

## Benefits of microprocessor-controlled prosthetic knees to limited community ambulators: Systematic review

Andreas Kannenberg, MD, PhD;<sup>1\*</sup> Britta Zacharias, Dipl-Ing (FH), CPO;<sup>2</sup> Eva Pröbsting, Dipl-Ing (FH), CPO<sup>2</sup>  
<sup>1</sup>Medical Affairs, Otto Bock HealthCare LP, Austin, TX; <sup>2</sup>Clinical Research and Services, Otto Bock HealthCare GmbH, Duderstadt, Germany

**Abstract**—The benefits of microprocessor-controlled prosthetic knees (MPKs) have been well established in community ambulators (Medicare Functional Classification Level [MFCL]-3) with a transfemoral amputation (TFA). A systematic review of the literature was performed to analyze whether limited community ambulators (MFCL-2) may also benefit from using an MPK in safety, performance-based function and mobility, and perceived function and satisfaction. We searched 10 scientific databases for clinical trials with MPKs and identified six publications with 57 subjects with TFA and MFCL-2 mobility grade. Using the criteria of a Cochrane Review on prosthetic components, we rated methodological quality moderate in four publications and low in two publications. MPK use may significantly reduce uncontrolled falls by up to 80% as well as significantly improve indicators of fall risk. Performance-based outcome measures suggest that persons with MFCL-2 mobility grade may be able to walk about 14% to 25% faster on level ground, be around 20% quicker on uneven surfaces, and descend a slope almost 30% faster when using an MPK. The results of this systematic review suggest that trial fittings may be used to determine whether or not individuals with TFA and MFCL-2 mobility grade benefit from MPK use. Criteria for patient selection and assessment of trial fitting success or failure are proposed.

**Key words:** community ambulator, limited community ambulator, Medicare Functional Classification Level-2, microprocessor-controlled knees, mobility, MPK, non-microprocessor-controlled prosthetic knees, perceived function, performance-based function and mobility, safety, transfemoral amputation.

### INTRODUCTION

Absence or amputation of a lower limb may be the life-altering consequence of congenital deficiency, trauma, malignancy, peripheral vascular disease, diabetic neuropathy, and other conditions. The risk of leg amputation increases with age for all etiologies; however, vascular disease accounts for up to 82 percent of lower-limb amputations [1]. A more proximal amputation results in greater physical and functional impairment to the individual, including a decreased likelihood of regaining household or community ambulation and an increased

**Abbreviations:** 2MWT = 2-min walk test, ABC = Activity-specific Balance Confidence Scale, ADL = activity of daily living, AMP = Amputee Mobility Predictor, GRF = ground reaction force, ICR = instantaneous center of rotation, LCI = Locomotor Capabilities Index, MDC = minimal detectable change, MFCL = Medicare Functional Classification Level, MP = microprocessor, MPK = microprocessor-controlled prosthetic knee, NMPK = non-microprocessor-controlled prosthetic knee, PEQ = Prosthesis Evaluation Questionnaire, RCT = randomized controlled trial, TFA = transfemoral amputation, TUG = Timed “Up and Go” test.

\*Address all correspondence to Andreas Kannenberg, MD, PhD; Otto Bock HealthCare LP, Riata Business Park, Building 8, Suite 250, 12365-B Riata Trace Pkwy, Austin, TX 78727; 763-489-5105; fax: 763-519-6153.

Email: [andreas.kannenberg@ottobock.com](mailto:andreas.kannenberg@ottobock.com)

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risk of falling in subjects with above-knee as compared with below-knee amputation [2–13]. According to a consolidation of recent epidemiological studies, the population of people with above-knee limb loss living in the United States may be as large as 400,000 [14–15].

Adequate selection of prosthetic components is one of the key processes to achieving the best possible rehabilitation outcomes. In subjects with transfemoral amputation (TFA), the prosthetic knee is a very important component tasked with restoring knee biomechanics while at the same time providing maximum stability and safety [16–19]. In the early 1990s, Medicare adopted the Medicare Functional Classification Levels (MFCLs), which are used to rate the person with amputation's ability and/or potential ability to ambulate. Shortly thereafter, based on the prosthetic knees available at that time, Medicare developed coverage criteria (indications/limitations and/or medical necessity) for prosthetic knees that were adapted to the MFCL. Medicare's prosthetic knee coverage criterion has not been modified since its inception and remains in effect today (**Table 1**) [20]. Additionally, the MFCL and coverage criteria have also been adopted by many third-party payors [21]. Fluid stance

control mechanisms available at that time were correctly considered too difficult to be safely operated by lower-functioning individuals, and the remaining traditional stance control mechanisms offered similar levels of inherent stability and support of function [16,22]. As a result, the coverage criteria for prosthetic knees were based on the ability and/or potential ability of subjects to vary cadence and walking speed as the decisive criterion for the selection of an appropriate swing control technology. As a consequence of these criteria, fluid control prosthetic knee mechanisms, regardless of their use for stance or swing control, have been reserved for usually younger persons with amputation of the higher MFCL-3 and MFCL-4 mobility grade.

In the past 15 yr, prosthetic technology has progressed to microprocessor (MP)-controlled fluid stance as well as stance and swing control mechanisms to overcome the inverse relationship between stability and support of function inherent in non-MP-controlled prosthetic knees (NMPKs). Clinical research, mainly conducted in the unlimited community ambulator (MFCL-3) population with low to moderate methodological quality, has

**Table 1.**

Definition of Medical Function Classification Level (or K-levels) and Medicare Guidelines for Covered Prostheses by K-level of mobility [20].

<b>K-Level</b>	<b>Description</b>	<b>Medicare Reimbursed Prosthesis</b>
K0	Nonambulatory: "Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility."	None
K1	Household Ambulator: "Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence."	Constant Friction Knee
K2	Limited Community Ambulator: "Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces."	Constant Friction Knee
K3	Unlimited Community Ambulator: "Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion."	Fluid Control Knee, Non-MP or MP-Controlled Knee
K4	Very Active: "Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete."	Fluid Control Knee, Non-MP or MP-Controlled Knee

MP = microprocessor.

demonstrated improved safety and superior function of MP-controlled prosthetic knees (MPKs) [23] in level walking [24–30], walking on uneven terrain [24–26,31–32], walking on slopes [21,26,33–34], walking on stairs [25,31,35], and stumble recovery [24–25], resulting in significantly reduced numbers of stumbles and falls and improved balance than with NMPKs [24–26,31,34,36].

With current coverage criteria restricting the provision of advanced prosthetic technology to usually younger, healthier, higher-functioning individuals, lower-limb prosthetics finds itself on a different pathway than other fields of healthcare. Typically, most advanced healthcare technologies serve the oldest, sickest, and most restricted patients, as reflected by the fact that 80 percent of lifetime healthcare expenditures are incurred in the second half of life [37] with a substantial share of these accruing in the last year before death [38–40]. Today, the majority of patients undergoing a TFA are over the age of 65 yr [1,41–43] and do not reach the level of unlimited community ambulation [13] using the prosthetic knees covered under current Medicare criteria, which are simple in technology, limited in function, and often developed decades ago. These findings raise the question whether limited community ambulators (MFCL-2) may also benefit more from using MPKs than from NMPKs as has been demonstrated in unlimited community ambulators (MFCL-3). We therefore conducted a systematic review of randomized and nonrandomized clinical trials comparing the effects of NMPK and MPK interventions in limited community ambulators (MFCL-2) with a unilateral TFA in three clinically meaningful areas.

First, falling is a major issue in this population [8,44–45], and recurrent falls and fear of falling are associated with functional limitations and deterioration in balance, coordination, and endurance, resulting in activity avoidance and decreased independence and mobility [46–50]. Falling and its detrimental consequences pose serious clinical challenges for persons with amputation, especially elderly, lower-functioning individuals who often experience various comorbidities and physical deconditioning [44–45]. Therefore, the evaluation of performance-based and self-reported outcome measures would help assess the effect of MPK use on the safety of ambulation with the prosthesis.

Second, the goal of rehabilitation is to enable patients to resume a lifestyle as independent as possible. Therefore, the analysis of performance-based function and

mobility to appraise the person with amputation's ability to perform household activities of daily living (ADLs) and activities required for community ambulation (e.g., walking on uneven terrain, slopes, and stairs) would allow for drawing conclusions on the effects of MPK use on function and overall mobility as indicators or prerequisites for an independent lifestyle and participation.

Third, the perception of function and satisfaction plays an important role on the behavior of patients, such as taking on or avoiding ADLs [9,46–47,51–54]. Thus, the evaluation of self-reported measures to assess perceived safety, function, and satisfaction with prosthesis use may allow for judging whether MPK use may create the basis for behavioral changes such as a more self-dependent lifestyle and an increase in general ambulation activity.

