Kenevo®

Reimbursement Guide

Quality for life

Information for practitioners and payers
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8. Clinical Studies using Microprocessor Knees with K2 Subjects
Falling is a major issue in patients with transfemoral amputations with a reported annual incidence of more than 50% [1]. On average, individuals who fall with their prosthesis experience 3-4 falls per year [2]. A systematic review found prostheses with microprocessor-controlled knees (MPK) have been demonstrated to improve both psychoemotional and physical aspects of balance and falls. At the time this review was performed, there were only publications of studies with Ottobock MPK in K2 patients [6]. Evidence suggests that use of microprocessor knees (MPKs) can significantly reduce falls by up to 80% in individuals with Medicare functional classification level-2 (MFCL-2) mobility [3, 6, 7, 8]. In addition, a recently published analysis of the RAND Corporation estimated that MPKs may also reduce the risk of fall-related death and sustaining fall-related injuries by up to 79%. In this study, 85% of the evidence analyzed and used as a basis for the authors’ simulation were studies with Ottobock products [2]. Fall-related injuries are costly occurrences. A recent study estimated that medical expenses for treatment related to falls by older adults that did not result in death were close to $50 billion in 2015 [13]. Of that, Medicare funded $37.6 billion, while other payers including private health insurances funded $12 billion. In 2015 there were also 28,486 accidental fall-related deaths that resulted in over $750 million in medical cost [13]. Burns et al. reported that in 2012, hospitalization cost for fall-related injuries was almost $30,000 per occurrence [14]. In individuals with above-knee amputation, MPKs may contribute to containing cost incurring for falls [2].

Since the early 1990s, Medicare adopted MFCLs to rate an amputee’s ability and/or potential to ambulate. Prosthetic knee coverage criteria developed based on these MFCLs, appropriate for the prosthetic devices available at the time have not been modified since. Although MPK technology has progressed to overcome the inverse relationship between stability and function, current coverage criteria restrict advanced technology to younger, healthier, higher-functioning individuals. This is in contrast to other fields of healthcare in which advanced technology serves the oldest, sickest and most restricted patients. As a result of the MFCL restrictions, many transfemoral amputees are unable to benefit from the microprocessor technology covered under their current policy criteria.

A published systematic review of clinical trials [6] investigated whether MFCL-2 amputees might also benefit from using an MPK in safety, performance-based function and mobility and perceived function and satisfaction. Based on a review of 6 publications with 57 subjects with transfemoral amputation (TFA) and MFCL-2 mobility grade [7-12], the study reported that (1) MPK use may significantly reduce uncontrolled falls by up to 80% and significantly improve the
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indicators of fall risk; (2) that walking speed may be increased by 14-25% on level surfaces, by 20% on uneven surfaces and by 30% descending a slope; and (3) that the MPK enabled them to better perform activities of community ambulation actually categorized as part of MFCL-3 mobility grade. This last point is further supported by the fact 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 based on two articles [6, 7, 8]. These results, especially the significant reduction in falls and risk of falling, were recently confirmed in bigger clinical studies with 50 and 30 subjects, respectively [3, 4]. In an observational study with 29 subjects using Kenevo, more than half of the individuals reported significant perceived improvements in activities of community ambulation as well as a significant reduction in additional wheelchair use from 87% to 37% of patients [5]. Finally, in three studies that measured personal preference, 90% of patients preferred the MPK over their previous non-microprocessor knee (NMPK) [5, 7, 8].

The results of the systematic review above suggest it is no longer appropriate to generally withhold MPK technology from MFCL-2 patients [6]. While current research does not justify an MPK fitting for all limited community ambulators, trial fittings could be used to determine whether or not patients with TFA and MFCL-2 mobility grade benefit from MPK use. The following proposal for patient selection and assessment is based on the 2-minute walk test (2MWT):

1) Patients walking up to 95m/305ft/0.8m/s in the 2MWT may qualify for a trial fitting with an MP stance controlled prosthetic knee.

2) Patients walking more than 95m/305ft/0.8m/s in the 2MWT may quality for a trial fitting with a MP stance and swing controlled C-Leg.

In addition to the sound evidence supporting the use of microprocessor knees for K2 transfemoral amputees, there have been two guidance documents recently released. First, the Veteran’s Administration updated their clinical practice guidelines for the rehabilitation of lower-limb amputees, and determined that microprocessor knees may reduce risk of falls and maximize patient satisfaction in limited and unlimited community ambulators. The guideline recommends microprocessor knees over non-microprocessor knees as the first definitive prosthesis [15]. Their decision was based on two systematic reviews, both of which reported a decrease in stumble and fall frequency with accommodation and use of a microprocessor knee system relative to a non-microprocessor knee system. The studies further support the prescription of microprocessor knees over non-microprocessor knees to improve an individual’s ability to walk faster on level ground, uneven surfaces, and downhill, thus providing the user with an improved sense of security and improved overall satisfaction. [6,16]
Second, a consensus statement was released by the Lower Limb Prosthetic Workgroup commissioned by the Centers for Medicare and Medicaid Services (CMS). In their statement, the workgroup acknowledged that an amputee functioning at the K2 level may benefit from MPK technology. The workgroup also added significant clarification to the K-Level descriptions, which we ask you to consider adding to your policy [17].

