Reference

Highsmith MJ, Kahle JT, Wernke MM, Carey, SL, Miro RM, Lura DJ, Sutton BS.

School of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, FL, USA.

Effects of the Genium knee system on functional level, stair ambulation, perceptive and economic outcomes in transfemoral amputees

Technology and Innovation 2016; 18: 139-150

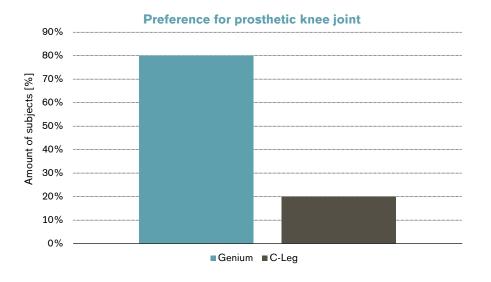
Products

Genium vs C-Leg

Major Findings

With Genium compared to C-Leg:

- → The quality of stair ascent and descent improved significantly
- → Mobility and functional level improved significantly
- → Perceived function and safety in ADLs was as good as with C-Leg or significantly better
- → 80% preferred Genium



Population

Subjects: 20 unilateral, transfemoral amputees

Previous prosthesis: C-Leg

Amputation causes: 70% trauma, 20% malignancy, 10% vascular

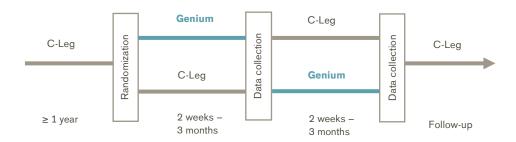
disease

Mean age: $46.5 \pm 14.2 \text{ yrs}$ Mean time since amputation: $17.7 \text{ yrs} \pm 15.6 \text{ yrs}$

MFCL: K3

Study Design

Interventional, randomized crossover design:



Results

Functions and Activities							Participation		
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Energy			Preference, Satisfac- tion, QoL	Health Economics

Category	Outcomes	Results for Genium		
Stairs	SAI (Stair Assessment Index)	SAI stair <i>ascent</i> score improved significantly from 6 to 11 points (median).		
		SAI stair <i>descent</i> median score was 11 for both knee joints. The mean score significantly improved by 9%.	++	
		Stair ascent and descent completion time did not differ significantly.	0	
Safety	Four Square Step Test	Time to complete the test significantly decreased by 9%.		
Activity, Mobility, Activities of Daily Living	AMP (Amputee mobility predictor)	Mobility increased significantly by 5%.		
(ADLs)	Step activity derived functional level	The functional level significantly increased by 6%.	++	
	ADL survey	Perceived function and safety in three of five ADL domains improved significantly. The other two domains showed no difference.	++	
Preference, Satisfaction, Quality of Life (QoL)	Survey	80% of the participants preferred Genium.		
Health Economics	ICER (Incremental cost- effectiveness ratio)	The ICER for reimbursing Genium ranges from \$6,000 to \$6,522 per unit of functional increase assuming a \$30,000 intervention cost difference.		

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

Author's Conclusion

"Accommodation and use of the Genium knee system compared with C-Leg improved stair walking performance, multi-directional stepping, functional level, and perceived function. Genium was also preferred compared to C-Leg in this group of high functioning community ambulators with unilateral transfemoral amputation. Finally, Genium is a more costly microprocessor knee system but, in this group of patients, is worth funding due to significant differences in functional performance with activities of daily living." (Highsmith et al., 2016)

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