The specific outcome measures representing each clinical area of interest were defined a priori and are described in detail in the “Inclusion Criteria” section.

## METHODS

### Search Strategy

The systematic search of publications was conducted on October 28 and 29, 2013, using the scientific literature databases Medline, EMBASE, and PsychInfo (all three accessed via DIMDI [German Institute for Medical Documentation and Information]); DARE; Cirrie; CINAHL; Cochrane Library; OTseeker; PEDro; and RECAL Legacy. The databases were searched with terms related to MPKs and individuals with a unilateral TFA and MFCL-2 mobility grade. The search terms were combined into a title, abstract, and key word search phrase using Boolean operators, resulting in the following syntax:

1. Unilateral.
2. Femoral.
3. Transfemoral.
4. Above?knee.
5. Through?knee.
6. Knee?disarticulation.
7. Or/2–6.
8. Amput\*.
9. Prosth\*.
10. Or/8–9.
11. Microprocessor.
12. MP\*.

13. Or/11–12.
14. Knee.
15. And/1,7,10,13,14.

The literature search was not extended to study types or specific outcome measures but limited to English- and German-language publications with no limit on the date of publication. In addition, the references of the analyzed full-text publications were searched for additional pertinent published studies.

### Screening

The titles and abstracts of the publications found were independently screened by two authors (A.K. and B.Z.) with regard to inclusion and exclusion criteria to classify them as relevant, not relevant, or possibly relevant. Full articles were reviewed for all publications classified as relevant or possibly relevant. Disagreements on references of possible relevance were settled by third author (E.P.) review, and joint discussion of full-text articles occurred among all three authors for final agreement on the classification of relevance of the article.

### Inclusion Criteria

Inclusion criteria included—

1. Randomized or nonrandomized comparative study that includes a prosthetic knee intervention with comparison of results of an MPK with those of one or more NMPKs.
2. Study that reports results of individuals with a unilateral TFA or knee disarticulation classified as MFCL-2 mobility grade either as the target study group, as a subgroup analysis, or as raw data that permits a post hoc analysis of the MFCL-2 subgroup of the study sample.
3. Study that uses and reports quantifiable results of objective and/or self-reported outcome measures in the areas of safety, function and mobility, and perceived function and satisfaction with the prosthesis. The included studies were explicitly screened for, but not limited to, the following outcome measures as validated representatives for the areas of clinical interest of this review:
  - a. Safety: Outcomes measures validated for assessing the risk of falling in individuals with lower-limb amputation, such as the self-reported number of stumbles and falls within a defined period of time [55–56], Timed “Up and Go” test (TUG) [57–61], Four Square Step Test [62], Berg Balance Scale

[63–64], obstacle avoidance test [65], Activity-specific Balance Confidence Scale (ABC) [6,66–68], Locomotor Capabilities Index (LCI) advanced score [62], and Prosthesis Evaluation Questionnaire (PEQ) Addendum [34].

- b. Performance-based function and mobility: MFCL classification if determined with all prosthetic interventions and validated outcome measures that objectively assess the physical abilities of subjects with lower-limb amputation, such as the Amputee Mobility Predictor (AMP) with and without prosthesis [69], timed walk tests on level ground [70–71] and uneven terrain [31], the Assessment of Daily Activity Performance in Transfemoral Amputees test for assessing performance in ADLs [72], divided attention tests while walking [34], performance and gait characteristics in slope and stair negotiation such as the Hill and Stair Assessment Indices [34], motion analysis [24,35,73–74], or the Montreal Rehabilitation Performance Profile [31,75].
- c. Perceived function and satisfaction: Validated self-reported outcome measures such as the PEQ [76–77], Orthotic and Prosthetic Users’ Survey [78], LCI [79–80], Amputee Activity Score [81], Functional Measure for Amputees [82–83], Houghton Scale [82,84–85], Prosthetic Profile of the Amputee [82], Orthotics and Prosthetics National Outcomes Tool [82,86], Special Interest Group in Amputation Medicine score [87], and Trinity Amputation and Prosthesis Experience Scales [88–89].

### Exclusion Criteria

Exclusion criteria included—

1. Studies with implantable knee joints (total knee arthroplasty or replacement).
2. Studies with patients with a bilateral amputation or an amputation level higher than transfemoral or lower than knee disarticulation.
3. Studies that only report opinions or judgments of the authors but no data that allow for an independent reappraisal.
4. Duplicate article.

### Assessment of Methodological Quality

After screening and sorting articles for pertinence to the subject of this review, methodological quality and risk of bias were separately assessed by two authors

(A.K. and B.Z. or E.P.) using the checklist of a Cochrane Systematic Review on prosthetic ankle-foot mechanisms published by Hofstad et al. [90]. It is based on two existing scales for methodological quality assessment of randomized controlled trials (RCTs) of van Tulder et al. [91] and Verhagen et al. [92] but was adapted to also evaluate internal and external validity as well as the risk of bias of nonrandomized studies as recommended by Downs and Black [93], Reisch et al. [94], and Zaza et al. [95]. We are not aware of any RCTs in prosthetic research, which is confirmed by the results of a recent systematic review of the entire prosthetic literature [96]. We therefore believe that the scale of Hofstad et al. [90], accepted by the Cochrane Collaboration, is an appropriate tool to assess the methodological quality of clinical trials in prosthetics. The Hofstad checklist comprises 13 criteria for methodological quality that are all scored using one out of three possible levels: no = 0, yes = 1, or not applicable.

## Criteria for Methodological Quality

### *Selection of Patients*

**A1.** Adequate description of inclusion and exclusion criteria (with a minimum of three of the following descriptors: age, amputation level, etiology, level of activity, time since amputation, residual limb condition, comorbidities, and sex)?

**A2.** Homogeneity of the study groups (at least for age, etiology and level of the amputation, and mobility grade)?

**A3.** Prognostic comparability of the study sample (e.g., for etiology and level of amputation, age, sex, condition of the residual limb, comorbidities, etc.; prognostic comparability is given by definition in within-subject studies with every patient acting as his or her own control)?

**A4.** Randomization (randomized order of intervention: 1 point, randomization of patients to intervention and control groups [RCT]: 2 points)?

### *Intervention*

**B5.** Description of experimental intervention (can the study be repeated)?

**B6.** Control of cointerventions?

**B7.** Blinding of patients and/or assessors?

**B8.** Timing of measurement (adequate adaptation)?

**B9.** Appropriateness of outcome measures to answer the research question of the study?

### *Statistical Validity*

**C10.** Attrition rate not exceeding 20 percent?

**C11.** Adequate sample size (sample size calculation and power analysis)?

**C12.** Intention-to-treat analysis?

**C13.** Data presentation (point estimates and measures of variability)?

The rules for scoring the individual criteria were reported in detail by Hofstad et al. [90] and have been strictly followed for this review.

### *Rating of Methodological Quality According to Hofstad et al. [90]*

**A grade (high quality).** Minimum of 11 points in total, with at least 6 points in the patient selection (A) and intervention (B) criteria with valid scores in blinding (B7) and accommodation (B8).

**B grade (moderate quality).** Minimum of 6 points in total, with at least 6 points in the patient selection (A) and intervention (B) criteria with a valid score in accommodation (B8).

**C grade (low quality).** Minimum of 6 points in total, with at least 6 points in the patient selection (A) and intervention (B) criteria with invalid scores in blinding (B7) and accommodation (B8).

Studies with a total score of less than 6 points were considered to have insufficient quality to be included in this systematic review.

## Data Extraction

Data extraction from each study included was conducted independently by two reviewers (A.K. and B.Z. or E.P.) using a standardized, self-developed data extraction form that covered the design of the study; inclusion and exclusion criteria, number, age, and sex of the patients; the level and etiology of the amputation; type and severity of comorbidities; control and study intervention; concurrent therapies and other potential confounders; follow-up times; outcome measures and their results for every study group; raw data of individual patients, if reported; and the results of statistical comparisons between the study groups ( $p$ -values, confidence intervals, etc.). The outcome measures were grouped according to the predefined areas of safety, performance-based function and mobility, and perceived function and satisfaction as described in detail in the "Inclusion Criteria" section.

Because the variability of patient characteristics within the MFCL-2 mobility grade is broad, an attempt was

made to stratify the subjects based on two well-validated objective measures of the overall physical capabilities, the AMP [69] and the walking speed in timed walk tests [70–71,97] on the NMPK, because such stratification might possibly allow for relating differing results to different levels of physical capabilities and thus help guide appropriate component selection.