We invite you to thoroughly review the included copy of the full text paper of the systematic review of MPK studies in the limited community ambulator population. We would greatly appreciate the opportunity to present the detailed evidence to you and to discuss a monitored pilot project with beneficiaries of your company with an above-knee amputation and MFCL-2 mobility grade.

References


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10. Theeven PJ, Hemmen B, Geers RP, Smeets RJ, Brink PR, Seelen HA


A workgroup consisting of members from Centers for Medicare and Medicaid (CMS), National Institute of Health (NIH), Extremity Trauma and Amputation Center of Excellence (EACE), Administration for Community Living, Walter Reed National Military Center, and Department of Veterans Affairs (VA) issued a consensus statement that acknowledged an amputee functioning at the K2 level may benefit from MPK technology, and included the following clarifications of the K-Level descriptions.

“Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.

a. The individual does not have sufficient cognitive ability to safely use a prosthesis with or without assistance.
b. The individual requires assistance from equipment or caregiver in order to transfer and use of a prosthesis does not improve mobility or independence with transfers.
c. The individual is wheelchair dependent for mobility and use of a prosthesis does not improve transfer abilities.
d. The individual is bedridden and has no need or capacity to ambulate or transfer.

Note: If a beneficiary has need of a lower limb prosthesis (LLP) to maintain sitting balance in an appropriately fitted wheelchair, but cannot ambulate or transfer using the prosthetic, the individual may be a candidate for a prosthesis which correlates with K1 activities. Example: A beneficiary with a trans-femoral amputation as well as a spinal cord injury (T4 ASIA B paraplegia) which precludes bi-pedal ambulation or weight bearing during transfers, depends on the resistance of the prosthetic socket portion to maintain sitting balance. Though this individual may exhibit the functional abilities consistent with K0, s/he may be a candidate for a prosthesis typically provided to a beneficiary with K1 activity abilities.

Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, typical of the limited and unlimited household ambulator.

a. The individual has sufficient cognitive ability to safely use a prosthesis with or without an assistive device and/or the assistance/supervision of one person.
b. The individual is capable of safe but limited ambulation within the home or on a similar flat surface like a home, with or without an assistive device and/or with or without the assistance/supervision of one person.
c. The individual requires the use of a wheelchair for most activities outside of their residence.
d. The individual is not capable of most of the functional activities designated in Level 2.

Level 2: Has the ability or potential for ambulation with the ability to transverse low level environmental barriers such as curbs, stairs or uneven surfaces. This level is typical of the limited community ambulator.

a. The individual can, with or without an assistive device (which may include one or two handrails) and/or with or without the assistance/supervision of one person:
   1. Perform the Level 1 tasks designated above
   2. Ambulate on a flat, smooth surface (e.g., concrete, asphalt) such as might be found outside the home. (e.g., porch, deck, patio garage, driveway)
   3. Negotiate a curb
   4. Access public or private transportation
   5. Negotiate 1-2 stairs
   6. Negotiate a ramp built to ADA specifications.
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b. The individual may require a wheelchair for distances that are beyond the perimeters of the yard/driveway, apartment building, etc.

c. The individual is only able to increase his/her generally observed speed of walking for short distances or with great effort.

d. The individual is generally not capable of accomplishing most of the tasks at Level 3 (or does so infrequently with great effort).

Level 3: Has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

a. With or without an assistive device (which may include one or two hand rails), the individual is independently capable (i.e. requires no personal assistance or supervision) of performing the Level 2 tasks above and can:
   1. Walk on terrain that varies in texture and level (e.g., grass, gravel, uneven concrete)
   2. Negotiate 3-7 consecutive stairs
   3. Walk up/down ramps built to ADA specifications
   4. Open and close doors
   5. Ambulate through a crowded area (e.g., grocery store, big box store, restaurant)
   6. Cross a controlled intersection within his/her community within the time limit provided (varies by location)
   7. Access public or private transportation
   8. Perform dual ambulation tasks (e.g. carry an item or meaningfully converse while ambulating)

b. The individual does not perform the activities of Level 4.

Note: If the beneficiary can accomplish the physical tasks described by the K3 level, but requires personal assistance or supervision due to cognitive, sensory or communicative disability, then the individual is a candidate for a prosthesis which correlates with K3 usage.

Example: In addition to the lower limb amputation, if the beneficiary has also experienced a TBI and is capable of performing the above K3 activities, but frequently needs supervision and assistance for safety purposes and redirection of attention, then s/he is a candidate for a prosthesis which correlates with K3 usage.

