

Genium® and Genium® X3 Evidence Summary

	Mobility need or deficit of the patient	Evidence for benefits of the Genium compared to an MPK billed with L5856
Activities of daily living (ADL)	Restrictions to performing activities of daily living	Genium significantly improves overall performance in activities of daily living; difference to able-bodied subjects was no longer statistically significant.
Level walking	Restrictions to walking longer distances	Genium's pre-flex function reduces the perception of having to "climb over the prosthesis" at loading response, reduces braking forces during level walking making it easier to "ride into the knee" and use stance flexion for shock absorption. Improved swing control provides more consistent knee swing flexion (=toe clearance) across all walking speeds.
Walking with heavy footwear	Patients has to walk with heavy footwear (e.g. hard-toed shoes or boots) on a regular basis	Genium's swing control is able to compensate for additional distal weight and provide sufficient knee swing flexion (=toe clearance).
Multi-directional ambulation and walking with small steps	Patient has to ambulate in confined areas and/or with small steps on a regular basis	Genium provides more reliable swing release and swing knee flexion (=toe clearance) in small steps. Greater self-reported ease of walking with small steps and executing ADLs with multi-directional movements.
Slope ambulation / uneven terrain	Difficulties to negotiate slopes / uneven terrain and/or considerable compensatory movements when walking on slopes / uneven terrain (uneven terrain = permanent switch between inclines and declines)	Genium improves self-selected walking speed and quality of slope descent (decreased reliance on handrail use), and provides increased knee flexion at initial contact and in swing phase (=toe clearance) during slope ascent and descent. Its pre-flex function also supports more physiologic and symmetric slope descent with higher prosthetic side weight bearing and step length. Greater self-reported ease of slope ascent and descent.
Stair negotiation	Difficulties to negotiate stairs and/or considerable compensatory movements when walking on stairs	More consistent positioning of the foot on the stair and increased prosthetic side weight-bearing during stair descent. Ability to walk upstairs step over step with unloading of the sound knee and more natural appearance. Greater self-reported ease of stair ascent and descent. The walk-upstairs function can also be used for stepping over bigger obstacles without cumbersome and dangerous compensatory movements.
Gait symmetry and unloading of the sound limb and spine	Patient suffers from pain in the joints of the sound limb and/or low back pain	Genium allows for a more natural gait, greater gait symmetry, and makes it easier to ride into the knee and use knee stance flexion for shock absorption. Increased symmetry of gait is an indicator of more even load distribution and may thus reduce short- and long-term comorbidities of the sound limb and spine.
Standing	Patient needs to stand for extended periods of time on a regular basis and has difficulties to do so	Genium has an intuitive standing function that automatically locks for standing and allows for significantly higher prosthetic side weight-bearing and thus more relaxed standing.
Walking backwards	Patient needs to walk backwards on a regular basis and has fallen repeatedly or has to use compensatory movements for safe backwards walking	Genium recognizes the direction of movement and prevents the knee from collapsing when walking backwards.

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Activities of daily living (ADL) and overall mobility

- Pre-flexion, intuitive stance function, obstacle and stairs function, and safe walking backwards provide the basis for improving the overall performance in 10 ADLs with Genium measured by the validated Physical Functional Performance assessment (PFP-10; $p=.03$) (2).
- Genium significantly improved the Upper Body Function ($p=.01$), Balance ($p=.03$) and Endurance ($p=.02$) subscores of the PFP-10 compared to C-Leg (2).
- The PFP-10 total score and its Upper Body Function, Upper Body Strength, Lower Body Strength and Balance subscores were no longer significantly lower with Genium compared to those of able-bodied individuals. Only the Endurance subscore was significantly lower in Genium users compared to able-bodied subjects (2).
- Genium significantly improved the functional performance as measured by the Amputee Mobility predictor (AMP, $p\leq.001$) (1).
- Genium significantly improved the step-activity-derived functional level (SAD-FL, $p=.01$) (1).
- Based on the significant improvements in ADL performance balanced with the difference in cost between Genium and C-Leg, the Genium was found to be a cost-effective prosthetic intervention (1).

