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C-Leg®
Evidence Summary

Mobility needs matched to C-Leg evidence

	Mobility need or deficit of the patient	Evidence for benefits of the C-Leg
Safety	Patient often stumbles and/or falls	C-Leg has been demonstrated to reduce the number and frequency of stumbles and falls
Safety	Patient avoids activities of daily living due to safety concerns and lack of balance and/or balance confidence	C-Leg has been shown to improve balance and balance confidence. This may result in the patient doing more activities with the prosthesis.
Slope negotiation	Patient has to ambulate on slopes/hills on a regular basis and struggles with slope descent and/or has to descend slopes and hills faster.	C-Leg has been shown to improve the quality of slope and hill descent to the more natural gait pattern of sound subjects and to significantly improve the downhill walking speed.
Stair negotiation	Patient has to ambulate on stairs on a regular basis and struggles with stair descent, needs to descent stairs faster.	C-Leg has been demonstrated to improve quality of stair descent from step-to pattern (body and prosthetic leg are lowered to the next step with the sound limb, sound limb is then placed on this step) to step-over-step pattern (normal). This pattern is an indicator of improved balance confidence and allows for descending stairs much faster.
Negotiation of uneven terrain /obstacles in the walkway	Patient has to ambulate on uneven terrain and/or clear obstacles in the walkway on a regular basis and struggles to do so and/or has to ambulate faster (e.g. for chasing kids).	C-Leg has been shown to have superior safety and allows for significantly walking faster on uneven terrain and obstacle courses with and without concurrent activities
Cognitive demand/multi-tasking during walking	Patient has to do concurrent activities while walking with the prosthesis on a regular basis and struggles with these activities (e.g. needs to stop walking or walk slower)	C-Leg has been demonstrated to increase multitasking capacities and cognitive burden while walking with the prosthesis. A recent study found no difference in the effect of a concurrent cognitive task on walking when users of MPKs were compared to sound, non-amputated subjects.

Continued	Mobility need or deficit of the patient	Evidence for benefits of the C-Leg
Overall mobility	Patient is a limited community ambulator (MFCL-2, K2)	In K2 amputees, C-Leg has been shown to reduce uncontrolled falls by up to 80%; improve validated indicators of the risk of falling; increase walking speed on level ground by 14-25%, on uneven terrain by up to 20%, and slope descent by 30%; improve stair negotiation and some patients were able to complete activities considered typical for K3 mobility, both in the community and in the house.
Gait symmetry as risk factor for pain and long-term comorbidities	Patient has an asymmetric gait pattern that may cause or contribute to low back pain and/or joint pain in the sound limb and puts the patient at risk for developing long-term comorbidities such as osteoarthritis and spinal degeneration	C-Leg has been demonstrated to produce a knee flexion moment at loading response contributing to shock absorption. The result is significantly greater kinetic gait symmetry that may contribute to alleviating low back and intact limb joint pain and long-term comorbidities and degeneration.

Safety: Reduced stumbles and falls

Several clinical and biomechanical studies have investigated the safety of prosthesis use as well as balance and balance confidence while walking with a prosthesis. Two systematic reviews (1,2) analyzed a total of eight studies of sufficient methodological quality that compared the safety of microprocessor controlled prosthetic knees (MPK) with that of non-MP controlled prosthetic knees (non-MPK). All of these studies had been conducted with the C-Leg or C-Leg Compact. Hafner et al. (3), Kahle et al. (4), and Hafner and Smith (5) observed persons with a transfemoral amputation transitioning from a non-MPK to a C-Leg prosthesis to collect data on stumbles and falls.

Hafner et al. (4) found a significant reduction of the number of stumbles and falls ($p<.05$). In a later publication (5), this group re-analysed their data separately for subjects with Medicare Functional Classification Levels 2 (MFCL-2, K2, limited community ambulator) and MFCL-3 (K3, community ambulator) mobility. Patients with MFCL-2 mobility had a significant reduction in the frequency of stumbles ($p<.05$) and uncontrolled falls ($p=.01$), as well as a significant 80% reduction ($p=.01$) in the number of uncontrolled falls (5). Kahle et al. reported a statistically significant 57% reduction in stumbles ($p=0.006$) and a significant 64% reduction in falls ($p=.03$). A systematic review that analyzed only the subgroup of this study with MFCL-2 (K2) mobility found a significant 80% reduction in falls ($p<.05$) in this patient group (1). Burnfield et al. studied the effect of using a C-Leg Compact on validated indicators of the risk of falling (6). Compared to non-MPKs, the use of the C-Leg Compact significantly improved the average time to complete the Timed-up-and-go-test (TUG) by 28% from 24.5 sec to 17.7 sec (p=.018), and thus below the established threshold of 19 sec that indicates an increased risk of multiple falls in below-knee amputees (7).

