

C-Leg in limited community ambulators

Safety

Major Findings

With C-Leg compared to NMPKs:

→ Decreased number of falls

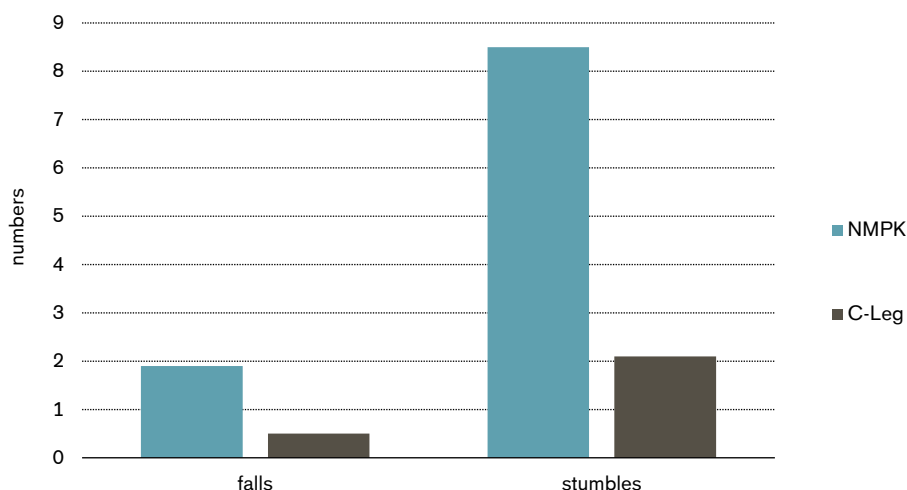
- Number of uncontrolled falls decreased by 80%
- Self-reported falling decreased by 81%
- Significant decrease in number of falls per year by 97.5% from an annual mean of 20 falls to an annual mean of 0.51 falls.

→ Fear of falling decreased by 86%

→ Improved balance

- Activities-specific balance confidence scale (ABC) score increased by 26%
- Increased balance in Activities of Daily Living (ADLs)

Improved safety with C-Leg in K2 subjects



K2 subjects self-assessed the number of falls and stumbles in the last 60 days (Kahle et al. 2008).

Clinical Relevance

Safety aspects of the prosthesis are highly relevant for the patients. Since the fear of falling can have a negative impact on activities of daily living as well as on participation, perceived safety is regarded as an important factor for quality of life of an amputee, prosthesis use and overall ambulation and activity. Information about safety is gathered through assessing the self-reported stumbles and falls over a certain period of time as well through test for balance confidence and the risk of falling. Moreover, patients with lower mobility range are more vulnerable to fall and therefore more likely to benefit from MPK stumble recovery features.

Summary

Due to transition from NMPKs to C-Leg, self-reported falling decreased by 81% in K2 subjects (Kahle et al. 2008, Kannenberg et al. 2014). Similar results were found by Hafner et al. (2009), Kaufman et al. (2018) and Hahn et al. (2021). The number of uncontrolled falls decreased by 80% in K2 subjects with C-Leg compared to

NMPKs (Drerup et al. 2008). The number of falls per year decreased by up to 97.5% (Davie-Smith et Carse 2021). In addition the fear of falling has decreased in 86% of subjects using C-Leg and 83% reported an individual increase of safety (Hahn et Lang 2015). Similar results were found by Jayaraman et al. (2021).

The time required to complete the timed up and go (TUG) test decreased with the transition from NMPKs to C-Leg Compact by 38% from 17.7 to 24.5 seconds (Burnfield et al. 2012, Kannenberg et al. 2014) and by 50 % from 138.3 to 68.3 seconds (Wong et al. 2015, single K1 patient). The risk of falling in transtibial amputees is decreased when the required time to complete the TUG lies under 19s (Dite et al. 2007).

Balance was assessed by the activities-specific balance confidence (ABC) scale. With the transition from NMPKs to C-Leg Compact, the ABC score increased in K2 subjects by 26% (Burnfield et al. 2012, Kannenberg et al. 2014).

