

# **The Benefits of Microprocessor-Controlled Knees for Persons with a Transfemoral Amputation Evaluated at the K2 Level**

Jo’Kia Greely, MSPO, CPO; Hanger Clinic; jgreely@hanger.com

**Creation Date: July 2023; Re-assessment Date: July 2028**

**Clinical Question:** In persons with a transfemoral amputation evaluated at the K2/community ambulator level, do microprocessor-controlled knees (MPKs) prevent falls and improve mobility relative to mechanical knees?

**Background:** Selection of a prosthetic knee after transfemoral amputation is one of the key steps in achieving satisfactory prosthetic use. Traditional knees used for K2 ambulators such as constant friction and polycentric knees require the patient to fully unload the toe before the knee flexes. If a person with a transfemoral amputation does not have the balance and/or proprioception to accomplish this task, safety becomes a concern.<sup>1,3,4</sup> Recurrent falls and fear are associated with activity avoidance and decreased independence and mobility.<sup>6</sup> Therefore, selecting a knee that makes patients feel safe and want to ambulate is paramount to ensuring reintegration into society. MPKs are prescribed to high functioning ambulators, but this technology has potential benefits for lower-functioning individuals in terms of safety, mobility, and integration into society.<sup>3,4</sup> Arguments against providing K2/community ambulators MPKs are that some of the technological features, such as step over step descent, cadence recognition, and walking backwards will not be usable or beneficial.<sup>5</sup> Subsequently, Medicare currently does not cover MPKs for persons with a transfemoral amputation classified as K2 per the definition of Medicare Functional Classification Levels (MFCL), and other third-party payors are now following suit.<sup>2,4</sup> A review of the literature was performed to investigate if features of MPKs, such as stumble recovery and stance yielding, could prevent falls and improve mobility relative to mechanical knees in the K2/community ambulator population.

## **Search Strategy:**

**Databases Searched:** PubMed, JPO Journal, [www.oandp.org](http://www.oandp.org), Google Scholar

**Search Terms:** (microprocessor knees OR MPK) AND (K2 amputees OR community ambulators)

**Inclusion Criteria:** 2010 - present, Systematic Reviews or Meta-Analyses

**Exclusion Criteria:** articles published prior to 2010, non-English articles

**Synthesis of Results:** Four studies and two systematic reviews explored the benefits of a microprocessor knee and its effect on preventing falls and improving mobility in the K2/community ambulator population. Three studies investigated a specific microprocessor knee (C-Leg Compact<sup>1,5</sup> and Kenevo<sup>3</sup>) while one investigated multiple MPKs (Ottobock Compact, Ossur Rheo 3, Endolite Orio 2, Freedom Innovation Plie 3).<sup>4</sup> It was concluded that stability was greater ascending and descending ramps in the C-Leg Compact prosthesis compared to the non-MPK (NMPK) and there was patient preference to keep C-leg vs. NMPK.<sup>1</sup> Both systematic reviews concluded that MPKs reduce the number of falls and the risk of falling, improve balance, and facilitate improved activities of community ambulation that are categorized as part of the MFCL-K3 mobility grade.<sup>2,6</sup> Mileusnic et al. reported that the Kenovo resulted in higher patient satisfaction and proved to be effective and beneficial in improving the safety challenges on lower activity amputees.<sup>3</sup> Improvement of function in free-living environment, reduction of falls, and improved patient satisfaction was also reported.<sup>4</sup> New prosthetic design features found in MPKs showed improvement in performance and safety in the environment for persons with a transfemoral amputation who care classified at MFCL-K2.<sup>5</sup> Most notable limitations for the studies include small sample sizes and inability to control completion of questionnaires.

**Clinical Message:** Based on the evidence available, MPKs offer significant benefits to preventing stumbles, falls, and enhancing mobility in the K2 population. The advanced sensor and control technology of MPKs provide improved stability and adaptability, resulting in a more natural gait and increased confidence in various activities. While further research is needed to explore the long-term effects and cost effectiveness of MPKs for this specific population, current evidence supports effective intervention for individuals with a transfemoral amputation at the MFCL-K2 functional level.