### Post Hoc Analyses, Data Pooling, and Meta-Analyses

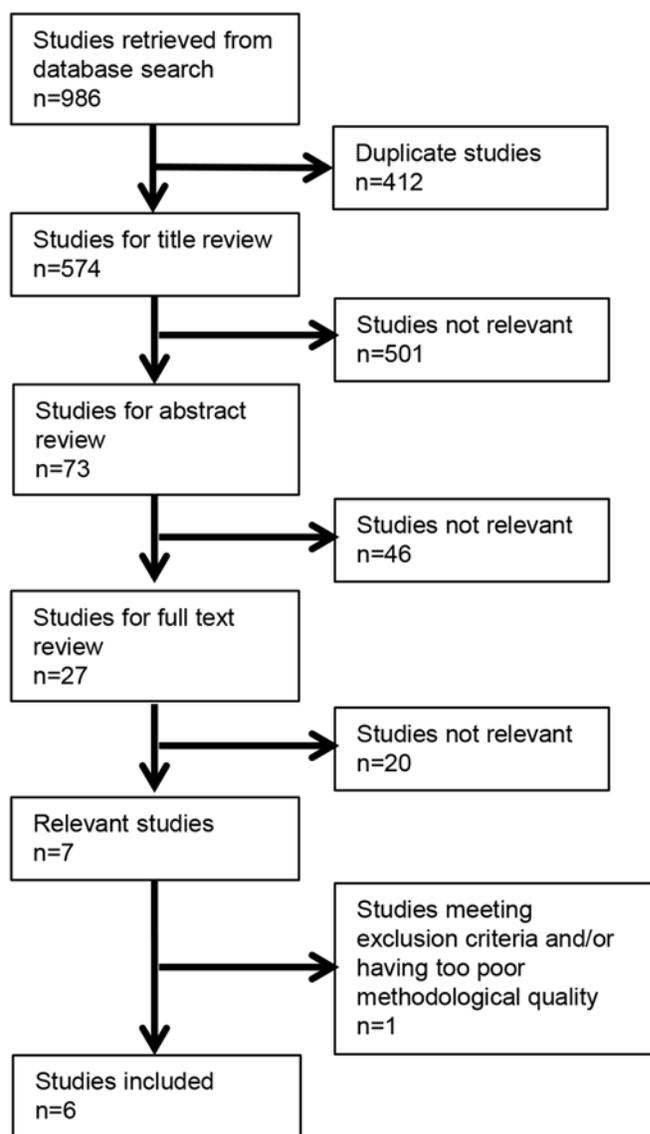
Raw data of all subjects allowing for a post hoc statistical analysis of the MFCL-2 subgroup was reported by one study included in this review [31]. In another study, individual results of the AMP were reported but not statistically analyzed for the different functional level subgroups [21]. Due to the low patient numbers of  $n = 9$  [31] and  $n = 8$  [21], the post hoc statistical analyses were conducted using the Wilcoxon signed rank test with a power of 80 percent in WinSTAT for Excel (Microsoft Corporation; Redmond, Washington). Differences between interventions with a  $p < 0.05$  were considered statistically significant.

Due to inhomogeneity in study designs, patient numbers, acclimation times, and outcome measures assessed, data pooling and meta-analyses were not suitable.

## RESULTS

### Literature Search

The literature search found 986 citations in all databases used. A total of 412 duplicates were identified and eliminated. Based on a review of the article titles, 501 publications were excluded as not pertinent. Then, the abstracts of the remaining 73 articles were analyzed to classify 46 as not pertinent, leaving 27 publications for full-text review, after which a further 20 publications were excluded as not pertinent (**Figure**). No additional pertinent citations were found in the references of the full-text articles. Thus, the literature search ultimately revealed seven publications on five clinical trials with subjects with a unilateral TFA and MFCL-2 mobility grade. Two clinical trials resulting in four publications exclusively studied individuals with MFCL-2 mobility grade [98–101], two studies reported subgroup analyses of MFCL-2 subjects [21,102], and one study reported individual raw data that permitted a post hoc analysis of the MFCL-2 subgroup [31]. Three studies investigated the effects of the MP stance and swing controlled C-Leg



**Figure.** Flowchart of literature search and analysis.

[21,31,102], one study investigated the MP stance controlled C-Leg Compact [100–101], and one study investigated both the C-Leg and C-Leg Compact in randomized order [98–99].

### Assessment of Methodological Quality

As expected, we have not been able to identify an RCT with MPKs in individuals with a unilateral TFA and MFCL-2 mobility grade. The German-language publication of Wetz et al. had to be excluded from further analysis

because it met predefined exclusion criterion number 3 [102]. This article only reported qualitative judgments of the authors on the benefits of individual subjects from using an MPK as compared with their existing NMPK after a 1 d trial fitting that did not allow for an independent reappraisal of the results. Nevertheless, it was included in the assessment of methodological quality, where it was found to not attain the minimum score to be included in further analyses. For the other six relevant publications identified in the literature search, methodological quality was rated B (moderate) in four articles and C (low) in two articles (Table 2).

Moreover, a methodological uncertainty of all studies was the determination of the MFCL of the individuals. In all studies, only the everyday clinical practice of subjective judgment of the prosthetist and/or physical therapist was used to assign the subjects to a certain MFCL. No study used a reproducible method such as the AMP [69] or the walking speed in timed walk tests [69,97] to support this determination. One study assessed the AMP but did not use it to determine the mobility grade [21]. The individual AMP values ranged from 34 to 41, with most values exceeding 36, the currently recommended upper cutoff for MFCL-2. However, in the original publication of Gailey et al., the mean and standard deviation of AMP values across the MFCL-2 patient sample was  $34.65 \pm 6.49$ , with a range of 19 to 41 [69]. The other studies assessed the fastest possible walking speed in timed walk tests [31,98–99] or during motion analysis [100–101]. Because a walking distance of up to 150 m in the 2-min walk test (2MWT) (equals a walking velocity of up to 4.5 km/h or 1.25 m/s) is still indicative of limitations of

the overall walking capabilities [97], the assignment of the patients studied to the MFCL-2 mobility grade appears justified. Table 3 describes the demographics of the 57 subjects included in the six studies as well as the NMPKs used at the time of enrollment and as controls.

### Stratification of Subjects With Medicare Functional Classification Level-2 Mobility Grade

Because only one of the four studies (six publications) reviewed had assessed the AMP, this measure could not be used for a stratification of subjects. One study used the walking speed in the 2MWT as one component for the stratification of the subjects into low, intermediate, and high subgroups [98–99]. The other component, daily activity, had not been assessed in the other studies, but the walking distance or speed in the 2MWT has been shown to correlate well with daily activity [97]. For this reason, the fastest possible walking speed with the NMPK was used to relate the results of three publications [31,100–101] to those of the study that had stratified its sample [98–99] as the best possible approximation. Based on the heterogeneity of the walking speed ranges in the study samples, no a priori subgroups across all studies and outcomes could be created. However, the relationship between the fastest possible walking speed on the NMPK and the results in the different outcome categories when using an MPK allow for interesting conclusions.

### Safety Outcomes

Three studies with a total of 27 limited community ambulators reported outcome measures related to safety

**Table 2.**  
Quality rating of five studies according to criteria of Cochrane review of Hofstad et al. [90].

Study	A1	A2	A3	A4	B5	B6	B7	B8	B9	C10	C11	C12	C13	Total: A + B Criteria	Total: C Criteria	Total: A + B + C Criteria	Overall Grade
Wetz et al., 2005 [102]	0	1	1	0	0	1	0	0	1	1	0	0	0	4	1	5	None
Kahle et al., 2008 [31]	1	0	1	0	1	1	0	1	1	1	0	0	1	6	2	8	B
Hafner & Smith, 2009 [21]	1	1	1	0	1	1	0	1	1	1	0	0	1	7	2	9	B
Theeven et al., 2011 [98]	1	1	1	1	1	1	0	0	1	0	1	0	1	7	2	9	C
Burnfield et al., 2012 [100]	1	0	1	0	1	1	0	1	1	1	0	0	1	6	2	8	B
Theeven et al., 2012 [99]	1	1	1	1	1	1	0	0	1	0	1	0	1	7	2	9	C
Eberly et al., 2014 [101]	1	1	1	0	1	1	0	1	1	1	0	0	1	7	2	9	B

**Table 3.**

Patient demographics and non-microprocessor-controlled prosthetic knees used as controls in clinical trials included and reviewed.