Level 4: 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.

With or without an assistive device (which may include one or two hand rails), this individual is independently capable (i.e. requires no personal assistance or supervision) of performing high impact domestic, vocational or recreational activities such as:

a. Running
b. Repetitive stair climbing
c. Climbing of steep hills
d. Being a caregiver for another individual
e. Home maintenance (e.g. repairs, cleaning)

Note: If the beneficiary can accomplish the physical tasks described by the K4 level, but requires personal assistance or supervision due to cognitive, sensory or communicative disability, then the individual is a candidate for a prosthesis which correlates with K4 usage.

Example: The beneficiary exhibits a significant visual impairment in addition to a lower limb amputation. Though s/he demonstrates no other significant co-morbidities, and performs physically at a very high level (e.g., running, climbing stairs), he sometimes requires supervision for safety. S/he is a candidate for a prosthesis which correlates with K4 usage.

The Workgroup also suggests that exceptions be considered if additional documentation is included.
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which justifies a medical need for componentry in an individual who does not necessarily “fit” the K Level descriptions (e.g., bilateral amputees cannot be strictly held to the K level system).

Please note: Not all traits listed for K levels must be realized by the patient in order to receive a K level assignment, but generally, documentation should demonstrate that equivalent activities can be achieved by the prosthetic user.”

Reference

Department of Veterans Affairs
Department of Defense


“C. Pre-Prosthetic Phase.
Recommendation [#15]
We suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction.”

Discussion
According to two fair quality SRs, microprocessor knees may reduce risk of falls and maximize patient satisfaction in limited and unlimited community ambulators.[93,94] Both reviews reported a decrease in stumble and fall frequency with accommodation and use of a microprocessor knee system relative to a non-microprocessor knee system.[93,94] The studies further support the prescription of microprocessor knees over non-microprocessor knees to improve an individual’s ability to walk faster on level ground, uneven surfaces, and downhill, thus providing the user with an improved sense of security and improved overall satisfaction.[93,94] The Work Group considered that the benefits to the patients, particularly decreasing risk of falling, far outweigh potential harms. The patient focus group participants also expressed a desire to have access to prosthetic devices that fit well and maximize their safety and function, so patient values and preferences were another important consideration when assessing the strength of the recommendation.

Falling is a major issue in patients with transfemoral amputations. Increased number of falls, fear of falling, as well as deterioration in balance, coordination, and endurance, resulting in activity avoidance, decreased independence and mobility have all been reported in this population.[93]
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Therefore, the prescription of microprocessor knees is supported for ambulatory individuals with complex medical conditions affecting balance, as well as for the geriatric population. These populations benefit from microprocessor knees, which have been demonstrated to decrease stumbles and prevent falls by an SR included in our evidence review[93] and two SRs that were excluded because they were superseded by a more recent and comprehensive SR.[95,96]

There is insufficient evidence to support using one type of microprocessor knee over another, but the provider should consider the many characteristics of each type of knee when making a selection. Most importantly, the potential impact on the patient’s functional level should be considered as there are a variety of microprocessor knee options available. Some knees may be best suited for the limited community ambulator[93] while others are more appropriate for the highly active patient.[72,97,98] Another consideration when choosing the right microprocessor knee for an individual is the mechanism of charging the knee; some have removable batteries, others have a port for a plug, while others have inductive charging systems. Still another consideration would be the default mode of the device when the power source is depleted. Some knees default to a locked knee while others default to free swing.” (Page 39)

References:


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Product Information

Kenevo Coding¹ (U.S. only)
The Healthcare Common Procedure Coding System (HCPCS) for prosthetics is an add-on code system. Rather than issuing new HCPCS Level II national codes to describe the various microprocessor knees that came to market, the Alpha-Numeric HCPCS Panel instead issued add-on codes to upgrade the mechanical (non-microprocessor) knee codes.

The following codes apply to Kenevo:

- L5828  Hydraulic Swing and Stance Phase Knee (base mechanical knee code)
- L5845  Stance flexion feature
- L5848  Stance extension damping feature
- L5858  Microprocessor control feature, stance phase, includes sensors
- L5850  Knee extension assist feature
- L5999²  Inertial Motion Unit Control feature for intuitive standing and walking backwards.

Kenevo Replacement Battery and Charger:

- L7367  Lithium Ion Battery, Replacement
- L7368  Lithium Ion Battery Charger, Replacement

2019 Manufacturer Suggested Retail Price (MSRP)³ (U.S. only)
MSRP for the Inertial Motion Unit code (L5999) is $5000.

FDA Status
Under FDA’s regulations, the Kenevo Microprocessor-Controlled Prosthetic Knee is a Class I device, exempt from the premarket notification [510(k)] requirements. The Kenevo prosthetic knee has met all applicable control requirements which include Establishment Registration (21 CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21 CFR part820), Labeling (21 CFR part 801), and Medical Device Reporting (21 CFR Part 803). The Kenevo prosthetic knee is listed under JOINT, KNEE, EXTERNAL LIMB COMPONENT; Listing Number is E253231 and Manufacturer Registration Number is 3005190268.