## References:

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3. Mileusnic, M. P., Hahn, A., & Reiter, S. (2017). Effects of a novel microprocessor-controlled knee, kenevo, on the safety, mobility, and satisfaction of lower-activity patients with transfemoral amputation. *JPO: Journal of Prosthetics and Orthotics*, 29(4), 198-205.
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5. Eberly, V. J., Mulroy, S. J., Gronley, J. K., Perry, J., Yule, W. J., & Burnfield, J. M. (2014). Impact of a stance phase microprocessor-controlled knee prosthesis on level walking in lower functioning individuals with a transfemoral amputation. *Prosthetics and orthotics international*, 38(6), 447-455.
6. Mundell, B., Maradit Kremers, H., Visscher, S., Hoppe, K., & Kaufman, K. (2017). Direct medical costs of accidental falls for adults with transfemoral amputations. *Prosthetics and orthotics international*, 41(6), 564-570.
7. Stevens, P. M., & Wurdeman, S. R. (2019). Prosthetic knee selection for individuals with unilateral transfemoral amputation: a clinical practice guideline. *JPO: Journal of Prosthetics and Orthotics*, 31(1), 2-8.
8. Hahn, A., Bueschges, S., Prager, M., & Kannenberg, A. (2022). The effect of microprocessor controlled exo-prosthetic knees on limited community ambulators: systematic review and meta-analysis. *Disability and Rehabilitation*, 44(24), 7349-7367.

**Evidence Table**

	<i>Eberly, 2014<sup>5</sup></i>	<i>Burnfield, 2012<sup>1</sup></i>	<i>Kannenberg, 2014<sup>2</sup></i>	<i>Mileusnic, 2017<sup>3</sup></i>	<i>Kaufman, 2018<sup>4</sup></i>	<i>Hahn, 2021<sup>6</sup></i>
<b>Population</b>	10 participants (5 Male, 5 Female); mean age 62 years old; average time amputation 9 years; unilateral transfemoral amputees classified as K2 ambulators using articulating non-microprocessor knees.	10 participants (5 Male, 5 Female); mean age 62 years old; average time amputation 9 years; unilateral transfemoral amputees classified as K2 ambulators using articulating non-microprocessor knees.	956 citations found, 412 identified and eliminated as duplicates; 501 excluded as not pertinent; additional 46 abstracts analyzed as not pertinent; further 20 publications excluded as not pertinent; 7 publications on five clinicals trial with subjects with a unilateral TFA and MCFCL-2 mobility grade were selected.	29 transfemoral/knee disarticulation amputees using mechanical knee joints classified as limited community ambulators (mostly MCFL-2).	50 subjects (28 male) from 19 states throughout the United States. The subjects had a mean age of $69 \pm 9$ years (range 55–93) and were enrolled a median of 1.5 years; classified as Medicare Functional Level K2 or K3 using NMPK.	704 Subjects MFCL: K2 Previous prosthetic knees: Locked, brake, polycentric, hydraulic, MPK, other Amputation causes: Vascular disease, Trauma, Other
<b>Study Design</b>	Crossover	Crossover	Systematic Review	Prospective Observational Study (Case Report)	Prospective non-randomized cross-over clinical trial	Systematic literature review for meta-analysis
<b>Intervention</b>	C-Leg Compact (Microprocessor-knee)	C-Leg Compact (Microprocessor-knee)	Not applicable	Kenevo Microprocessor-Knee	Randomly assigned MPK (Ottobock Compact, Ossur Rheo 3, Endolite Orio 2, Freedom Innovation Plie 3)	Not applicable
<b>Comparison</b>	Non-Microprocessor Knee	Non-Microprocessor-controlled knee	Not applicable	Mechanical Knee Joints	Non-Microprocessor-controlled knees	Not applicable