Walking longer distances

- Pre-flexion allows for easier “riding into the knee” with easier use of physiologic knee stance flexion for shock absorption (5, 6, 9) and a reduction of braking forces during walking (reduction of the feeling to have to “climb over the prosthesis”). Research has shown that mean knee stance flexion for shock absorption is 2-4° higher with Genium than with C-Leg over all walking velocities (5, 6, 9), reaching statistical significance for slow ($p=.01$) and normal walking speed ($p=.02$) (5). Mean vertical and horizontal ground reaction (braking) forces are reduced for medium and fast walking speed (6, 9). The reduction of braking forces makes it easier to walk longer distances.
- The Genium offers an optimized swing phase control with a nearly physiologic swing knee flexion angle of 64° independent of walking speed. This provides improved toe clearance in slower walking speeds as well as timely shank swing in higher walking speeds – that patient doesn’t have to wait for a lagging shank to swing forward (6, 9). The improved swing control also supports to walk longer distances.

Improved and consistent toe clearance across all walking speeds and with heavy footwear

- The Genium offers an optimized swing phase control with a nearly physiologic swing knee flexion angle of 64° independent of walking speed. This provides improved toe clearance in slower walking speeds as well as timely shank swing in higher walking speeds – that patient doesn’t have to wait for a lagging shank to swing forward (6, 9). It is also able to compensate for an additional 500 g (16.6 Oz) weight simulating heavy shoes or boots. Peak knee swing flexion increases by a significant 3-6° ($p\leq.02$) for all walking speeds, ensuring adequate toe clearance (5).

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Improved negotiation of slopes and uneven terrain

- Pre-flexion improves self-selected walking speed ($p=.041$) and quality of slope descent ($p=.026$), mainly due to reduced reliance on handrail use (4).
- Pre-flexion facilitates significantly increased prosthetic leg weight-bearing during slope descent, represented by a significant 12% increase in the knee stance flexion moment ($p<.05$) (4, 6, 9) and a significant 3-4° increase in knee flexion peaks with Genium as compared to C-Leg (5). This results in a more physiologic and symmetric step-over-step gait pattern with unloading of the sound limb (3, 5, 6, 9) and improved perceived ease ($p=.002$ and $p<.03$, respectively) (7, 8) and safety of slope descent (8).
- Pre-flexion also supports easier and more physiologic and symmetric step-over-step slope ascent by increased prosthetic knee stance flexion and weight-bearing (3, 5), reducing the need to “climb up over the limb” (3, 5-9). Consequently, ascending slopes and hills was rated significantly easier ($p<.001$ and $p<.02$, respectively) and considerably safer with Genium as compared to C-Leg (7, 8).
- The optimized swing phase control results in increased knee flexion and thus toe clearance and safety when ascending and descending slopes (4-9). Compared to C-Leg, knee swing flexion during slope ambulation with Genium is significantly increased by 8-9° ($p<.01$) in slope descent and 3-8° ($p<.01$) in slope ascent (4, 5, 6, 9), thus ensuring improved toe clearance and longer prosthetic side step length (4).
- The improvements in safety and gait patterns in slope ambulation also facilitate the negotiation of uneven terrain that is basically a permanent switchover between inclines and declines. Thus, patients rated walking on uneven and unknown terrain considerably easier and safer with the Genium as compared to using a C-Leg (8).

