

Reference

Hahn A, Lang M.

Effects of Mobility Grade, Age and Etiology on functional benefit and safety of subjects evaluated in over 1200 C-Leg trial fittings in Germany

J Prosthet Orthot. 2015;27(3):86-94

Products

C-Leg and C-Leg Compact

Major Findings

With C-Leg and Compact compared to the previous prosthesis:

→ **Utilization of functional benefit is high even after one-day test fittings.**

(ranging from 83% to 95%, reduction of walking aids 46%)

→ **Utilization of functional benefit is independent from age, mobility grade and/or etiology.**

Largest correlation < 0.251

→ **Age, mobility grade and/or etiology have no meaningful diagnostic predictive power**

Ranging from 0.7% to 9%

→ **Even within test fitting significant changes in mobility grade can be observed**

50% of subjects increased their mobility grade from MFCL 2 to MFCL 3

22% of subjects increased their mobility grade from MFCL 3 to MFCL 4

→ **Fear of falling decreased by 86%**

→ **Gait was improved by C-Leg**

Harmonized gait pattern
(88-95% of subjects)

Reduction of walking aids
(23-29%)

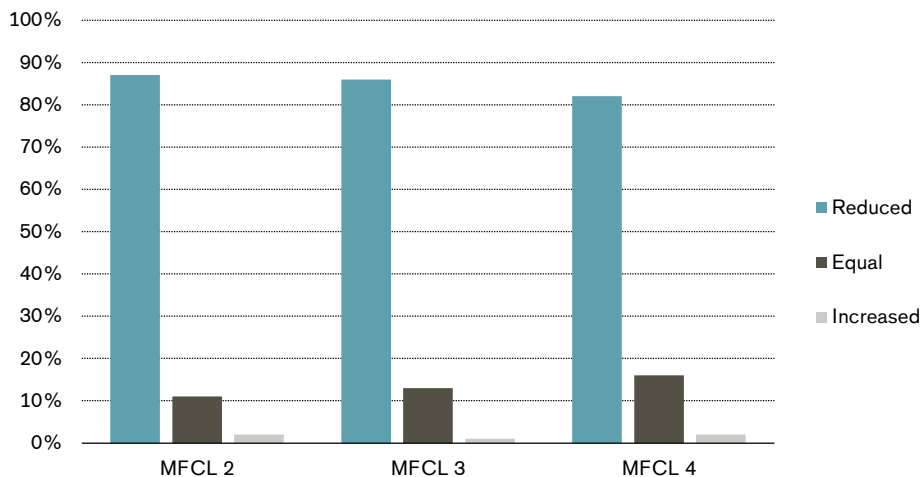
Relief of sound limb
(95% of subjects)

Divided attention while walking
(81-88%)

Walking with varying speeds
(71-93%)

Walking effort
(81-88%)

Fear of falling with C-Leg compared to previous prosthesis

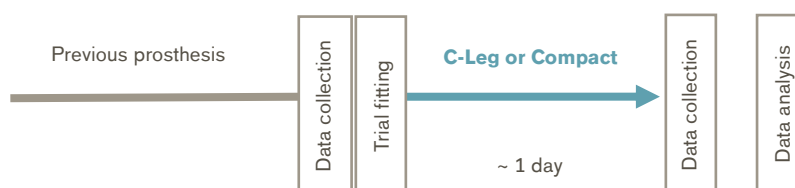


Population

Subjects:	1223 amputees (Transfemoral 84%, Knee disarticulation 13%, Hip disarticulation 3%)
Previous prosthesis:	not reported
Amputation causes:	Trauma (43%), vascular disease incl. diabetes (26%), tumor (13%), infection (6%), combat trauma (4%), malformation (2%), others (6%), not specified (13%)
Mean age:	55.6 ± 15.1 yrs
Mean time since amputation:	17.5 ± 18.9 yrs
MFCL:	K2 (38.4%), K3 (39.2%), K4 (6.5%) (K1 (6.1%) excluded from analysis)

Study Design

Retrospective, cross sectional analysis:



Data of C-Leg or C-Leg Compact trial fittings were gathered from ca. 445 prosthetic clinics during the process of requesting advice or customer service or during the C-Leg prosthetists certification process.

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 (Compact in brackets)	Sig.*
Response on C-Leg	Subgroup correlation analysis	Age, mobility grade and etiology do not correlate with subjects capability to benefit from C-Leg (Kendal tau $-0.251 < \tau < 0.140$).	++
	Diagnostic power	Age, mobility grade and etiology do not possess relevant diagnostic power to predict the outcomes. Perceived safety: 1.9% Relief of sound leg: 0.8% Divided attention: 3.7% Gait pattern harmonization: 0.7% Variable gait speed: 9.0 % Reduction of effort: 1.4 % Reduction of walking aids: 6.4 %	++
Level Walking	Prosthetist's questionnaire	A relief of the sound limb was documented in 95% (95%) of the subjects.	n.a.
		Gait pattern was harmonized in 95% (88%) of the subjects.	n.a.
		The capability to vary gait speed increased in 93% (71%) of the subjects.	n.a.

Category	Outcomes	Results for C-Leg (Compact in brackets)	Sig.*
		In 23 % (29%) of the subjects the use of walking aids could be reduced.	n.a.
Cognitive Demand	Prosthetist's questionnaire	The capability to divide attention while walking increased in 94% (85%).	n.a.
Energy	Prosthetist's questionnaire	Walking effort was reduced in 88% (81%) of the subjects.	n.a.
Safety	Patients survey	82% of subjects reported at least one fall in the last 12 months, 49% reported multiple falls.	n.a.
		Fear of falling decreased by 86% and across all ages and mobility grades.	++
		83% (91%) of subjects reported a clear or very clear increase of safety.	n.a.
Activity, Mobility, ADL	MFCL	50 % of the subjects rated as MFCL 2 prior to the test fitting were re-rated as MFCL 3 with C-Leg. Another 17% demonstrated a considerable intra-class increase.	++
		22 % of the subjects rated as MFCL 3 prior to the test fitting were re-rated as MFCL 4 with C-Leg. Another 29% demonstrated a considerable intra-class increase.	++

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

Author's Conclusion

"Trial fittings are an appropriate and effective method to identify C-Leg responders. In the cohort of likely and preselected responders we observe a high degree of utilization of functional benefit. The degree of the utilization seems to be of similar magnitude when compared those observed in C-Leg populations. Responders can be found in all age groups, all mobility grades and all amputation etiologies.

Safety and specifically falls are a severe challenge in the transfemoral amputee population. The rates of subjects reporting annual falling is higher than reported before.

Age, mobility grade and amputation etiology do not correlate with a subjects capability to exhibit functional benefits when fitted with a C-Leg. Neither do any of these parameters possess relevant diagnostic power. We rather observe that trial fitting with a C-Leg does severely influences mobility grade rating itself. We therefore conclude that the assessment of an individual's potential is required to reveal the subjects potential and that none of those demographic factors and specifically the use of the evaluation of mobility grade rating are justified to deny such an assessment." (Hahn et al., 2015)

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