Health Canada Compliance
This device meets the requirements of the Medical Device Regulations (SOR/98-282). It has been classified as a class I medical device according to the classification criteria outlined in schedule 1 of the Medical Device Regulations.

Warranty
Kenevo comes with a three-year manufacturer warranty (extendable to six years) which includes a complimentary condition-based service inspection within the 3-year term. During the warranty period, repair costs are covered except for those associated with damages resulting from improper use.

Who Can Provide a Kenevo?
The Kenevo is prescribed by a physician and may only be provided by a qualified Prosthetist who has received specific product training. Ottobock employs a team of orthotists and prosthetists to educate practitioners on fabricating and fitting our products. This includes in-person and online training, webinars, and technical bulletins. We also provide Cooperative Care Services for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

¹ The product/device “Supplier” (defined as an O&P practitioner, O&P patient care facility, or DME supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier’s responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier’s contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides are based on reasonable judgment and are not recommended to replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

² It is not recommended to bill L5999 to Medicare for Microprocessor Knees.

³ The manufacturer’s suggested retail pricing (MSRP) is a suggested retail price only. Ottobock has provided the suggested MSRP in the event that third-party and/or federal healthcare payers request it for reimbursement purposes. The practitioner and/or patient care facility is neither obligated nor required to charge the MSRP when submitting billing claims for third-party reimbursement for the product(s).
Kenevo Features and Benefits

Microprocessor Stance Control
Kenevo’s main microprocessor gathers sensoric information at a rate of 100 times per second. It processes this information following programmed instructions to adjust the valve positions via servo motors in real time. The valve positions define the hydraulic fluid resistance of the two independent valves (extension and flexion valves) and therefore the resistances of the knee against flexion and extension separately and variably.

Kenevo is a default stance knee, which means that it always has high stance flexion resistance to support the body weight until stance is disengaged. Its microprocessor stance control monitors each step to reliably detect the safest moment to release swing. This ensures safe body weight support even for the highly variable gait patterns of patients with low mobility and walking aid use. In addition, the microprocessor stance control provides Stumble Recovery Plus and supported sit-to-stand and stand-to-sit functions.

Stumble Recovery Plus
Kenevo delivers unmatched safety for your K2 patients through the implementation of Stumble Recovery Plus. After heel rise, as soon as the shank starts the extension movement during the swing phase, Kenevo activates high flexion resistance that is even higher than that adjusted for control of the regular stance phase. This stumble recovery allows the patient to fully load the prosthesis in case of a trip and represents the highest level of safety that is technically possible. Benefits include:

- Reduced risk of falling: if the user trips, it is easier to regain his or her balance
- The increased safety can increase the user’s confidence in the prosthesis
- Taking steps backward is possible with consistently high level of safety

Supported Safe Stand-to-Sit Function
The Kenevo automatically detects when your K2 patient begins to sit down, adjusting the hydraulic resistance so the knee joint provides progressive support during sitting. This allows the amputee to shift the body weight to both legs and complete the sit down motion in a smooth and controlled manner and at a controlled rate.

Once the amputee is seated, if the knee is still extended, Kenevo will relax into a seated position and will switch to energy-saving mode. Benefits include:

- Supports safety and balance during sitting down
- Automatic unlock allows for hands-free operation without the need to unload the prosthesis, which is especially important for those who use walking aids such as canes or walkers.
- Relieves the contralateral side and increases the area of support by shifting load to both legs.
Kenevo Features and Benefits

Supported Safe Sit-to-Stand Function

The Kenevo also automatically detects when the patient begins to stand up.

If the patient pauses during the standing-up motion, the knee will not collapse as long as the patient has made it at least half way (prosthesis has reached at least $45^\circ$ flexion), which allows the patient to rest on the prosthesis and reposition their weight to the sound limb if standing up in a single motion is too tiring.

The knee switches automatically to Supported Stand-to-sit function if the patient tends to fall backward.

Inertial Motion Unit (IMU) Control

**Backward Walking**

This patented microprocessor control technology provides safety and stability when your K2 patient is forced to step backwards (such as when opening a door). Many microprocessor knees do not accommodate backward stepping, which may cause the knee to collapse if a backward step is taken.

**Intuitive Standing**

Maintaining safety and balance while standing is critical for K2 patients. Kenevo allows the patient to intuitively stand on a flexed and stable knee when on level, uneven, or inclined surfaces (e.g. ramps and hills).

Contrast this to traditional K2 prosthetic knees, which require the user to extend the hip to stabilize the knee or cognitively ensure that their center of mass stays ahead of their knee axis to prevent unexpected buckling of the prosthetic knee.