References of summarized studies

Burnfield, J. M., Eberly, V. J., Gronely, J. K., Perry, J., Yule, W. J., & Mulroy, S. J. (2012). Impact of stance phase microprocessor-controlled knee prosthesis on ramp negotiation and community walking function in K2 level transfemoral amputees. *Prosthetics and Orthotics International*, 36(1), 95–104. doi:10.1177/0309364611431611

Davie-Smith, Fiona; Carse, Bruce (2021): Comparison of patient-reported and functional outcomes following transition from mechanical to microprocessor knee in the low-activity user with a unilateral transfemoral amputation. In: *Prosthet Orthot Int* 45 (3), S. 198–204. DOI: 10.1097/PXR.0000000000000017.

Drerup, B., Wetz, H. H., Bitterle, K., & Schmidt, R. (2008). Langzeitergebnisse mit dem C-Leg - Ergebnisse einer retrospektiven Studie: Long Term Results with the C-Leg - Results of a Retrospective Study. *Orthopädie-Technik*, 3, 169–174.

Hafner, B. J., & Smith, D. G. (2009). Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control. *The Journal of Rehabilitation Research and Development*, 46(3), 417–433.

Hahn, Andreas; Bueschges, Simon; Prager, Melanie; Kannenberg, Andreas (2021): The effect of microprocessor controlled exo-prosthetic knees on limited community ambulators: systematic review and meta-analysis. In: *Disability and rehabilitation*, S. 1–19. DOI: 10.1080/09638288.2021.1989504.

Hahn, Andreas; Lang, Michael (2015): Corrigendum - Effects of Mobility Grade, Age, and Etiology on Functional Benefit and Safety of Subjects Evaluated in More Than 1200 C-Leg Trial Fittings in Germany. In: *Journal of Prosthetics and Orthotics* 27 (3), S. 86–94. DOI: 10.1097/JPO.0000000000000064.

Jayaraman, Chandrasekaran; Mummidisetty, Chaithanya K.; Albert, Mark V.; Lipschutz, Robert; Hoppe-Ludwig, Shenan; Mathur, Gayatri; Jayaraman, Arun (2021): Using a microprocessor knee (C-Leg) with appropriate foot transitioned individuals with dysvascular transfemoral amputations to higher performance levels: a longitudinal randomized clinical trial. In: *Journal of neuroengineering and rehabilitation* 18 (1), S. 88. DOI: 10.1186/s12984-021-00879-3.

Kahle, J. T., Highsmith, M. J., & Hubbard, S. L. (2008). Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. *The Journal of Rehabilitation Research and Development*, 45(1), 1–14.

Kannenberg, Andreas; Zacharias, Britta; Pröbsting, Eva (2014): Benefits of microprocessor-controlled prosthetic knees to limited community ambulators: Systematic review. In: *Journal of Rehabilitation Research & Development* 51 (10), S. 1469–1496. DOI: 10.1682/JRRD.2014.05.0118.

Kaufman, Kenton R.; Bernhardt, Kathie A.; Symms, Kevin (2018): Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees. In: *Clinical Biomechanics* 58, S. 116–122. DOI: 10.1016/j.clinbiomech.2018.07.012.

Wong, C. K. , Rheinstein, J. and Stern, M. A. (2015). Benefits for adults with transfemoral amputations and peripheral artery disease using microprocessor compared with nonmicroprocessor prosthetic knees. *American Journal of Physical Medicine & Rehabilitation*, 94(10), 804-810.
doi: 10.1097/PHM.0000000000000265

Other references

Dite, W., Connor, H. J., & Curtis, H. C. (2007). Clinical Identification of Multiple Fall Risk Early After Unilateral Transtibial Amputation. *Archives of physical medicine and rehabilitation*, 88(1), 109–114. doi:10.1016/j.apmr.2006.10.015

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