Improved negotiation of stairs and bigger obstacles

- Pre-flexion facilitates a consistent positioning of the foot for step-over-step stair descent, resulting in more confidence and prosthetic side weight-bearing, represented by a significant 15% increase ($p<.05$) in the prosthetic side knee flexion moment (6, 9). Consequently, patients rated the ease of descending stairs significantly greater with Genium than with C-Leg ($p=.019$ and $p<.03$, respectively) (7, 8).
- Genium allows for ascending stairs in the natural step-over-step manner with a prosthetic knee that bends to maximize clearance of the stair with each step (1, 6, 8, 9-12). In the walk upstairs mode, the bent prosthetic knee produces enough flexion resistance that the patient can use the prosthesis as a counter bearing to lift his/her body up to the next step using his/her hip and residual limb muscles (6, 8, 9-12). The conventional method for ascending stairs with a prosthetic knee is to take two steps at a time with the sound limb and drag the prosthetic leg up (“skip-step”), which results in a significant strain to the sound limb joints and muscles (9-12). Research has shown that most above-knee amputees are able to walk upstairs step over step with the Genium, resulting in a movement pattern that clearly approximates that of non-amputated subjects (6, 9-12). With the conventional prosthetic knees, including C-Leg (10 out of 14 patients), the median score on the Stair Assessment Index (SAI) was 5, representing step-to-step pattern (one step with the sound limb at a time) without handrail use. With the Genium, the median SAI score improved significantly to 11 ($p=.005$), representing a step-over-step pattern with handrail use (1, 10). Participants were also more symmetrical while using the Genium to include more similar peak knee and hip flexion during swing and peak hip power generation during push-up when comparing between the prosthetic and the sound limb (10). The extent of movements of the knee and hip of both legs while ascending stairs with the Genium was very similar to that of healthy subjects after only 1 day (9, 11) and further improved and became more consistent after accommodation of 3 months (6). When compared to the conventional skip-step method, the loading of the sound knee, demonstrated by the maximum knee extension power, was significantly reduced by 12% ($p<.05$). The mean maximum residual limb extension power during step-over-step stair ascent with Genium was comparable with the leg extension power in

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sound subjects (9, 11). Consequently, patients rated the ease of walking upstairs significantly greater ($p=.04$) with Genium than with a C-Leg (8).

- The Genium allows for nearly normal stepping over large obstacles (8) with the prosthetic leg first – the knee can be normally flexed and the prosthesis be moved over the obstacle like taking a long step. Using this function, Genium is safe in a loaded and bent position when landing past the obstacle (6, 9-12). All other MPK’s require that the patient move the extended/stiff prosthetic leg around obstacle using circumduction, which is associated with a high risk of catching the toes, stumbling and falling.
- The Genium also enables nearly normal stepping over large obstacles (8) with the sound leg first. Using this function of Genium, the trailing prosthetic leg can be normally bent and moved over the obstacle (6, 9-12). All other MPK’s require that the patient move the trailing extended/stiff prosthetic leg around the obstacle using circumduction or to hop forward on the sound leg and drag the stiff prosthetic leg over the obstacle. Both ways are associated with a substantial risk of catching toes, stumbling, and falling.
- The benefit of the obstacle function is reflected by a significant improvement in the completion time of the Four Square Step Test (FSST), a validated outcome measure for the risk of falling in higher functioning amputees ($p=.04$) (1). The test requires stepping over crutches on the ground with both the sound and prosthetic leg first.

Improved multi-directional ambulation walking with small steps

- Genium allows for safe multi-directional motion and transitional gait by controlling the switch from stance to swing. Thus, it significantly improves overall prosthetic function, especially utility (7) as well as the perceived ease and safety of many activities of daily living (8).
- Genium provides a considerably more reliable swing initiation for improved toe clearance in small and shuffling steps, as needed for ambulation in crowds and confined spaces (5, 9). The mean maximum knee swing flexion angle in small steps with Genium is a significant 5.4° greater ($p<.05$) than with C-leg (6, 9), thus ensuring greater toe clearance. Consequently, walking with small steps and in close spaces is rated significantly easier ($p=.025$) and considerably safer with Genium than with a C-leg (7, 8).