Unlike mechanical knees, Kenevo offers clinicians a range of programmable stance stability options that can be customized to support each patient’s individual capabilities.

Hydraulic Swing and Stance

**Hydraulic Stance Control**

Hydraulic stance control provides resistance against knee flexion to support the body weight of the patient and prevent knee collapse. Knee flexion during weight-bearing is damped and controlled, mimicking the eccentric contraction of the quadriceps muscle during gait, to provide for shock absorption during level walking to minimize hip and low-back stress. It also enables step-over-step slope and stair descent and uneven terrain ambulation, allowing patients to “ride” the knee when descending stairs and slopes.

**Hydraulic Swing Control**

The hydraulic swing phase control of Kenevo accommodates walking speeds of up to 3 km/h (1.9 mph). It also provides for terminal swing extension damping that prevents a hard terminal impact that would be hard to control for the patient by decelerating the prosthetic shank prior to heel strike. This mimics the eccentric contraction of the anatomical hamstrings and gluteus maximus muscle. Full extension is then reached smoothly in preparation for heel strike.
Kenevo Features and Benefits

Hydraulic Stance Extension Damping
After the knee is flexed during stance phase (stance flexion), it needs to extend again to advance the body forward through mid-stance. This feature provides a smooth extension of knee. Without this function, the patient would feel a pronounced “snap back” or “jerk” at the knee, and would also present with an unnaturally looking gait pattern. Energy is conserved by having this feature, as the patient will not have to attempt to control this motion with his residual limb muscles.

Knee Extension Assist
The knee extension assist is used in promoting knee extension at the beginning of swing phase extension. This function allows the user to walk more efficiently at variable cadence since the spring extension assist mechanically limits the knee flexion at the end range and begins to bring the knee into extension for a more symmetrical gait at faster walking speeds. It also ensures the knee comes to full extension for the beginning of stance phase for a more secure loading condition during level walking but in particular when descending stairs where full extension facilitates the positioning of the foot on the edge of a stair.
Benefits of microprocessor-controlled prosthetic knees to limited community ambulators: Systematic review

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1Medical Affairs, Otto Bock HealthCare LP, Austin, TX; 2Clinical 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.

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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.

<table>
<thead>
<tr>
<th>K-Level</th>
<th>Description</th>
<th>Medicare Reimbursed Prosthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>K0</td>
<td>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.”</td>
<td>None</td>
</tr>
<tr>
<td>K1</td>
<td>Household Ambulator: “Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence.”</td>
<td>Constant Friction Knee</td>
</tr>
<tr>
<td>K2</td>
<td>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.”</td>
<td>Constant Friction Knee</td>
</tr>
<tr>
<td>K3</td>
<td>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.”</td>
<td>Fluid Control Knee, Non-MP or MP-Controlled Knee</td>
</tr>
<tr>
<td>K4</td>
<td>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.”</td>
<td>Fluid Control Knee, Non-MP or MP-Controlled Knee</td>
</tr>
</tbody>
</table>

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 provi-
sion 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 pro-
thetic 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 con-
ducted a systematic review of randomized and nonran-
domized clinical trials comparing the effects of NMPK
and MPK interventions in limited community ambulators
(MFCL-2) with a unilateral TFA in three clinically mean-
ingful 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 avoid-
ance and decreased independence and mobility [46–50].
Falling and its detrimental consequences pose serious
clinical challenges for persons with amputation, espe-
cially elderly, lower-functioning individuals who often
experience various comorbidities and physical decon-
ditioning [44–45]. Therefore, the evaluation of perform-
ance-based and self-reported outcome measures would
help assess the effect of MPK use on the safety of ambu-
lation with the prosthesis.

Second, the goal of rehabilitation is to enable patients
to resume a lifestyle as independent as possible. There-
fore, 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 prereq-
usites 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 per-
ceived 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 Doc-
umentation and Information]); DARE; Cirrie; CINAHL;
Cochrane Library; OTseeker; PEDro; and RECAL Leg-
acy. 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.
7. Or/2–6.
8. Amput*.
9. Prosth*.
11. Microprocessor.
12. MP*.
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) [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
KANNENBERG et al. Benefits of MPKs to limited community ambulators

(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 [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 ± 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].

