analysis performed	Yes	Yes	No
All study outcome measures	Costs (2006 Euros), Quality Adjusted Life Years (QALYs)	Costs (Euros base year not specified), QALYs	Costs (Euros base year not specified), SF-36 scores, QALYs
Results of outcome measures of interest with statistical significance†	No statistical analysis reported	EQ-5D Physical mobility section ($p = 0.045$) EQ-5D Mean utility score 9% increase ($p = 0.007$)	Intervention costs and prosthetics costs ($p = 0.000$), patient/family cost ($p = 0.007$), SF-6D and SF-36 sub scores (range of p values from 0.001–0.071)
Reported incremental ratio (C-leg vs. NMPK)	€3218/QALY (US$ 4560/QALY)	€258/QALY (US$ 870/QALY)	€52864/QALY (US$7 4697/QALY) 1st time users, €65398/QALY (US$ 92407/QALY) all users

(*continued*)

Table III. (*Continued*).

Study	Brodtkorb et al. (2008)	Gerzeli et al. (2009)		Seelen et al. (2009)	
Sample					
Total *n*	20	100		26*	
		50 C-Leg	50 NMPK	13 C-Leg*	13 NMPK
Dysvascular PVD and/or DM	NR	0	0	1	4
Trauma	NR	49	47	9	7
Other	NR	1	3	3	2
Age††	41 ± 3 (NR)††	46 ± 12 (18–65)	45 ± 12 (18–65)	47 ± 12 (18–65)	47 ± 11 (18–65)
Accommodation time on C-Leg	45 ± 5 months††	> 1 year	n/a	2.4 (± 1.2) years	n/a

NMPK is non-microprocessor knee. †Statistically significant outcomes related to improvement with the C-Leg. ††Standard Error (not reported [NR]). *Sample included one subject with hip disarticulation who utilized a C-Leg.