Blumentritt et al. (8) simulated typical situations of everyday life that expose prosthesis users to an increased risk of falling in an instrumented motion analysis laboratory to evaluate the safety of the C-Leg and various types of non-MPKs. Among the situations simulated were stepping onto obstacles, sudden stopping and stepping to the side with the prosthetic or sound leg first, respectively, as well as tripping that would result in a fall if the prosthetic knee did not provide enough stability or a stumble recovery function. In all conditions tested, the C-Leg never collapsed whereas the non-MPKs, depending on the type of knee mechanism, either collapsed in some or even all safety-critical situations (8).

Safety: Improved balance and balance confidence

Balance and balance confidence with the prosthesis are related to and/or associated with falling, fear of falling, and activity avoidance in persons with an above-knee amputation (9-15). Kaufman et al. (16) directly evaluated balance with the prosthesis using the Sensory Organization Test (SOT) assessed with dynamic posturography. Compared to their previous non-MPKs, patients demonstrated a significantly improved balance performance (p=0.01) when using the C-Leg (16). Using a 50-question survey in 368 patients, Berry et al. (17) evaluated balance more subjectively in several items. About 70% of patients rated the C-Leg “better” or “safer” in those questions related to balance confidence and perceived safety of prosthesis use. These items of interest were positioned in two separate sections of the survey, each of which demonstrated a statistically significant improvement (p=0.0001) with the C-Leg (17). Hafner et al. (5) confirmed the significantly increased confidence (p=.08) and multi-tasking ability (p=.04) while walking with the C-Leg using several items of the Prosthesis Evaluation Questionnaire (PEQ). Burnfield et al. assessed balance confidence with the validated Activity-specific balance confidence (ABC) scale that improved significantly from 60.1 to 75.7 (p=.001) when using the C- Leg Compact as compared to non-MPKs (6). Scores below 67 indicate an increased risk of falling (8-10) and are associated with fear of falling and avoidance of activities (9, 18, 19).

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Evidence Summary

Summarizing all studies that had investigated the safety of MPKs compared to non-MPKs, two systematic reviews of the literature have concluded that the C-Leg and C-Leg Compact (used in all studies), significantly reduced falls and significantly improved balance and balance confidence (1, 2).

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Improved slope descent

Ambulation on sloped terrain such as ramps and hills is associated with increased potential for slipping, loss of balance, and falling. Among the many causes for this is the fact that ramp and slope walking requires changes in the range of motion and strength compared to traditional stepping patterns used to traverse flat ground (2, 6). Sound people use reciprocal (step-over-step) slope and hill descent, in which the supporting leg lowers the whole body down using knee flexion while the swinging leg swings and lands past the supporting leg. Usually, the step length is even between both legs. In above-knee amputees, most non-microprocessor controlled prosthetic knee mechanisms do not allow for any or enough knee flexion during weight bearing to lower the body with the supporting prosthetic leg or are too difficult to control for most patients to do so safely (2, 7). That's why above-knee amputees usually use a step-to or even a side- step pattern to descend slopes and hills. In the step-to pattern, the supporting sound leg lowers the body using knee flexion while the prosthetic leg swings and lands past the sound leg. Then the sound leg is positioned next to the prosthetic leg to become the supporting leg again for lowering the body down for the next step with the prosthetic limb (5, 6). The side-step pattern is similar to the step-to pattern, but in addition the patient turns the whole body to one side to descend the slope not with a straight but oblique step-to pattern to further reduce the downhill- slope force to be controlled (3, 4, 6). Both patterns allow for only slow slope and hill descent, with the side-step pattern being even slower than the straight step-to pattern. Both gait patterns expose the patient as a disabled person to the public. The C-Leg has been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (1, 3, 8), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$) (5), significantly improve objective balance performance as measured with the Sensory Organization Test (p=.01) (9) and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale (p=.001) (5), and to be safe during stepping onto obstacles, sudden stopping on and side-stepping with the prosthetic leg as well as to provide effective stumble recovery during tripping (10). Consequently, the C-leg has been demonstrated to significantly improve the quality of slope and hill descent (p=.002) (2), allowing for a significantly more natural gait pattern (1-5) as well as a significantly 23-40% faster downhill walking speed (p=.008 to < .001)(1-5). Patients with MFCL-2 mobility may be able to significantly increase their downhill walking speed by 27-36% (p=.002/<.001) when using the C-Leg (1, 3, 5). Patients with MFCL-3 mobility may significantly increase their downhill walking speed by 23-40% (p=.002) on a C-Leg as compared to non-microprocessor controlled prosthetic knees (2, 3).