Demographic	Study			
	Kahle et al., 2008 [31]	Hafner & Smith, 2009 [21]	Theeven et al., 2011/2012 [98–99]	Burnfield et al., 2012 [100] and Eberly et al., 2014 [101]
Total ( <i>n</i> )	19	17	30	10
MFCL-2 ( <i>n</i> )	9	8	30*	10
Etiology				
Dysvascular PVD and/or Diabetes	7	1	6	6
Trauma	1	5	23	2
Other	1	2	1	2
Sex				
Male	Not Reported	6	22	5
Female	Not Reported	2	8	5
Age, yr (mean ± SD)	67.1 ± 11.8	57.1 ± 15.4	59.1 ± 13.0	62.0 ± 11.3
Intervention	C-Leg	C-Leg	C-Leg and C-Leg Compact	C-Leg Compact
Control Knee				
Locked	—	—	3	—
Weight-Activated Brake	4	—	5	4
Polycentric	4	6	17	5
Hydraulic	1	2	5	1
Accommodation Time to Intervention	90 d	1–33 wk (mean: 13.5 wk)	1 wk	3 mo

\*MFCL-2 subclassification based on walking speed in 2-min walk test and daily activity: 6 patients “low,” 12 patients “intermediate,” and 12 patients “high.”

MFCL = Medicare Functional Classification Level, PVD = peripheral vascular disease, SD = standard deviation.

of prosthesis use (**Table 4**) [21,31,100]. All three studies had a moderate methodological quality. Because safety is of utmost clinical importance to lower-functioning individuals with a TFA and the patient number of the studies reviewed in this area was rather small ( $\leq 10$ ), we did not only analyze significant differences but also statistical trends with  $0.05 \leq p < 0.1$  because they may have only been insignificant because the studies were statistically underpowered.

Kahle et al. [31] allowed for a post hoc analysis of the number of stumbles and falls that demonstrated a statistically significant reduction of 80 percent in falls that was confirmed by Hafner and Smith [21]. The latter also found a significant decrease in the frequency of stumbles and uncontrolled falls with the C-Leg as well as a statistical trend to reduce frustration with falls and improved confidence while walking. The number of stumbles, embarrassment with falls, and frequency and number of semicontrolled falls did not differ between the knee joint

conditions. Burnfield et al. reported a significant improvement in the performance-based time to complete the TUG and in perceived balance in 16 ADLs as measured by the ABC with the MPK [100].

In summary, out of the 13 validated safety-related outcome measures assessed in the three studies, not a single outcome measure showed a significant benefit or statistical trend in favor of the NMPKs. Four outcome measures (39%) showed no difference between the knee joint conditions. Six outcome measures (46%), including the only performance-based one, demonstrated a significant improvement, and two outcome measures (15%) showed a statistical trend toward improvement when using a C-Leg or C-Leg Compact. A significant reduction in falls and the risk of falling as well as a significant improvement in balance were obtained in subjects across the whole MFCL-2 mobility spectrum studied, from fastest possible walking velocities between 1.8 and 3.3 km/h

**Table 4.**

Safety outcomes. Due to low patient number of studies, safety outcomes with statistical trend toward significance ( $p < 0.10$ ) were also analyzed.

Outcome	Study		
	Kahle et al., 2008 [31]	Hafner & Smith, 2009 [21]	Burnfield et al., 2012 [100]
Methodological Quality	B	B	B
Study Design	Crossover	Crossover (reanalysis)	Crossover
Fastest Walking Speed on NMPK Prosthesis	75 m walk test: $2.68 \pm 0.68$ km/h ( $0.75 \pm 0.19$ m/s)	Not reported	Gait analysis: $2.48 \pm 0.79$ km/h ( $0.69 \pm 0.22$ m/s)
Study Outcome Measures Related to Prosthesis Safety	Self-reported number of stumbles and falls	PEQ-Addendum	TUG, ABC
Measurement Method	Interview	Questionnaire (VAS)	Clinical test, questionnaire (VAS)
Results with Statistical Significance ( $p < 0.05$ ) in Favor of MPK	Number of falls decreased 81% from $2.1 \pm 1.5$ to $0.4 \pm 0.7$ ( $p = 0.05$ )*	Frequency of stumbles decreased 15.8% ( $p = 0.05$ ); Number of uncontrolled falls decreased 80% ( $p = 0.01$ ); Frequency of uncontrolled falls decreased 4.5% ( $p = 0.01$ )	TUG decreased 28% from 24.5 to 17.7 s ( $p = 0.02$ ); ABC improved 26% from 60.1 to 75.7 ( $p = 0.001$ )
Results with Statistical Trend ( $0.05 \leq p < 0.10$ ) in Favor of MPK	None	Confidence while walking improved 12% ( $p = 0.08$ ); Frustration with falls decreased 23.4% ( $p = 0.06$ )	None
Results Showing No Statistical Difference Between MPK and NMPK	Number of stumbles	Embarrassment with falls; Number of stumbles; Frequency of semicontrolled falls; Number of semicontrolled falls	None
Results with Statistical Trend ( $0.05 \leq p < 0.10$ ) in Favor of NMPK	None	None	None
Results with Statistical Significance ( $p < 0.05$ ) in Favor of NMPK	None	None	None

\*Analyzed from individual data of MFCL-2 subjects reported in article, Wilcoxon signed rank test.

ABC = Activity-specific Balance Confidence Scale, MFCL = Medicare Functional Classification Level, MPK = microprocessor-controlled knee, NMPK = non-microprocessor-controlled prosthetic knee, PEQ = Prosthesis Evaluation Questionnaire, TUG = Timed "Up and Go" test, VAS = visual analog scale.

(0.50–0.92 m/s) to subjects presenting AMP values between 34 and 41 on their NMPK.

### Performance-Based Function and Mobility Outcomes

Performance-based function and mobility outcomes were reported by all six articles with a total of 57 subjects with MFCL-2 mobility grade (Table 5) [21,31,98–101]. Four articles were ranked moderate and two ranked low in methodological quality. The studies analyzed have reported on a variety of different mobility outcomes with the synthesis of results suggesting that persons with unilateral TFA and MFCL-2 mobility grade are able to walk

about 14 to 25 percent faster on level ground [31,101], around 20 percent quicker on uneven surfaces [21,31], and almost 30 percent faster when descending a slope or hill [21,100] when using an MPK than with an NMPK. Two studies each consistently demonstrated an improvement in stair descent [21,31] and slope descent [21,100] qualities when using an MPK. Hafner and Smith also saw an increase in divided attention walking speed on the C-Leg but no difference in the accuracy of the divided attention tasks between the knee conditions [21]. In a reevaluation of the patients' mobility grade after accommodation to the C-Leg, two studies found that 44 [31] or

**Table 5.**

Function and mobility outcomes. Note that AS1 = standing activities requiring adequate balance, AS2 = activities requiring sitting down and standing up, and AS3 = ambulation activities heavily depending on patient's prosthesis-related skills.

Outcome	Study					
	Kahle et al., 2008 [31]	Hafner & Smith, 2009 [21]	Theeven et al., 2011 [98]	Theeven et al., 2012 [99]	Burnfield et al., 2012 [100]	Eberly et al., 2014 [101]
Methodological Quality	B	B	C	C	B	B
Study Design	Crossover	Crossover (reanalysis)	Randomized double crossover	Randomized double crossover (additional data)	Crossover	Crossover (additional data)
Fastest Walking Speed on NMPK Prosthesis	75 m walk test: 2.68 ± 0.68 km/h (0.75 ± 0.19 m/s)	Not reported	2MWT: Low 2.5 ± 0.4 km/h (0.69 ± 0.11 m/s); Intermediate 3.2 ± 0.4 km/h (0.89 ± 0.11 m/s); High 4.0 ± 0.5 km/h (1.11 ± 0.11 m/s)	2MWT: Low 2.5 ± 0.4 km/h (0.69 ± 0.11 m/s); Intermediate 3.2 ± 0.4 km/h (0.89 ± 0.11 m/s); High 4.0 ± 0.5 km/h (1.11 ± 0.11 m/s)	Gait analysis: 2.48 ± 0.79 km/h (0.69 ± 0.22 m/s)	Gait analysis: 2.48 ± 0.79 km/h (0.69 ± 0.22 m/s)
Study Outcome Measures Related to Function and Mobility	Walking tests on level and uneven ground, stairs performance (MRPP), MFCL	Walking tests on hills and stairs, dual task performance, AMP	Performance in ADLs (ADAPT test)	Daily activity	Biomechanical assessment and muscle activation (EMG) on ramp	Biomechanical assessment of walking on level ground
Measurement Method	Performance-based tests	Performance-based tests	Performance-based test	Activity monitoring in home environment	Biomechanical assessment (gait analysis)	Biomechanical assessment (gait analysis)
Results of Outcome Measures of Interest with Statistical Significance ( $p < 0.05$ )	Fastest possible walking speed on 75 m level ground increased 14.4% ( $p = 0.01$ );* Walking speed on 38 m uneven terrain increased 19.9% ( $p = 0.008$ );* Stair descent improved 62.8% ( $p = 0.04$ )*	Stair descent (Stair Assessment Index) improved 273% ( $p = 0.008$ ); Hill descent (Hill Assessment Index) improved 38.9% ( $p = 0.008$ ); Downhill walking speed increased 29.4% ( $p = 0.002$ ); Obstacle course walking speed increased 11.3% ( $p = 0.02$ ); Attention walking speed increased 12% ( $p = 0.02$ )	Performance times in AS1 decreased with C-Leg and C-Leg Compact in total group ( $p = 0.0001$ and 0.002), in high MFCL-2 ( $p = 0.01$ and 0.02), and in intermediate MFCL-2 ( $p = 0.004$ and 0.008); Performance times in AS2 decreased in intermediate MFCL-2 with C-leg ( $p = 0.02$ ); Performance times in AS3 decreased in high MFCL-2 with C-Leg Compact ( $p = 0.02$ )	None	Walking speed on ramp increased: ascent 28% ( $p = 0.006$ ), descent 36% ( $p = 0.001$ ); Stride length on ramp increased: ascent 14% ( $p = 0.02$ ), descent 17% ( $p = 0.003$ ); Cadence on ramp increased: ascent 14% ( $p = 0.007$ ), descent 16% ( $p = 0.02$ ); Prosthetic limb support on ramp increased: ascent 17% ( $p = 0.005$ ), descent 17% ( $p = 0.002$ ); Increased hip and knee flexion and ankle dorsiflexion during ramp descent ( $p = 0.05$ )	Free and fast walking speed increased 20% ( $p = 0.002$ ) and 25% ( $p < 0.001$ ), respectively; Free and fast walking cadence increased 9% ( $p = 0.001$ ) and 11% ( $p = 0.002$ ), respectively; Free and fast walking stride length increased 12% ( $p = 0.003$ ) and 14% ( $p < 0.001$ ), respectively; Free walking prosthetic single-leg support increased 3% ( $p = 0.05$ ); Free and fast walking prosthetic limb heel rise ( $p = 0.03$ and 0.02, respectively); Free