More natural gait, improved gait symmetry, unloading of the sound limb and spine

- Unlike all other microprocessor controlled knees that have to be (unphysiologically) fully extended at heel strike, these simulated physiologic rule sets allow Genium for optimized prosthetic gait (OPG) with a nearly physiologic pre-flexion of the knee at heel strike (5, 6, 9). Compared to the C-Leg, this results in increased symmetry of gait (step length) at all walking velocities, reaching statistical significance ($p<.05$) for very slow, slow, and medium walking speeds (5, 6, 9). Increased symmetry of gait is an indicator of more even load distribution between the prosthetic and sound limbs and may thus reduce long-term comorbidities of the sound limb and spine (13).
- Pre-flexion allows for easier “riding into the knee” with easier use of physiologic knee stance flexion for shock absorption (5, 6, 9) and a reduction of braking forces during walking (reduction of the feeling to have to “climb over the prosthesis”). Research has shown that mean knee stance flexion for shock absorption is $2-4^\circ$ higher with Genium than with C-Leg over all walking velocities (5, 6, 9), reaching statistical significance for slow ($p=.01$) and normal walking speed ($p=.02$) (5). Mean vertical and horizontal ground reaction (braking) forces are reduced for medium and fast walking speed (6, 9).
- Genium significantly improves overall prosthetic function, especially utility, social burden, perceived response and well-being (8) as well as the perceived ease and safety of many activities of daily living (7, 8).

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Improved ability to stand still for longer periods of time

Genium allows the patient to intuitively stand on a flexed and stable knee on level, uneven, or inclined surfaces (ramps or hills) (7-9). The user does not need to activate or deactivate the stance function; both occur intuitively. Stance function is ended with a simple step (prosthesis side or sound side) (7). With traditional prosthetic knees it is imperative that the user cognitively ensure at all times that the center of mass stays ahead of the knee axis in order to prevent unexpected flexing of the prosthetic knee, which can cause the knee to collapse. In a study, prosthetic leg weight-bearing and mean sagittal knee flexion moment while standing on a 10° slope with Genium were significantly increased by 85% or 92%, respectively ($p < .05$ each), while the prosthetic side mean hip moment was reduced by 69% compared to standing with a C-Leg. Also, prosthetic side postural sway was significantly reduced ($p < .01$) when standing on the Genium as compared to a C-Leg (9). This means that the user is able to stand longer periods of time in a more relaxed manner with Genium, by loading the prosthesis with significantly more weight while requiring much less hip force to stabilize the prosthesis and being able to unload the sound limb at the same time (9). These objective findings have been supported by self-reported outcomes in the corresponding items of the Prosthesis Evaluation Questionnaire (PEQ) and an Activity of Daily Living Questionnaire, confirming the significantly increased perceived ease of standing still for longer periods of time (7, 8).

Safe walking backwards

- Genium provides stability when taking steps backwards. Traditional microprocessor knees do not accommodate backward walking, because the knee is programmed to go into swing when the toe is loaded, which may cause the knee to collapse when stepping backwards. Being that the Genium reliably detects the direction in which the prosthesis is moving in real time, there is no danger of the knee collapsing while walking backwards. This was confirmed in a study surveying patients and the perceived ease and safety of activities of daily living. Walking backwards was rated significantly easier ($p = .04$) and considerably safer when using the Genium as compared to the C-Leg (8).

Results of 899 trial fittings with Genium in Germany

- Based on the prosthetists' assessment, more than 85% of patients benefit from Genium in the domains of safety, ability to vary walking speed, ability for divided attention during walking, unloading of the sound limb, necessary effort to walk, and gait symmetry compared to previous C-Leg use (14).
- Based on the patients' self-assessment, they benefit from Genium in walking up and down stairs, clearing larger obstacles, walking up and down slopes, standing for longer periods of time on level surface or slopes, varying walking speed, walking with small steps, walking backwards, carrying heavy loads, and in activities in confined spaces such as in the bathroom, compared to previous use of the C-Leg (14).
- It turned out to be impossible to predict success (additional benefits) or failure (no additional benefits) of Genium fitting compared to C-Leg use. A multitude of patient characteristics including but not limited to age, mobility grade, amputation etiology, time since amputation, comorbidities, and many others (26 in total) failed to demonstrate any predictive value whether or not a patient would benefit from Genium as compared to C-Leg (14).

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References

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