<table>
<thead>
<tr>
<th>Study</th>
<th>A1</th>
<th>A2</th>
<th>A3</th>
<th>A4</th>
<th>B5</th>
<th>B6</th>
<th>B7</th>
<th>B8</th>
<th>B9</th>
<th>C10</th>
<th>C11</th>
<th>C12</th>
<th>C13</th>
<th>Total: A + B Criteria</th>
<th>Total: C Criteria</th>
<th>Total: A + B + C Criteria</th>
<th>Overall Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wetz et al., 2005 [102]</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>5</td>
<td>None</td>
</tr>
<tr>
<td>Kahle et al., 2008 [31]</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>2</td>
<td>8</td>
<td>B</td>
</tr>
<tr>
<td>Hafner &amp; Smith, 2009 [21]</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>7</td>
<td>2</td>
<td>9</td>
<td>B</td>
</tr>
<tr>
<td>Theeven et al., 2011 [98]</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>7</td>
<td>2</td>
<td>9</td>
<td>C</td>
</tr>
<tr>
<td>Burnfield et al., 2012 [100]</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>2</td>
<td>8</td>
<td>B</td>
</tr>
<tr>
<td>Theeven et al., 2012 [99]</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>7</td>
<td>2</td>
<td>9</td>
<td>C</td>
</tr>
<tr>
<td>Eberly et al., 2014 [101]</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>7</td>
<td>2</td>
<td>9</td>
<td>B</td>
</tr>
</tbody>
</table>
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 (≤10), we did not only analyze significant differences but also statistical trends with 0.05 ≤ 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 3.
Patient demographics and non-microprocessor-controlled prosthetic knees used as controls in clinical trials included and reviewed.

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Study</th>
<th>Study</th>
<th>Study</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total (n)</td>
<td>19</td>
<td>17</td>
<td>30</td>
<td>10</td>
</tr>
<tr>
<td>MFCL-2 (n)</td>
<td>9</td>
<td>8</td>
<td>30*</td>
<td>10</td>
</tr>
<tr>
<td>Etiology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dysvascular PVD and/or Diabetes</td>
<td>7</td>
<td>1</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Trauma</td>
<td>1</td>
<td>5</td>
<td>23</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>Not Reported</td>
<td>6</td>
<td>22</td>
<td>5</td>
</tr>
<tr>
<td>Female</td>
<td>Not Reported</td>
<td>2</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Age, yr (mean ± SD)</td>
<td>67.1 ± 11.8</td>
<td>57.1 ± 15.4</td>
<td>59.1 ± 13.0</td>
<td>62.0 ± 11.3</td>
</tr>
<tr>
<td>Intervention</td>
<td>C-Leg</td>
<td>C-Leg</td>
<td>C-Leg and C-Leg Compact</td>
<td>C-Leg Compact</td>
</tr>
<tr>
<td>Control Knee</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locked</td>
<td>—</td>
<td>—</td>
<td>3</td>
<td>—</td>
</tr>
<tr>
<td>Weight-Activated Brake</td>
<td>4</td>
<td>—</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Polycentric</td>
<td>4</td>
<td>6</td>
<td>17</td>
<td>5</td>
</tr>
<tr>
<td>Hydraulic</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Accommodation Time to Intervention</td>
<td>90 d</td>
<td>1–33 wk (mean: 13.5 wk)</td>
<td>1 wk</td>
<td>3 mo</td>
</tr>
</tbody>
</table>

*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.
Table 4.
Safety outcomes. Due to low patient number of studies, safety outcomes with statistical trend toward significance ($p < 0.10$) were also analyzed.

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

$^*$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.

<table>
<thead>
<tr>
<th>Study Outcome Measures Related to Function and Mobility</th>
<th>Study Design</th>
<th>Methodological Quality</th>
<th>Outcome</th>
<th>Measurement Method</th>
<th>Results of Outcome Measures of Interest with Statistical Significance (p &lt; 0.05)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fastest Walking Speed on NMPK Prosthesis</td>
<td>Crossover</td>
<td>B</td>
<td>Kahle et al., 2008 [31]</td>
<td>Performance-based tests</td>
<td>Fastest possible walking speed on 75 m level ground increased 14.4% (p = 0.01); Stair descent 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)</td>
</tr>
<tr>
<td>Walking tests on level and uneven ground, stairs performance (MRPP), MFCL</td>
<td>Crossover (reanalysis)</td>
<td>B</td>
<td>Hafner &amp; Smith, 2009 [21]</td>
<td>Performance-based tests</td>
<td>Walking tests on hills and stairs, dual task performance, AMP</td>
</tr>
<tr>
<td>Walking tests on hills and stairs, dual task performance, AMP</td>
<td>Randomized double crossover</td>
<td>C</td>
<td>Theeven et al., 2011 [98]</td>
<td>Performance-based test</td>
<td>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)</td>
</tr>
<tr>
<td>Performance in ADLs (ADAPT test)</td>
<td>Randomized double crossover (additional data)</td>
<td>C</td>
<td>Theeven et al., 2012 [99]</td>
<td>Activity monitoring in home environment</td>
<td>Non</td>
</tr>
<tr>
<td>Gait analysis:</td>
<td>Crossover</td>
<td>B</td>
<td>Burnfield et al., 2012 [100]</td>
<td>Biomechanical assessment and muscle activation (EMG) on ramp</td>
<td>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)</td>
</tr>
</tbody>
</table>
| Gait analysis: | Crossover (additional data) | B                      | Eberly et al., 2014 [101] | Biomechanical assessment (gait analysis) | 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.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-selected walking speed on 75 m level ground;*</td>
<td>Kahle et al., 2008 [31]</td>
</tr>
<tr>
<td>AMP;** Accuracy of divided attention task while walking</td>
<td>Hafner &amp; Smith, 2009 [21]</td>
</tr>
<tr>
<td>Performance time in AS1 activities in low MFCL-2 with both MPKs; Performance time in AS2 activities in total group and all subgroups 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;</td>
<td>Theeven et al., 2011 [98] Theeven et al., 2012 [99] Burnfield et al., 2012 [100] Eberly et al., 2014 [101]</td>
</tr>
<tr>
<td>Up-time per day; Active time per day; Activity (counts and bouts) per day in total, high, and low subgroup with</td>
<td>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)</td>
</tr>
<tr>
<td>Prosthetic limb stance duration in percent of GC during ascent and descent; Prosthetic limb heel-off in percent of GC during ascent;</td>
<td>Fast walking prosthetic limb single-leg support; Free and fast walking peak knee and ankle angles; Free walking peak hip stance moment;</td>
</tr>
</tbody>
</table>
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].