**Table 5. (cont)**

Function and mobility outcomes. Note that AS1 = standing activities requiring adequate balance, AS2 = activities requiring sitting down and standing up, and AS3 = ambulation activities heavily depending on patient's prosthesis-related skills.

Outcome	Study					
	Kahle et al., 2008 [31]	Hafner & Smith, 2009 [21]	Theeven et al., 2011 [98]	Theeven et al., 2012 [99]	Burnfield et al., 2012 [100]	Eberly et al., 2014 [101]
					each); Earlier prosthetic limb heel-off during ramp descent: 21% ( $p = 0.01$ )	and fast walking peak hip and thigh extension angles during stance ( $p = 0.005$ each); Free and fast walking peak ankle stance moment ( $p = 0.001$ and $0.008$ , respectively); Fast walking peak knee loading moment ( $p = 0.05$ ); Free and fast walking peak knee terminal stance moment ( $p = 0.04$ and $0.03$ , respectively); Fast walking peak hip stance moment ( $p = 0.02$ ); Fast walking preswing ankle power generation ( $p = 0.04$ ); Fast walking peak hip loading response generation ( $p = 0.05$ ); Free and fast walking intact limb tibialis anterior muscle activity ( $p = 0.002$ and $0.003$ , respectively) and prosthetic limb gluteus maximus activity ( $p = 0.02$ and $0.02$ , respectively)
Results Showing No Statistical Difference Between MPK and NMPK	Self-selected walking speed on 75 m level ground; * Fastest possible walking speed on 6 m level ground*	AMP; * Accuracy of divided attention task while walking	Performance time in AS1 activities in low MFCL-2 with both MPKs; Performance time in AS2 activities in total group and all subgroups with	Up-time per day; Active time per day; Activity (counts and bouts) per day in total, high, and low subgroup with either MPK and in	Prosthetic limb stance duration in percent of GC during ascent and descent; Prosthetic limb heel-off in percent of GC during ascent;	Fast walking prosthetic limb single-leg support; Free and fast walking peak knee and ankle angles; Free walking peak hip stance moment;

**Table 5. (cont)**

Function and mobility outcomes. Note that AS1 = standing activities requiring adequate balance, AS2 = activities requiring sitting down and standing up, and AS3 = ambulation activities heavily depending on patient's prosthesis-related skills.

Outcome	Study					
	Kahle et al., 2008 [31]	Hafner & Smith, 2009 [21]	Theeven et al., 2011 [98]	Theeven et al., 2012 [99]	Burnfield et al., 2012 [100]	Eberly et al., 2014 [101]
			C-Leg Compact and in total group, high and low subgroups with C-Leg; Performance time in AS3 activities in total group and all subgroups with C-Leg and in total group and intermediate and low subgroups with C-Leg Compact	intermediate group with C-leg Compact	Prosthetic limb peak angles during ascent; Prosthetic limb weight acceptance curve during ascent and descent; Muscle activity (EMG pattern)	Free walking peak knee loading moment; Free and fast walking terminal stance peak ankle power absorption; Free walking preswing ankle power generation; Free walking peak hip loading response power generation; Free and fast walking terminal stance peak hip power absorption; Muscle activity of all leg muscles except intact limb tibialis anterior and prosthetic limb gluteus maximus
Results with Statistical Significance ( $p < 0.05$ ) in favor of NMPK	None	None	None	Activity count per day in intermediate group with C-leg ( $p = 0.02$ )	None	None
Change in MFCL Classification with MPK	4 of 9 subjects (44%) improved to MFCL-3	4 of 8 subjects (50%) improved to MFCL-3	—	—	—	—

\*Analyzed from individual data of MFCL-2 subjects reported in article, Wilcoxon signed rank test.

2MWT = 2-min walk test, ADAPT = Assessment of Daily Activity Performance in Transfemoral Amputees, ADL = activity of daily living, AMP = Amputee Mobility Predictor, EMG = electromyography, GC = gait cycle, MFCL = Medicare Functional Classification Level, MPK = microprocessor-controlled prosthetic knee, MRPP = Montreal Rehabilitation Performance Profile, NMPK = non-microprocessor-controlled prosthetic knee.

50 [21] percent, respectively, of the MFCL-2 individuals had improved their mobility grade to MFCL-3. Theeven et al. reported significant improvements in performance times for different categories of ADLs in the total group and/or the intermediate and/or high subgroups of MFCL-2 individuals when using the C-Leg and/or the C-Leg Compact [98]. Both the C-Leg and C-Leg Compact significantly improved performance in ADLs requiring adequate balance in the total group and the intermediate and high subgroups. In addition, the C-Leg Compact significantly

improved performance in ADLs requiring sitting down and standing up in the intermediate subgroup, whereas the C-Leg significantly improved performance in ADLs heavily dependent on the patient's prosthesis-related skills in the high subgroup. In a later publication, no differences between up-time, active time, and activity during the day were seen when using the different prosthetic knees, with the exception of the intermediate subgroup demonstrating a reduced activity count after 1 wk of accommodation to the C-Leg [99].

In summary, out of a total of 51 performance-based outcome measures and 40 biomechanical gait parameters that are related to function and mobility subjected to statistical analysis, only the activity count per day in the intermediate subgroup of Theeven et al. showed a significant effect in favor of the NMPK as compared with the C-Leg [99]. In 23 outcome measures (45%) and 22 biomechanical gait parameters (55%), no differences were found between the prosthetic knee conditions. For 28 outcome measures (55%) and 18 biomechanical gait parameters (45%), a significant improvement was demonstrated when using an MPK, enabling patients to better and/or faster execute indoor ADLs as well as activities of community ambulation typical for MFCL-3 mobility grade such as medium-distance level, uneven terrain, slope, and hill walking as well as stair negotiation. However, an interesting relationship between the fastest possible walking speed on the NMPK and these improvements was seen. Improvements in abilities necessary for community ambulation were demonstrated in individuals across all subgroups of the MFCL-2 mobility grade range, represented by slow to medium maximum walking velocities between 1.8 and 3.3 km/h (0.50–0.92 m/s) and high AMP values between 34 and 41. In contrast, improvements in indoor ADLs were only seen in individuals walking with medium to high maximum velocities between 2.8 and 4.5 km/h (0.78–1.25 m/s).