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Evidence Summary

Improved negotiation of uneven terrain and obstacles in the walkway

Negotiation of uneven terrain and clearance of obstacles in the walkway are common activities in daily living. As most non-microprocessor controlled knee mechanisms have been designed for ambulation on level ground (8-10), uneven terrain and obstacles in the walkway expose above-knee amputees to an increased risk of stumbling and falling (9-10). Therefore, many patients usually avoid walking on uneven terrain or walkways with obstacles, or negotiate them very cautiously and slowly. The C-Leg has been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (1-3), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$) (6), significantly improve objective balance performance as measured with the Sensory Organization Test ($p=.01$) (7) and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (6), and to be safe during stepping onto obstacles, sudden stopping on and side-stepping with the prosthetic leg as well as to provide effective stumble recovery during tripping (9). Consequently, timed walk tests on uneven terrain and obstacle courses have shown that patients using the C-Leg are able to negotiate these terrains at significantly faster walking speeds (3, 5). Uneven terrain may be negotiated 21% faster ($p=.001$) (3) and obstacle courses 7-10% faster ($p=.02$ to .004) without a concurrent task (2, 4, 5) and even 27% faster ($p=.007$) while carrying a 10 lbs. basket (5). Thus, above-knee amputees are able to negotiate uneven terrain and clear obstacles in the walkway significantly better and faster with the C-Leg than with any non-microprocessor controlled knee.

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Improved stair descent

Stairs are often encountered barriers in daily living and require greater lower-extremity range of motion and strength to negotiate, compared to level ground walking. Sound people use reciprocal (step-over-step) stair descent, in which the supporting leg lowers the whole body down to the next step where the swinging leg becomes the supporting leg after landing. In above-knee amputees, most non-microprocessor controlled prosthetic knee mechanisms do not allow for any or enough knee flexion during weight bearing to lower the body with the supporting prosthetic leg or are too difficult to control for most patients to do so safely (4, 5). That´s why above-knee amputees usually use a step-to pattern to descend stairs: The supporting sound leg lowers the body down to the next step where the patient lands on the prosthetic leg. Then the sound leg is positioned on the same step next to the prosthetic leg to become the supporting leg again for lowering the body down to the next step (2, 4, 5, 6). This step-to pattern allows for only slow stair descent and exposes the patient as a disabled person. The C-Leg has been shown to significantly reduce falls by up to 80% (p<.05 to .01) (1-3), significantly improve validated indicators of the risk of falling such as the timed up and go test (p=.018) (7), significantly improve objective balance performance as measured with the Sensory Organization Test (p=.01) (8) and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale (p=.001) (7). Consequently, the C-Leg has been demonstrated in several studies to significantly improve the gait pattern (p<.001) and allow for nearly normal step-over-step stair descent in which the supporting prosthetic leg can be used to lower the body down to the next step (1-5). It has also been shown that both patients with MFCL-2 (p=.008) and MFCL-3 (p=.004) mobility can adopt a reciprocal stair descent with the C-Leg and usually do so (1-5) as this gait pattern is considerably faster than a step-to pattern and does not expose them as disabled persons to the public.

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Evidence Summary

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Reduced cognitive demand / Improved multitasking capacity while walking

The need to execute a concurrent task while walking is a common activity in daily living. As most non-microprocessor controlled knee mechanisms have been designed for ambulation on level ground and require a permanent alertness of the patient to actively stabilize the knee (9- 11), above-knee amputees usually spend a lot of concentration and mental energy on screening their walkway for any kind of perturbation (2, 4, 10, 11). Therefore, their capacity to execute a concurrent task while walking with the prosthesis is considerably limited. The C-Leg has been shown to significantly reduce falls by up to 80% ($p<.05$ to .01) (2, 3), significantly improve validated indicators of the risk of falling such as the timed up and go test ($p=.018$) (7), significantly improve objective balance performance as measured with the Sensory Organization Test ($p=.01$) (8) and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale ($p=.001$) (7), and to be safe during stepping onto obstacles, sudden stopping on and side-stepping with the prosthetic leg as well as to provide effective stumble recovery during tripping (10). Consequently, tests assessing the cognitive demand and the capacity to execute a concurrent task while walking with the prosthesis have shown significant improvements when using the C-Leg as compared to non-microprocessor controlled knees (2, 4, 5). One study found a significant 33% reduction (p<.001) in cognitive burden while walking as measured on the Prosthetic Cognitive Burden Scale (PCBS) and 40% less attention paid to walking during concurrent cognitive tasks (p<.001) when using the C-Leg (6). Another study demonstrated a significant 28% reduction (p<.05) in the difficulty multitasking while walking when the patients used the C-Leg (4). The later sub-analysis showed that the C-Leg was able to significantly improve multi-tasking while walking by 21% (p=.004) in patients with MFCL-2 mobility and mental energy expenditure by 36% (p<.05), confidence while walking by 23% (p=.004), and multi-tasking while walking by 26% (p=.03) in patients with MFCL-3 mobility (2).

