Reference

Hafner BJ, Smith DG.

Prosthetics and Orthotics Program, Department of Rehabilitation Medicine, University of Washington, Seattle, USA.

Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control

Journal of Rehabilitation Research and Development 2009; 46 (3):417–433.

Products

C-Leg vs NMPKs

Major Findings

With C-Leg compared to NMPKs:

MFCL K2 subjects

→ 50% of subjects improved to MFCL K3

→ Improvements in stair and hill mobility during descent

Stair assessment index score improved from 3.3 to 9 (173% increase)
Hill assessment index score improved from 5.4 to 7.5 (39% increase)

→ Walking velocity improved during hill ambulation, obstacle course and ambulation with an attentional demand by up to 27%

→ Improvements in stability and safety

Number of uncontrolled falls decreased by 80%

MFCL K3 subjects

→ 33% of subjects improved to MFCL K4

→ Improvement in stair mobility during descent

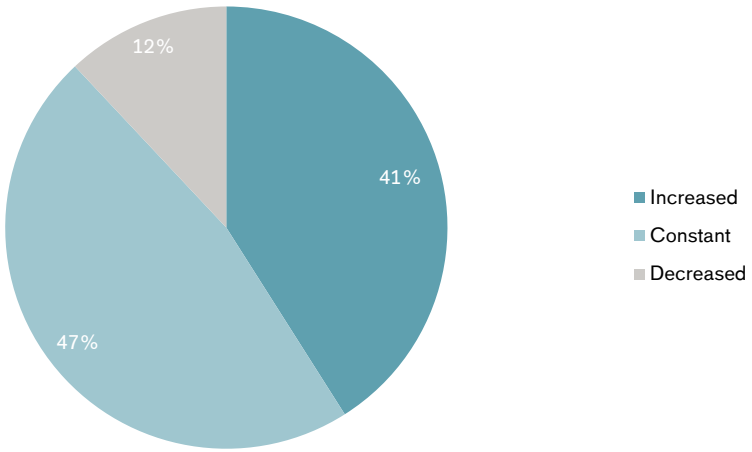
Stair assessment index score improved from 4.4 to 10.1 (173% increase)

→ Walking velocity improved during hill ambulation and obstacle course by up to 40%

→ Improvements in stability and safety

Frequency of stumbles decreased by 31%

Changes in mobility level when transitioning from NMPK to C-Leg



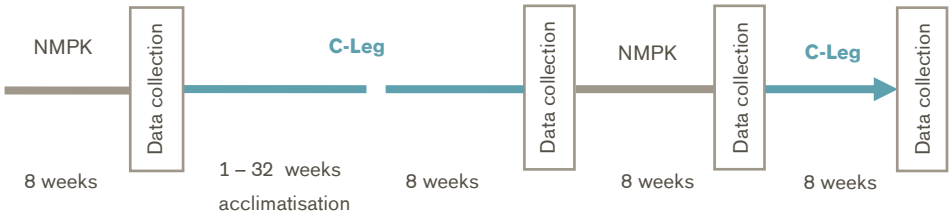
Assessment of mobility level MFC when transitioning from NMPK to C-Leg (n=17).

Population

Subjects:	17 unilateral, transfemoral amputees
Previous prosthesis:	NMPK
Amputation causes:	59% trauma, 18% malignancy, 12% infection, 6% dysfunction, 6% vascular disease
Mean age:	49.5 yrs (range from 21 – 77 yrs)
Mean time since amputation:	17.6 yrs (range from 2 – 67 yrs)
MFCL:	47% K2, 53% K3

Study Design

Interventional, A-B-A-B design:



After 4, 8 and 12 months of extended use they returned for another functional evaluation and assessment. After completing the study, subjects were provided with both prostheses and could choose between wearing C-Leg, NMPK or both prosthesis interchangeably.