### Perceived Function, Satisfaction, and Prosthesis Preference

Results on perceived function and satisfaction were reported by five articles with a total of 57 subjects with MFCL-2 mobility grade (Table 6) [21,31,98–100]. Three of these articles [21,31,100] had a moderate methodological quality and two [98–99] had a low methodological quality. Hafner and Smith reported a significant improvement of the perceived ability for multitasking while walking with the C-Leg [21]. Burnfield et al. found a significant improvement in the PEQ Mobility scale, but not in the Houghton Scale, when using the C-Leg Compact [100]. Theeven et al. found a significant reduction in perceived difficulty to perform ADLs requiring sitting down and standing up and those heavily dependent on the patient's prosthesis-related skills in the total MFCL-2 study group with the C-Leg but not in the subgroups and not when using the C-Leg Compact [98]. In a later article, the same research group reported significant improvements in self-reported ambulation, utility,

residual-limb health, and satisfaction with walking in the total group and/or certain subgroups of the same MFCL-2 sample when using the C-Leg and/or C-Leg Compact [99]. Satisfaction with the prosthesis improved significantly in the total group with the C-Leg (Table 6).

In summary, out of the 96 self-reported outcome measures not a single one demonstrated superiority of the NMPKs. For the majority of 74 perceived outcome measures (77%), no significant differences were found between the prosthetic knee interventions. Use of an MPK resulted in significant improvements in 22 self-reported outcome measures (23%). These were mainly demonstrated for subjects walking at medium to higher velocities between 2.8 and 4.5 km/h (0.78–1.25 m/s).

In their earlier article, Theeven et al. reported that 70 percent of the MFCL-2 individuals subjectively preferred the C-Leg, 23 percent preferred the C-Leg Compact, and only 7 percent preferred their previous NMPK [98]. These results are consistent with the findings of Kahle et al., who found that 90 percent of the MFCL-2 subjects in their study preferred the C-Leg [31].

In addition, it is noteworthy that neither study reported any adverse events in association with the use of the C-Leg or C-Leg Compact.

## DISCUSSION

We conducted a systematic review of the literature in order to analyze whether or not individuals with a unilateral TFA and MFCL-2 mobility grade may benefit from using MPKs, as has been demonstrated for higher-functioning MFCL-3 individuals [21,23–36]. We were able to identify four studies with six articles that had investigated the effects of MPK use in subjects with a unilateral TFA and MFCL-2 mobility grade and sufficient methodological quality. The moderate to low methodological quality found for the studies complies with the findings of earlier systematic reviews of MPK intervention studies [23,36,96]. Consider, however, that there are serious challenges to prosthetic research, such as limited patient numbers and limited access of research institutions to patients, great functional and prognostic heterogeneity of patients, and practical impossibility of blinding, that result in a comparatively limited methodological quality of prosthetic studies in general [96,103]. Nevertheless, the quality of many clinical studies with MP-controlled components is the highest in the field of prosthetics.

**Table 6.**

Perceived function and mobility, satisfaction, and preference outcomes. Note that AS1 = standing activities requiring adequate balance, AS2 = activities requiring sitting down and standing up, and AS3 = ambulation activities heavily depending on patient's prosthesis-related skills.

Outcome	Study				
	Kahle et al., 2008 [31]	Hafner & Smith, 2009 [21]	Theeven et al., 2011 [98]	Burnfield et al., 2012 [100]	Theeven et al., 2012 [99]
Methodological Quality	B	B	C	B	C
Study Design	Crossover	Crossover (reanalysis)	Randomized double crossover	Crossover	Randomized double crossover (additional data)
Fastest Walking Speed on NMPK Prosthesis	75 m walk test: 2.68 ± 0.68 km/h (0.75 ± 0.19 m/s)	Not reported	2MWT: Low 2.5 ± 0.4 km/h (0.69 ± 0.11 m/s); Intermediate 3.2 ± 0.4 km/h (0.89 ± 0.11 m/s); High 4.0 ± 0.5 km/h (1.11 ± 0.11 m/s)	Gait analysis: 2.48 ± 0.79 km/h (0.69 ± 0.22 m/s)	2MWT: Low 2.5 ± 0.4 km/h (0.69 ± 0.11 m/s); Intermediate 3.2 ± 0.4 km/h (0.89 ± 0.11 m/s); High 4.0 ± 0.5 km/h (1.11 ± 0.11 m/s)
Outcome Measures Related to Perceived Function and Mobility, Satisfaction, and Prosthesis Preference	Prosthesis preference	PEQ, PEQ-Addendum	Perceived difficulty to perform 17 ADLs of ADAPT, prosthesis preference	PEQ Mobility, Houghton Scale	PEQ
Measurement Method	Interview	Questionnaire (VAS)	Questionnaire (VAS), interview	Questionnaire (VAS)	Questionnaire
Results with Statistical Significance ( $p < 0.05$ ) in Favor of MPK	No statistical comparisons	Multitasking while walking improved 21.2% ( $p = 0.04$ )	Perceived difficulty of AS2 and AS3 activities decreased in total group with C-Leg ( $p = 0.02$ and 0.008)	PEQ Mobility score improved 25% ( $p = 0.04$ )	PEQ Ambulation improved with C-Leg in total group 11.5% ( $p = 0.01$ ) and in intermediate MFCL-2 group 11.3% ( $p = 0.009$ ); PEQ Utility improved with C-Leg in total group 12% ( $p = 0.006$ ), in high group 12.9% ( $p = 0.04$ ), and in intermediate group 17.1% ( $p = 0.02$ ) and with C-Leg Compact in total group 11.9% ( $p = 0.02$ ) and in high group 15.5% ( $p = 0.02$ ); PEQ Residual Limb Health improved with C-Leg and C-Leg Compact in total group 16.0% and 22.0% ( $p = 0.003$ and 0.002) and in high MFCL-2 group 27.0% and 37.3% ( $p = 0.01$ and 0.006); Satisfaction with walking

**Table 6. (cont)**

Perceived function and mobility, satisfaction, and preference outcomes. Note that AS1 = standing activities requiring adequate balance, AS2 = activities requiring sitting down and standing up, and AS3 = ambulation activities heavily depending on patient's prosthesis-related skills.

Outcome	Study				
	Kahle et al., 2008 [31]	Hafner & Smith, 2009 [21]	Theeven et al., 2011 [98]	Burnfield et al., 2012 [100]	Theeven et al., 2012 [99]
					improved with C-Leg in total group 23.7% ( $p = 0.003$ ) and in high MFCL-2 15.0% ( $p = 0.04$ ) with both C-Leg 49.8% ( $p = 0.007$ ) and C-Leg Compact 36.5% ( $p = 0.05$ ) in intermediate MFCL-2; Satisfaction with prosthesis improved with C-Leg 15.2% in total group ( $p = 0.05$ )
Results Showing No Statistical Difference Between MPK and NMPK	No statistical comparisons	PEQ Satisfaction; PEQ Ambulation; PEQ Appearance; PEQ Frustration; PEQ Perceived Response; PEQ Residual Limb Health; PEQ Social Burden; PEQ Utility; PEQ Well-being; Mental Energy Expenditure; Difficulty with concentration; Activity avoidance	Perceived difficulty with AS1 in total group and all subgroups with both MPKs; Perceived difficulty with AS2 and AS3 activities in total group with C-Leg Compact and with both MPKs in 3 MFCL-2 subgroups	Houghton Scale	PEQ Ambulation in high and low subgroup with C-Leg and total group and all subgroups with C-Leg Compact; PEQ Appearance in total group and all subgroups with both MPKs; PEQ Residual Limb Health in low and intermediate subgroup with both MPKs; PEQ Sounds in all groups with both MPKs; PEQ Utility in low subgroup for C-Leg and in low and intermediate subgroup for C-Leg Compact; PEQ Well-being in all groups with both MPKs; Satisfaction with prosthesis in all subgroups with C-Leg and all groups with C-Leg Compact;

**Table 6. (cont)**

Perceived function and mobility, satisfaction, and preference outcomes. Note that AS1 = standing activities requiring adequate balance, AS2 = activities requiring sitting down and standing up, and AS3 = ambulation activities heavily depending on patient's prosthesis-related skills.

Outcome	Study				
	Kahle et al., 2008 [31]	Hafner & Smith, 2009 [21]	Theeven et al., 2011 [98]	Burnfield et al., 2012 [100]	Theeven et al., 2012 [99]
Results with Statistical Significance ( $p < 0.05$ ) in Favor of NMPK	No statistical comparisons	None	None	None	None
Prosthesis Preference	8 subjects (90%) preferred C-Leg	—	21 subjects (70%) preferred C-Leg, 7 subjects (23%) preferred C-Leg Compact	—	—
					Satisfaction with walking in low subgroup with C-Leg and in all groups with C-Leg Compact

2MWT = 2-min walk test, ADAPT = Assessment of Daily Activity Performance in Transfemoral Amputees, ADL = activity of daily living, AMP = Amputee Mobility Predictor, EMG = electromyography, GC = gait cycle, MFCL = Medicare Functional Classification Level, MPK = microprocessor-controlled prosthetic knee, NMPK = non-microprocessor-controlled prosthetic knee, PEQ = Prosthesis Evaluation Questionnaire, VAS = visual analog scale.