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<tr>
<td></td>
<td></td>
<td>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</td>
<td>None</td>
<td>intermediate group with C-leg Compact</td>
<td>Prosthetic limb peak angles during ascent; Prosthetic limb weight acceptance curve during ascent and descent; Muscle activity (EMG pattern)</td>
<td>None</td>
<td>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</td>
</tr>
<tr>
<td>Results with Statistical Significance (p &lt; 0.05) in favor of NMPK</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Activity count per day in intermediate group with C-leg (p = 0.02)</td>
<td>None</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Change in MFCL Classification with MPK</td>
<td>4 of 9 subjects (44%) improved to MFCL-3</td>
<td>4 of 8 subjects (50%) improved to MFCL-3</td>
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</table>

*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.
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.

<table>
<thead>
<tr>
<th>Outcome Measures Related to Perceived Function and Mobility, Satisfaction, and Prosthesis Preference</th>
<th>Study</th>
<th>Study</th>
<th>Study</th>
<th>Study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Crossover</td>
<td>Crossover (reanalysis)</td>
<td>Randomized double crossover</td>
<td>Crossover</td>
</tr>
<tr>
<td>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)</td>
<td>Not reported</td>
<td>Gait analysis: 2.48 ± 0.79 km/h (0.69 ± 0.22 m/s)</td>
<td>PEQ Mobility, Houghton Scale</td>
<td>PEQ Mobility score improved 25% (p = 0.04)</td>
</tr>
</tbody>
</table>
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.

<table>
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<tbody>
<tr>
<td>Results Showing No Statistical Difference Between MPK and NMPK</td>
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<td>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 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 ($p = 0.05$)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>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;</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>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</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Houghton Scale</td>
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<td></td>
<td>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</td>
</tr>
</tbody>
</table>
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 prosthetic knees are all indicators of events that are certainly unpleasant, such as stumbles and semi-controlled 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

### Table 6. (cont)

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcome</th>
<th>Satisfaction with walking in low subgroup with C-Leg and in all groups with C-Leg Compact</th>
</tr>
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<td>Hafner &amp; Smith, 2009 [21]</td>
<td>Prosthesis Preference</td>
<td>8 subjects (90%) preferred C-Leg</td>
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<tr>
<td>Theeven et al., 2011 [98]</td>
<td>Preference</td>
<td>21 subjects (70%) preferred C-Leg, 7 subjects (23%) preferred C-Leg Compact</td>
</tr>
<tr>
<td>Burnfield et al., 2012 [100]</td>
<td>Preference</td>
<td>None</td>
</tr>
<tr>
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<td>Preference</td>
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</tbody>
</table>

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.

**Safety**

**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.

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</table>

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.
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 vascular 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 stumble 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 ambulation, 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 prosthetics safety [62]. Likewise, an improvement of perceived balance on the ABC [6–7, 66] indicates improved confidence in prosthetic 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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Clinical Research Summary

Mobility and Safety with a Microprocessor-Controlled Knee in Moderately Active Amputees


This was a multinational (France, Germany, Austria), multi-center (16 sites), randomized crossover trial comparing the effects of a microprocessor-controlled prosthetic knee specifically designed for subjects with above-knee amputation and low to moderate mobility (Kenevo®) to those of non-microprocessor knees (NMPK) typically covered and prescribed for subjects with MFCL-2 mobility. Participants were eligible for enrollment if they presented a moderate level of mobility as defined by ICF items d4601 and d4602 (corresponds to MFCL-2 in the U.S.) and a completion time for the Timed-up-and-go test (TUG) of >19 sec, which indicates an increased risk for multiple falls in transtibial amputees (Dite et al., 2007).

Subjects were randomized to either continue to use their NMPK for 30 days and then use the Kenevo MPK for 90 days, or to start using the Kenevo MPK right away for 90 days and then return to their previous NMPK for 30 days.