The study of Seymour et al. demonstrated that, no matter if the patients did or did not have to carry a 10 lbs. basket, they were able to negotiate a defined obstacle course at the exact same walking speed or time, respectively, when using the C-Leg (5). In contrast, when using their non-microprocessor controlled knees, they walked 23% slower while carrying the 10 lbs. basket compared to the hands-free condition (5). Furthermore, a recent study found no difference between the effects of a concurrent cognitive task on walking in patients using a microprocessor-controlled prosthetic knee and sound, non-amputated subjects (1). Thus, above-knee amputees are able to significantly improve their multi-tasking capacities while walking on the prosthesis with a C-Leg compared to any non-microprocessor controlled knee.

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Improved overall mobility, especially in K2 patients

The more proximal the amputation, the greater is the physical and functional impairment to the individual, including a decreased likelihood of regaining household or community ambulation and an increased risk of falling (13-15). In subjects with an above-knee amputation, the prosthetic knee is a very important component, tasked with restoring knee biomechanics while at the same time providing maximum stability and safety. Most non-microprocessor controlled knee mechanisms have been designed for ambulation on level ground and require a permanent alertness of the patient to actively stabilize the knee in case of any pertubations (8-10). The C-Leg has been shown to significantly reduce falls (p<.05 to .01) (1-3), significantly improve validated indicators of the risk of falling such as the timed up and go test (p=.018) (4), significantly improve objective balance performance as measured with the Sensory Organization Test (p=.01) (11) and balance confidence as assessed with the Activity-specific balance confidence (ABC) scale (p=.001) (4), and to be safe during stepping onto obstacles, sudden stopping on and side-stepping with the prosthetic leg as well as to provide effective stumble recovery during tripping (9). Consequently, many patients are able to improve their overall mobility when using the C-Leg. Two studies demonstrated that 44% (3) or 50% (2), respectively, of patients with MFCL-2 mobility increased their overall mobility level to MFCL-3. With the C- Leg, patients with MFCL-2 mobility significantly reduced uncontrolled falls by up to 80% (p<.05 to =.01) as well as validated indicators of the risk of falling (1-3). Performance-based outcome measures suggest that these patients may be able to walk about 14-25% faster (p=.01 to .000) on level ground (1, 3, 5), around 20% quicker (p=.008) on uneven surfaces (1, 3), and descend a slope 30% faster (p=.002 to .001) when using the C-Leg (1, 2, 4). Furthermore, negotiation of stairs is significantly improved (p=.04 to .008) (1-3) and patients are enabled to perform many activities of community ambulation and in the house that are considered typical of MFCL-3 mobility (1, 6, 7). It is therefore no longer justified to generally withhold microprocessor- controlled prosthetic knees from patients with MFCL-2 mobility.

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Improving gait symmetry to reduce the risk of pain and long-term comorbidities

Walking is more difficult for transfemoral amputees to perform because they need to depend on an artificial limb for body weight support and gait mobility. Walking biomechanics is altered with the use of a prosthesis. Research on non-amputee subjects reported global symmetry when the general behavior of the limbs was considered (3). In contrast, the gait of persons with a unilateral transfemoral amputation is asymmetrical (4). Asymmetry, or lack of symmetry, appears to be a relevant aspect for differentiating a normal and pathological gait. Altered load distribution may lead to back and/or intact limb pain (5, 6, 8), osteoarthritis in the intact limb (5, 7, 8), osteopenia/osteoporosis in the residual limb (7, 8), and other musculoskeletal problems (6, 8). These degenerative changes can prevent the performance of everyday tasks and lead to a reduction in the quality of life.

A study of Kaufman et al. demonstrated that amputees have significantly improved kinetic gait symmetry (in forces and moments loading the joints of both limbs) when using a C-Leg (p=.01 to .002) compared to non-microprocessor knees (1). Similarly to the study of Segal et al. (2), they also found the C-Leg to produce a knee flexion moment at loading response that contributes to shock absorption, whereas non-microprocessor knees usually produce a knee extension moment that transfers loads directly to the residual hip and spine (1, 2). The results of the study suggest that the C-Leg improves amputee gait through more natural movements that could explain the improved balance and stability found in a number of other studies (9-13). Greater kinetic gait symmetry improves the load distribution between the prosthetic and sound limbs and may thus contribute to alleviating low back and intact limb joint pain as well as reduce long-term comorbidities and degeneration (1).

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