	<i>Eberly, 2014<sup>5</sup></i>	<i>Burnfield, 2012<sup>1</sup></i>	<i>Kannenberg, 2014<sup>2</sup></i>	<i>Mileusnic, 2017<sup>3</sup></i>	<i>Kaufman, 2018<sup>4</sup></i>	<i>Hahn, 2021<sup>6</sup></i>
<b>Methodology</b>	<p>Participants were first tested in their existing NMPK. The knee joint was then converted to an MPK Compact, and the foot was converted to a Compact compatible foot. The participants then received training in their Compact and a 3-month accommodation period prior to the second laboratory testing session. Training consisted of five to seven 1-h sessions with a physical therapist which included education to enhance each participant's understanding of the Compact's capabilities and practice on stairs, ramps, curbs, and uneven surfaces.</p>	<p>Participants were first tested in their existing NMPK. The knee joint was then converted to an MPK Compact, and the foot was converted to a Compact-compatible foot. The participants then received training in their Compact and a 3-month accommodation period prior to the second laboratory testing session. Training consisted of five to seven 1-h sessions with a physical therapist which included education to enhance each participant's understanding of the Compact's capabilities and practice on stairs, ramps, curbs, and uneven surfaces.</p>	<p>Three databases (Medline, EMBASE, and Psych Info) searched using selected keywords MPKs and individual with unilateral TFA and MFCLS-2 mobility grade. Two authors independently screened titles and abstracts of the publications according to inclusion and exclusion criteria, and were deemed pertinent, non-pertinent, or uncertain. Disagreements on references of possible relevance were settled by a third author review, and all joint discussion of full-text articles occurred among all three authors for final agreements on classification of relevance of article.</p>	<p>A questionnaire was designed and given to each subject to obtain information on user's daily prosthetic utilization ("baseline subject questionnaire"). Data was collected first with old prosthesis, patients were then fit with Kenevo; two-month acclimation period then a follow up questionnaire; validated clinical tests (LCI-5, PLUS-M, and Houghton Scale) were also conducted during baseline and follow up testing.</p>	<p>Participants were fit by their own prosthetists and given about a three-month acclimation period; prosthetic feet were in 1951 class (if foot was changed, they were given an additional month of acclimation time); Outcome measures were assessed at baseline, 10 weeks after conversion to the MPK, and 4 weeks after reversion to their NMPK.</p>	<p>The following databases were searched: Medline, Cochrane Library, CINAHL Complete, EMBASE, Google Scholar, DARE, Cirrie (now NARIC Rehab Database), PEDRO, and OT Seeker</p> <p>Publications were assessed based on the State of the Science Evidence Report Guidelines as recommended by the American Academy of Orthotists and Prosthetists (AAOP)</p>

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<b>Outcomes</b>	Characteristics of stride, Kinematics, Kinetics, Electromyographic activity	Gait mechanics, stability during ramp negotiation	Performance Based Function and Mobility, Outcome, Perceived function and satisfaction	Safety, Mobility and activities of daily living, Perceived concentration and exertion, Pain and comfort, Prosthetic use, satisfaction, and preference	Patient satisfaction, Safety assessed using PEQ	Safety, Activity, Mobility, Activities of Daily Living (ADLs), Preference, Satisfaction, Quality of Life (QoL)
<b>Key Findings</b>	<p>Walking speed increased by approximately 20% in the Compact compared to the NMPK in both free and fast conditions</p> <p>There were no statistically significant differences between prostheses in peak ankle or knee joint angles of either limb during free or fast walking</p> <p>The peak external ankle dorsiflexion moment in late stance increased by more than 20% while walking with the Compact compared to the NMPK during both free (<math>p = 0.001</math>) and fast (<math>p = 0.008</math>) walking (Table 3).</p>	<p>Ramp ascent was markedly faster (28%) in the C-Leg Compact compared to NMPK, owing to 14% increases in both stride length and cadence.</p> <p>Differences between prosthetic conditions were even more pronounced during ramp descent, with velocity 36% more rapid when using the C-Leg Compact compared to NMPK.</p> <p>The percentage of gait cycle spent in residual limb single limb support was significantly longer when descending in the C-Leg Compact compared to NMPK (4% GC difference</p>	<p>Limited community ambulators may significantly improve their abilities to perform activities of community ambulation such as negotiating uneven terrain and environmental obstacles, ramps, hills, stairs, and multitasking while walking.</p> <p>Significant reduction in the self-reported number and frequency of uncontrolled falls</p>	<p>Study shows an increase in “never having fallen with prosthesis”, “reduction of stumbling”, “lack of fear of falling” among subjects; 89% of person prefer Kenevo over their previous fitting.</p> <p>The number of subjects who reported never falling increased from 45% with their old prosthesis to 72% with Kenevo.</p> <p>In the case of stumbling, subject reported frequency of stumbles was significantly reduced with 50%</p>	<p>Use of a MPK resulted in a significant reduction in falls (<math>p = 0.01</math>).</p> <p>Subjects spent significantly less time sitting (<math>p = 0.01</math>) when using the MPK</p> <p>Complexity of the gait as measured by the entropy increased when using the MPK</p> <p>Significant improvement in PEQ satisfaction subscales when using the MPK (<math>p &lt; 0.01</math>). The greatest improvements were in ambulation, appearance, and utility</p>	<p>Use of MPKs resulted in a reduction of falls, fear of falling, and risk of falling</p> <p>Improvement of patient reported ambulation, mobility, and utility</p> <p>Increase in mobility grade and self-selected walking speed</p>