The primary outcome measure of the study was the TUG completion time, secondary outcome measures chosen were the Locomotor Capabilities Index 5 (LCI-5), the SF-36v2 for quality of life, and the QUEST questionnaire for satisfaction with the prosthesis.

The trial originally enrolled 35 patients, of whom five dropped out or were excluded for medical reasons before the baseline assessment. Eventually, 30 individuals with transfemoral amputation and a mean age of 65.6 ± 10.1 years were available for the intention-to-treat (ITT) analysis. Because of three protocol violations, 27 individuals with a mean age of 64.5 ± 9.7 years were subjected to a per-protocol (PP) analysis.

Results: With the Kenevo MPK, subjects performed the TUG significantly faster [ITT median Q1-Q3: 18.2 sec. (16.2-25.2) versus 21.8 sec. (19.5-28.4), p=.001; PP median Q1-Q3: 17.9 sec. (15.4-22.7) versus 21.4 sec. (19.3-26.6), p=.001] as compared to the NMPK condition, indicating a reduced risk of falling with the MPK. Perceived mobility as assessed with the LCI-5 improved significantly in both the ITT (p=.006) and the PP analysis (p=.02), as did the SF-36v2 mental component score (p=.01), physical activity score (p=.04), limitations related to physical health score (p=.005), mental health score (p=.009) and vitality score (p=.02) in the ITT analysis, and the mental component score (p=.03), limitations related to physical health score (p=.002), mental health score (p=.007) and vitality score (p=.03) in the PP analysis. Subject satisfaction was also significantly improved with the Kenevo MPK.

Conclusion: In conclusion, this multi-center randomized cross-over trial confirms the results of earlier research suggesting that individuals with transfemoral amputation and MFCL-2 mobility may benefit from using MPKs in terms of improved safety, increased mobility and better quality of life.
Clinical Research Summary

Functional Assessment and Satisfaction of Low Mobility Transfemoral Amputees with Microprocessor Knees


This study was a prospective non-randomized crossover clinical trial. Each subject was tested using their current non-microprocessor knee (NMPK), fit and tested with a microprocessor knee (MPK) after approximately 3 months of use, and then refit with their NMPK and tested again after 4 weeks, i.e. A-B-A study design.

This study enrolled 50 unilateral transfemoral amputees (TFA) fit in prosthetic clinics in 19 states throughout the United States. Subjects had a mean age of 69±9 years (range 55-83 yr.) and were Medicare Functional Classification Level K2 (n=48) or K3 (n=2). The primary amputation etiologies were peripheral arterial disease (50%), total knee arthroplasty infection (14%), infection (12%), trauma (10%), deep vein thrombosis (8%), cancer (4%), or blood disorder (2%). The subjects received a randomly assigned MPK knee from one of four manufacturers (OttoBock Compact [MP stance control knee], Ossur Rheo 3, Endolite Orion 2, Freedom Innovation Plié 3 [all MP swing and stance control knees]). All prosthesis fittings were performed by the subjects' own certified prosthetist according to the manufacturer's fitting guidelines with oversite provided by the manufacturer's representative.

Outcome measures were self-reported falls in the month prior to each assessment, patient activity (ActiGraph GT3X) over 4 days, and patient satisfaction as assessed by the Prosthesis Evaluation Questionnaire (PEQ).

**Results:** Seventeen subjects dropped out before they could be fit with a MPK, leaving 33 datasets for the per-protocol analysis. Use of a MPK resulted in a significant reduction in falls (p=0.01). The median number of falls of 2.0 (IQR 0.0–6.0) at baseline when using a NMPK was reduced to 0.0 when using the MPK (IQR 0.0–3.25) and increased to 3.0 falls (IQR 0–3.0) falls per person per month when reverting back to the NMPK. Notably, when reverting back to the NMPK, patients reported a greater fear of falling and the prosthetists had concerns about patient safety, which resulted in 10 subjects declining to participate in the reconversion to the NMPK.

The subjects spent significantly less time sitting (p=0.01) when using the MPK, and the decrease in amount of time seated was offset by a significant increase in median activity counts (p=0.02). The time spent sitting increased and the time active decreased again when subjects returned to their NMPK. Further, the complexity of the gait as measured by the entropy increased when using the MPK and returned toward the baseline level when reverting back to the NMPK. However, the increase in gait entropy did not attain statistical significance. Patient satisfaction reflected the reduction in falls and improvement in activity. There was a significant improvement in PEQ satisfaction subscales when using the MPK (p≤0.01).

**Conclusion:** “This clinical trial confirmed that the provision of a MPK to patients with a TFA and low, i.e. K2, mobility will result in improved function in the free-living environment, a reduction in falls, and, subsequently, improved patient satisfaction.”
Clinical Studies
Using Microprocessor Knees with K2 Subjects


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