## Safety

Objective and perceived safety is the foundation of proficient prosthesis use and improvement in function and mobility [8,44–50,104]. The two studies that investigated the MP stance and swing controlled C-Leg demonstrated a significant reduction in the self-reported number and frequency of uncontrolled falls than with the use of the NMPKs [21,31]. The only study that investigated the MP stance controlled C-Leg Compact found a significant reduction in the completion time of the performance-based TUG [57–61] that was almost twice as large as the minimal detectable change (MDC) as reported by Resnik and Borgia [105]. The TUG even fell below the cutoff value of 19 s as reported by Dite et al. to indicate a risk of multiple falls in people with transtibial amputation [62]. This finding was accompanied by a significant improvement in self-reported balance as measured by the ABC exceeding the validated score of 67, indicating a low risk of falling [6–7,66]. In summary, the best validated performance-based safety outcome measure and those self-reported measures indicating the most dangerous adverse events of prosthesis use consistently demonstrated a significant gain in safety when using an MPK. In contrast, the measures that found no difference between the pros-

thetic knees are all indicators of events that are certainly unpleasant, such as stumbles and semicontrolled falls, but involve considerably lesser risks of serious consequences. Two of the studies found improvements in safety in subjects capable of walking between 1.8 and 3.3 km/h on their NMPK prosthesis [31,100]. The third article did not report walking speeds, but the AMP values suggest that the patients belonged to the medium- to high-functioning segment of the MFCL-2 population [21]. Thus, it can be concluded that the two hydraulic MPKs studied may improve the safety of prosthesis use in individuals with a unilateral TFA and MFCL-2 mobility grade to the same extent as they do in subjects with a higher mobility grade level [23,36].

The significant gain in safety can be explained by the difference in technology between the MP default stance control and the non-MP default swing control knees that are usually prescribed for MFCL-2 subjects, namely weight-activated “safety” brake knees and 4-bar or multi-axial polycentric knees. In brake knees, stance control and stability is activated by the combination of full knee extension and weight loading. In polycentric knees, stance stability is achieved by projection of the instantaneous center of rotation (ICR) behind the vector of the

vertical ground reaction force (GRF) at full knee extension. If not fully extended at heel strike, both brake and polycentric knees may fail to provide knee stability due to lever moments exceeding the braking capacity (brake knees) or shift of the ICR close to or even in front of the GRF (polycentric knees) resulting in a knee flexion moment that immediately voids knee stability. Full knee extension at loading response can be achieved by walking straight on level ground with more or less fixed velocity, cadence, and stride length as is postulated for MFCL-2 individuals. However, many ADLs and community ambulation require locomotion in confined spaces with turns, stepping in different directions, variation of step length, negotiation of barriers and obstacles, and movements of the upper body that may change the position of the center of mass and the resulting GRF, which may prevent the prosthetic knee from reaching full extension [25]. Designed as default swing knees, brake and polycentric knees will inevitably collapse when loaded in such situations [16–22,106–108], thus exposing the patient to a substantial risk of falling. The very limited safety of weight-activated brake knees has been demonstrated in a clinical trial with elderly persons with a dysvascular above-knee amputation [104]. Although accommodated to the brake knee, the patients preferred a locked knee for safety reasons [104].

In contrast, the default setting of the two MPKs studied is to control stance stability unless they are explicitly switched into swing control. But even when in the swing mode, the two MPKs provide high flexion resistance for stumble recovery during the swing extension movement that is able to prevent knee collapse even if the prosthesis is fully loaded [27,35]. Unlike in the typical MFCL-2 knee joints, turns, changes in walking direction, movements of the upper body, stepping onto obstacles, walking on ramps, walking on stairs, and even stumbles do not affect the stance safety of the C-Leg or C-Leg Compact [24–25,27,35].

With the safety limitations described previously, the prosthetic knees typically prescribed for MFCL-2 individuals may even contribute to activity avoidance, increased dependency, and limited community ambulation. Because the C-Leg and C-Leg Compact have been demonstrated to reduce uncontrolled falls, to lower the risk of falling, and to improve balance, they may create a safe foundation for increasing community ambulation and independence in individuals with a TFA and MFCL-2 mobility grade.

### Performance-Based Function and Mobility

All six articles consistently reported that, when using an MPK, limited community ambulators may significantly improve their abilities to perform activities of community ambulation such as negotiating uneven terrain and environmental obstacles [21,31], ramps [100], hills [21], and stairs [21,31] and multitasking while walking [21]. The higher-functioning MFCL-2 subgroups may also improve the ability to perform many indoor ADLs [98]. The reduction in the activity count seen in the intermediate subgroup of Theeven et al. [99] when using an MPK might possibly be explained by the increase in stride length as demonstrated in one of the other articles [101], resulting simply in fewer steps required to ambulate the same distance. The significant improvements in 55 percent of all performance-based outcome measures assessed indicate that the two hydraulic MPKs studied may enable limited community ambulators to perform activities that, by definition, are typical for unlimited community ambulators with MFCL-3 mobility grade. This is further supported by the fact that two articles found that 44 to 50 percent of MFCL-2 subjects were able to improve their overall functional level to MFCL-3 when using a C-Leg [21,31]. However, these findings must be interpreted with caution, because the definition of the MFCL is very general and grants much room for subjective interpretation by the assessor, especially when speculating about the functional “potential” of the patient (**Table 1**). To date, no approved tests exist to objectify the assignment of a patient to a certain functional level. The AMP has been proposed to address this issue, but the currently recommended cutoff values to distinguish the functional levels have not yet been validated [69]. Nevertheless, one or more performance-based tests to objectify the functional classification or even a completely new, validated, and unambiguously quantifiable functional classification of patients that ideally may also be used as outcome measures would represent substantial progress away from the current ambiguous classification. Based on the fastest possible walking speed on the NMPK, the studies reviewed have demonstrated a huge patient variability within the MFCL-2 mobility grade. Performance-based tests might therefore also help indicate clinically meaningful improvements within a functional classification level that are inevitably missed today.

Across the studies, there was an interesting relationship between the maximum walking speed on the NMPKs

as a validated indicator of the overall walking capabilities [97] and the improvements in activities of community ambulation on the one hand and in indoor ADLs on the other. While improvements in activities of community ambulation have been demonstrated across the entire MFCL-2 mobility range [21,31,100–101], improvements in performance in indoor ADLs have only been shown for higher-functioning individuals within the MFCL-2 mobility spectrum, capable of walking at fast velocities of about 2.8 to 4.5 km/h [98]. This discrepancy may be explained by the difference in accommodation time between the trials, which was 3 mo on average in the studies that investigated community ambulation and only as short as 1 wk in the study of indoor ADLs. It could well be that lower-functioning individuals need more time and training to adapt to a prosthetic intervention than higher-functioning subjects and that the results of the latter might have further improved with longer accommodation [27,34,109]. Comparing the statistical and individual results in the various subgroups, Theeven et al. stressed the importance of an individual patient assessment because some individuals of the high subgroup did not improve their performance on either MPK whereas some subjects of the low subgroup did [98].

As for safety of prosthesis use, the improvement in performance-based function and mobility outcomes can be explained by the differences in technology between the prosthetic knees. Many ADLs in the house and activities of community ambulation such as sitting down and walking on slopes, on stairs, on uneven terrain, and over obstacles are physiologically performed by nondisabled subjects with knee flexion during weight-bearing. In subjects with a TFA, this control must be provided by the prosthetic knee. The knee mechanisms typically fitted in limited community ambulators have in common that they do not allow for knee flexion during weight-bearing (yielding). Therefore, consider that the assignment of an individual to the MFCL-2 mobility grade and the commonly consequent selection of prosthetic componentry may technically restrict the achievable mobility of a part of this population. Knee flexion during weight-bearing (yielding) is only permitted by hydraulic stance control knees [16–19,22,106–108]. Based on technical considerations [16–19,22,106–108] and one older study [110], MFCL-2 subjects are hardly able to safely control the switching mechanisms of hydraulic NMPKs. Meanwhile, sensor input and MP control have overcome the physical challenges to safely use hydraulic knees. As the results of

the studies reviewed have consistently shown, the hydraulic default stance MPKs C-Leg and C-Leg Compact may enable individuals with a TFA and MFCL-2 mobility grade to execute activities of community ambulation, as well as indoor ADLs, better and faster while increasing safety of prosthesis use at the same time. These findings are consistent with those for individuals with MFCL-3 mobility grade [23].