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	<p>External knee flexion moment in early stance was significantly decreased with the Compact compared to the NMPK (p = 0.045)</p> <p>Statistically significantly greater external knee extension moment in SLS (mid and terminal stance) during free and fast ambulation</p> <p>Fast walking with the Compact resulted in a significantly greater external flexion moment in early stance compared to the NMPK</p>	<p>The time required to complete the TUG was significantly shorter when wearing the C-Leg Compact compared to the NMPK</p> <p>Functional questionnaire scores were higher after using the C-Leg Compact compared to those recorded while using the NMPK</p> <p>Mean and peak EMG values did not differ significantly between the NMPK and C-Leg Compact conditions for the eight muscles studied</p> <p>The residual limb's peak angles did not vary significantly between prostheses during ramp ascent despite a trend towards higher values in the C-Leg Compact for single limb support hip extension single limb support knee flexion and single limb support ankle</p>		<p>of subjects reporting of never stumbling with Kenevo compared with 8% with their previous prosthesis.</p> <p>50% of the subjects reported an improvement in fear of falling, whereas 8% (1/12) reported a worsening.</p> <p>15 subjects (79%) found Kenevo as being better or much better, 2 (11%) equal, and 1 (5%) worse than their previous prosthetic knee</p> <p>Walking on uneven ground improved for 64% of the subjects with Kenevo</p> <p>Stair ascent was perceived by 63% as being not affected by Kenevo and by 37% as improved. Stair</p>		

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		dorsiflexion compared to the NMPK.		<p>descent was ranked by more than half of the subjects as being improved with Kenevo</p> <p>The use of Kenevo did not result in change of walking aids that subjects use for ambulation. Wheelchair use, however, was significantly reduced when transitioning to Kenevo. Whereas 87% of subjects reported using a wheelchair with their previous prosthesis, this number decreased to 37% with Kenevo.</p> <p>89% of the persons with amputation fitted with Kenevo prefer Kenevo over their previous fitting</p>		

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<b>Study Limitations</b>	<p>Small sample size and relatively large intersubjective differences for some types of data which may have reduced statistical power for finding significant differences between prostheses.</p> <p>The number of variables tested in this study increases the likelihood of type I statistical error, and thus, the results must be viewed with caution changing the prosthetic foot between the two conditions from their customary foot to a C-Leg Compact-compatible foot may have impacted results</p>	<p>Only relatively short-term outcomes when using the C-Leg Compact prosthesis were explored.</p> <p>A longer follow-up period would be beneficial for understanding the impact of the prosthesis not only on changes in function, but also cardiovascular fitness and the development and management of secondary medical conditions often associated with inactivity.</p> <p>While the training sessions were purposefully kept short and an accommodation period was provided, it is possible that patient's performance may have been impacted by the training</p>	<p>It is possible not all existing clinical studies and publication on the effect of MPK use in the limited community ambulator population have been identified.</p> <p>Restriction on English- and German-language publications may have resulted in missing important studies on this subject published in other languages; relatively low total patient number and low number of individuals with dysvascular amputation.</p>	<p>Nothing in place to ensure all 29 subjects completed both initial and follow up questionnaire</p>	<p>Safety data is directly linked to the ability to accurately monitor falls, Number of subjects did not complete final data capture due to decline in health, Large number of subjects refused to continue study.</p>	<p>Exclusion of non-English publication may have resulted in missing important information</p> <p>Some patients had already previously used MPKs</p>