

Reference

Lansade C, Chiesa G, Paysant J, Vicaut E, Cristina M-C, Ménager D.

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Impact of C-LEG on mobility, satisfaction and quality of life in a multicenter cohort of femoral amputees

Annals of Physical and Rehabilitation Medicine, Available online:

<https://doi.org/10.1016/j.rehab.2020.03.011>

Products

C-Leg

Major Findings

With C-Leg compared to previous knee joint (mostly non-microprocessor controlled knees "NMPKs"):

→ Significantly increased mobility

LCI-5 global score increased significantly by 11.2%

→ Higher satisfaction

QUEST 2.0 global score increased significantly by 19.6%

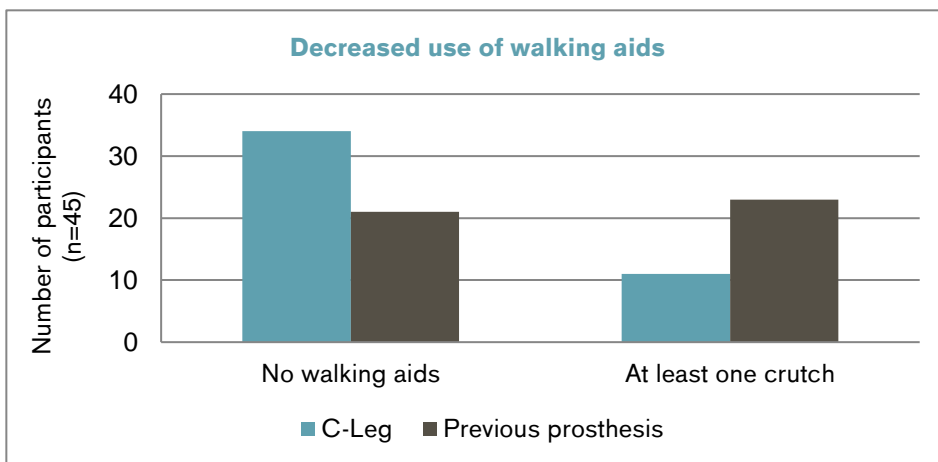
→ Improved physical quality of life

SF-36 v2 physical component score improved significantly by 11.4%

→ Higher daily use of the prosthesis and decreased use of walking aids.

→ Reduced risk of falling

Number of subjects that reported of never falling increased from 9 (20%) with previous prosthesis to 39 (87%) with C-Leg.

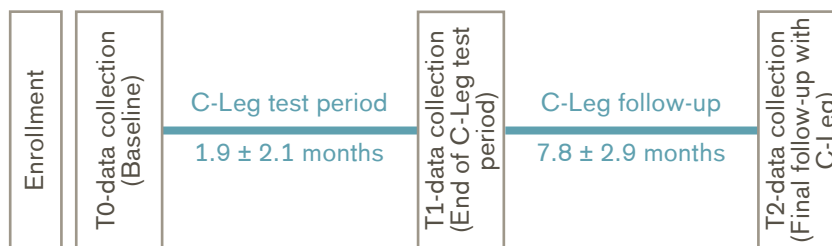


Population

Subjects:	75 prosthetic users (55 women, 20 men): <ul style="list-style-type: none">- 89% transfemoral, 3% knee disarticulation, 8% hip disarticulation- 96% unilateral, 4% bilateral
Previous knee joint:	96% NMPK (83% free with hydraulic/pneumatic assistance, 7% free mechanical, 4% break knee, 2% locked knee) and 4% micro-processor controlled knee "MPK".
Amputation causes:	59% traumatic, 27% tumor, 8% vascular, 2% congenital, 1% diabetic, 6% other
Mean age:	47.6 ± 14.1 years
Mean time since amputation:	15.8 ± 14.8 years

Study Design

Real World Evidence: Prospective, multicenter cohort study:



The study was conducted in 25 rehabilitation centers in France (detailed list of active investigators/centers can be found at the end of this document), with an inclusion period from May 13, 2013 to June 15, 2015. Clinical data was recorded for 100 participants, of which 75 were already prosthetic users at the time of enrollment and 25 who had not been fitted previously. During the study, 30 participants were lost to follow-up for different reasons. Data was analysed for 45 participants who were prosthetic users at enrollment and were assessed with C-Leg at T2. C-Leg data (T2) were compared to baseline (T0) conducted with the previous prosthesis. Furthermore, C-Leg data (T2) was collected for 11 participants having no previous prosthetic experience (no baseline).

Results

Functions and 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 previous fitting						Sig.*	
Safety	Number of falls	The number of subjects that reported of never falling increased significantly (from 9 with previous prosthesis to 39 with C-Leg)						++	
Activity, Mobility, Activities of Daily Living (ADLs)	LCI-5 (Locomotor Capability Index)	The LCI-5 global score increased significantly by 11.2%. <i>Basic activities score: +9,8%</i> <i>Advanced activities score: +13%</i>						++ ++ ++	
	Daily use	Higher number of participants that reported to use their prosthesis more than 12hours per day (17 with previous prosthesis to 25 with C-Leg)						++	
	Number of walking aids	Significantly decreased used of walking aids: The number of participants without walking aids increased from 21 with previous prosthesis (48%) to 34 (76%) with C-Leg The number of participants that used at least one crutch decreased significantly (from 23 with previous prosthesis to 11 with C-Leg)						++ ++	
Preference, Satisfaction, Quality of Life (QoL)	QUEST 2.0 (Quebec User Evaluation of Satisfaction with assistive Device)	The QUEST global score increased significantly by 19.6%. <i>Technology score: 26.1%</i> <i>Service score: +6.5%</i>						++ ++ ++	
	SF-36 (Short Form 36, v2)	All sub-scores of SF-36 were increased, indicating a higher quality of life. <i>Physical component score: +11.4%</i> <i>Mental component score: +5.5%</i>						+ ++ +	

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

Author's Conclusion

“This study suggests that active transfemoral amputees with a prescribed C-LEG may show improved locomotor ability, satisfaction and physical component of quality of life as compared with the experience with a previous mechanical device. Data also suggest that some moderately active amputees may benefit from such a device with electronically controlled stance and swing phases.” (Lansade et al., 2020)

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