In addition, those individuals who are capable of walking at a faster velocity of more than 2.9 km/h (0.8 m/s) on their NMPK tend to benefit more from the C-Leg than from the C-Leg Compact [98]. This might be explained by the fact that patients who walk faster are also more likely to walk with a broader range of walking speeds, thus possibly taking advantage of the additional MP hydraulic swing control of the C-Leg rather than of the conventional hydraulic swing control of the C-Leg Compact.

### **Perceived Function and Satisfaction**

Somewhat unexpectedly, the improvements in perceived function and mobility as assessed by self-reported outcome measures for use of an MPK lag behind the performance-based improvements. Only 22 percent of the self-reported outcome measures related to function, mobility, and satisfaction showed a significant improvement as a result of MPK use, mainly in the higher-functioning subset of the MFCL-2 mobility range for indoor ADLs. Note, however, that the perceived difficulty to perform the ADLs investigated in Theeven et al. was relatively low across all subgroups, even when using a NMPK, leaving not much room for further improvement [98]. For the lower-functioning, slower-walking subset of the MFCL-2 mobility range, only Burnfield et al. reported a significant increase in the PEQ Mobility scale [100], but the reported increase was twice as big as the MDC as reported by Resnik and Borgia [105]. This means that MFCL-2 individuals, especially at the lower end of the studied mobility spectrum, experience greater improvements in objective performance by MPK use than they subjectively acknowledge. In contrast, the two studies that asked the subjects for their personal prosthesis preference found that 90 percent of patients preferred the MPK over their previous NMPK [31,98]. The explanation for this discrepancy between the limited perceived functional improvements and the clear prosthetic knee preference may be found in the far better improvement of perceived safety of prosthesis use with either MPK as discussed previously.

### Recommendation for Practice

The results of this systematic review suggest that the use of MP hydraulic stance only or MP stance and swing control prosthetic knees may improve safety, function, and mobility of limited community ambulators with unilateral TFA. In light of these findings, it no longer appears appropriate to generally withhold this advanced prosthetic technology from MFCL-2 individuals. On the other hand, the current state of the research does not justify fit of an MPK in all limited community ambulators. But even high-quality clinical research with RCTs only allows for conclusions on the basis of means and averages of the studied population but not on an individual patient [111]. Several European healthcare systems, e.g., in Germany, Austria, the Netherlands, Italy, and France, have addressed the issue of individual decision-making in prosthetics by allowing trial fittings to study whether an individual patient benefits from an MPK intervention, as supported by the findings of Theeven et al. [98]. Many factors contribute to the success or failure of prosthetic interventions, including the actual everyday mobility needs, the basic physical capabilities, and the personal objectives and motivation of the patient [112]. Based on the clinical studies analyzed in the present systematic review, the following suggestions for preliminary qualifying and decision-making criteria can be made:

1. Patients who walk less than 60 m (195 ft) on their NMPK in the 2MWT, which equals an average walking speed of less than 1.8 km/h (1.1 mph), have not yet been studied with MPK interventions. That does not necessarily mean that these patients disqualify for an MPK trial fitting, but no research-based suggestions or recommendations for this patient group can be given.
2. Patients who are capable of walking between 60 and 95 m (195 to 310 ft) in the 2MWT on their NMPK, which equals an average walking speed between 1.8 and 2.9 km/h (1.1–1.8 mph) may benefit from using an MPK for safety and to improve the abilities required for community ambulation. Their walking speed and ability to vary walking velocity suggests that MP swing control may not necessarily be required; therefore, a trial fitting with the MP stance controlled C-Leg Compact may be considered.
3. Patients who are able to walk more than 95 m (310 ft) in the 2MWT on their NMPK, which equals a walking speed of faster than 2.9 km/h (1.8 mph) may benefit from using an MPK for safety, community ambula-

tion, and indoor ADLs. Their higher walking speed is likely to result in a higher ability to vary walking velocities and may therefore justify a trial fitting with the MP stance and swing controlled C-Leg.

After appropriate training and accommodation, the patient should demonstrate an improvement in the distance walked in the 2MWT as a validated outcome measure for the overall walking capabilities and mobility [104,113]. The MDC in subjects with a lower-limb amputation has been reported to be between 17 m (56 ft) [104] and 34.3 m (113 ft) [105], but the latter value has been established for mixed groups of higher-functioning subjects with transtibial amputation and TFA. In elderly, nonamputated, prefrail, and frail subjects; patients with stroke; and patients with hip fracture, improvements in short-distance (3–10 m) walking speed of 0.1 m/s are considered clinically meaningful [114–119] and correlate with the risk of falling [120], frailty [121], and even survival [122–123]. We therefore believe that a minimum improvement in average walking speed in the 2MWT of 0.1 m/s, which would result in an increase in the distance walked of at least 12 m (40 ft), may also be considered clinically meaningful and justify the use of an MPK in individuals with a TFA and MFCL-2 mobility grade. In addition, an improvement in the TUG exceeding the MDC of 3.6 s [105], preferably under the cutoff value of 19 s that indicates a risk of multiple falls in subjects with transtibial amputation, may be considered a clinically relevant improvement in prosthesis safety [62]. Likewise, an improvement of perceived balance on the ABC [6–7,66] indicates improved confidence in prosthesis use. An MDC for the ABC score in subjects with an amputation has not yet been established, but an improvement over the cutoff value of 67 for a low risk of falling may be considered clinically relevant.

In everyday practice, the AMP is increasingly used to objectify the determination of the functional level of an individual with a lower-limb amputation [69]. Unfortunately, none of the studies reviewed used the AMP, neither to determine the functional level nor as an outcome measure. However, based on the published research on the AMP [69,105], an improvement of the score that exceeds the MDC of 3.4 points [105] may also be considered clinically meaningful. Further research with more patients and improved methodological quality is warranted to corroborate and refine or revise these preliminary suggestions.

## Limitations

This systematic review has several limitations. Although the literature search strategy and the medical databases searched were quite comprehensive, it is possible that not all existing clinical studies and publications on the effects of MPK use in the limited community ambulator population have been identified. Also, the restriction on English- and German-language publications may have resulted in missing important studies on this subject published in other languages. Moreover, a publication bias toward favorable results of the use of the MPKs cannot fully be excluded.

The relatively low total patient number of 57 limited community ambulators and especially the low number of individuals with a dysvascular amputation is a limitation of this systematic review. There is some evidence, however, that many of these individuals may belong to the very low-functioning segment of the MFCL-2 mobility spectrum that has not yet been studied with MPK interventions [104]. The challenges to prosthetic research in this population became obvious in Theeven et al. in that only 40 percent of patients who met the inclusion criteria agreed to participate and almost all of the dropouts had been subjects with a dysvascular amputation [98–99]. Nevertheless, future research will have to address the specific conditions and needs of that population.

Also, grouping study results according to the fastest possible walking speed and basing the recommendations for preliminary qualifying and decision-making criteria for trial fittings has limitations. Only one study [98–99] used the 2MWT to determine walking speed. One study [31] used the 75 m fastest possible walking speed on level ground test that, when analyzing the completion times, comes close to the 2MWT; one study [100–101] only reported the walking speed measured during motion capture in the gait laboratory; and one study did not report any walking speed at all [21]. Hafner and Smith, however, reported individual AMP values that indicated that the patients belonged to the intermediate- and high-functioning MFCL-2 mobility segment [21]. It seems likely that some of the patients in the motion analysis study may not be able to maintain the walking speed measured in the gait laboratory as the average walking velocity in the 2MWT [100–101]. We therefore believe that patients who walk less than 60 m (195 ft) in the 2MWT should not generally be excluded from MPK trial fittings. However, in light of the consistent results of this systematic review, it seems appropriate to make MPK

trial fittings available to the higher-functioning subset of limited community ambulators first. This approach also complies with the current paradigm that a certain basic physical fitness is required to likely benefit from using an MPK.

## CONCLUSIONS

The results of this systematic review of clinical trials on interventions with MPKs in individuals with a unilateral TFA and MFCL-2 mobility grade suggest that these subjects may significantly reduce the number of falls and their risk of falling, improve their balance, and better perform activities of community ambulation that are actually categorized as part of the MFCL-3 mobility grade. Because these results have been derived from studies with low to moderate methodological quality in a yet limited number of patients, trial fittings with different types of MPKs (MP stance only or MP stance and swing control) may be considered to evaluate whether an individual benefits from using an MPK compared with NMPKs usually prescribed for MFCL-2 individuals. Criteria for appraising success or failure of the trial fitting based on the 2MWT, AMP, TUG, and ABC have been suggested. Given the challenges to objectify the current general and ambiguous definitions of the MFCLs, an evidence-based and unambiguously quantifiable functional classification or one or more validated outcome measures to corroborate the classification would help better define patient groups to be subjected to clinical research and sharpen coverage and reimbursement criteria.

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