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 compared to NMPKs	Sig.*
Stairs	Stair Assessment Index (SAI)	K2: **SAI score for descent improved from 3.3 to 9 (173% increase).** 3 points represent step-to pattern with rail, 9 points represent skipping step pattern without rail or assistive device.	++
		K3: **SAI score for descent improved from 4.4 to 10.1 (173% increase).** 4 points represent step-to pattern with assistive device, 10 points represent step-over-step pattern with rail and assistive device.	++
Ramps, Hills	Hill Assessment Index (HAI)	K2: **HAI score for descent improved from 5.4 to 7.5 (39% increase).** 5 points represent step a little past with assistive device, 8 points represent step-to without assistive device.	++
		K3: HAI score for descent tended to improve from 7.2 to 8.6 (19% increase). 7 points represent even step with assistive device, 9 points represent step a little past without assistive device.	+

Category	Outcomes	Results for C-Leg compared to NMPKs	Sig.*
		K2: **Walking velocity increased by 27%.**	++
		K3: **Walking velocity increased by 40%.**	++
Uneven Ground, Obstacle Course	Obstacle course (grass, wood chips, sand, a cement ramp, and cement stairs)	K2: **Walking velocity increased by 11%.**	++
		K3: **Walking velocity increased by 6.7%.**	++
Cognitive Demand	Ambulation with an attentional demand (verbal reverse-numbers test as subjects walked two sides of a busy city block)	K2: **Walking velocity increased by 12%.**	++
		K3: Walking velocity tended to be increased by 2.7%.	+
		K2: Attention accuracy tended to be increased.	+
		K3: Attention accuracy tended to be increased.	+
	Self-assessed confidence and concentration (PEQ addendum)	K2: **Multitasking while walking improved.**	++
		Mental energy expenditure, confidence while walking and difficulty with concentration tended to be improved.	+
		K3: **Confidence while walking and multitasking while walking improved.**	++
		Mental energy expenditure and difficulty with concentration tended to be improved.	+
Safety	Self-assessed stability and safety	K2: **Number of uncontrolled falls decreased by 80%.**	++
		Number of stumbles and semicontrolled falls tended to be decreased.	+
		K3: **Frequency of stumbles improved by 31%.**	++
		Number of stumbles, semicontrolled falls and uncontrolled falls tended to be decreased.	+
Activity, Mobility, Activities of daily living (ADLs)	Mobility Level	K2: 50% of subjects improved to K3. 50% of subjects stayed at K2.	n.a.
		K3: 33% of subjects improved to K4. 44% of subject stayed at K3. 22% of subjects decreased to K2.	
Preference, Satisfaction, Quality of Life (QoL)	Prosthetic Evaluation Questionnaire (PEQ) and Addendum	K2: Satisfaction tended to be improved by 21%.	+
		8 out of 9 subscales tended to be improved.	+
		K3: **Satisfaction improved by 38%.**	++
		3 out of 9 subscales improved: Ambulation, Sounds and Utility.	++
		5 out of 9 subscales tended to be improved.	+

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

Author's Conclusion

"This study examined the influence of active and passive knee control on the function and safety of persons with transfemoral amputation who were classified as MFCL-2 and MFCL-3. Both the MFCL-2 and MFCL-3 cohorts showed significant improvements in negotiating environmental obstacles (i.e., walking down inclines, walking downstairs, and walking over uneven terrain) while using the active-control knee as compared with the passive-control knee. Active control of the prosthetic knee also resulted in significantly fewer UC falls (MFCL-2 cohort). These benefits provided by active control of the knee allowed 50 percent of MFCL-2 subjects and 33 percent of MFCL-3 subjects to transition to a higher activity level by the end of

the study. Such a transition indicates that advanced technology, typically reserved for the most active subjects, equally benefits less active subjects and may address the functional limitations that prevent them from reaching higher levels of activity. Furthermore, the reduction in adverse events obtained with active knee control may lead to fewer injuries and lowered long-term medical costs in a population that is at-risk for falls and injury." (Hafner & Smith 2009)