GENIUM

Quality for life

Clinical Study Summaries

This document summarizes clinical studies conducted with the Genium. The included studies were identified by a literature search made on PubMed and within the journals Der Orthopäde, JPO Journal of Prosthetics and Orthotics, Orthopädie-Technik and Technology & Innovation.

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Genium Study Summaries

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g. level walking, safety, activities, etc). By clicking on individual categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

Reference		Category									
		Functions and Activities								Participation	Environment
Author	Year	Level walking	Stairs	Ramps, Hills	Uneven ground Obstacles	Cognitive demand	Metabolic Energy Consumption	Safety	Activity Mobility ADL	Preference Satisfaction QoL	Health economics
Lura	2017		x								
Hahn	2016	x	x	x	x	x	x	x	x		
Highsmith	2016								x		
Highsmith	2016		x					x	x	x	x
Highsmith	2016			x							
Huppert*	2016	x	x	x				x	x	x	
Bell	2016			x							
Schalk**	2015								x	x	
Lura	2015	x		x							
Aldridge Whitehead	2014		x								
Highsmith	2014									x	
Highsmith	2014	x			x			x			

Highsmith	**2014**		x	x	x						
Kannenberg	**2013**	x	x	x	x			x	x		
Bellmann	**2012**	x	x	x				x			
Bellmann	**2012**		x								
Blumentritt	**2012**	x	x	x				x			
Kampas	**2011**	x	x	x	x			x			
Total number: 18 *Review ** Case study		**8**	**11**	**10**	**5**	**1**	**1**	**8**	**6**	**4**	**1**

2 Summaries of categories

On the following pages you find summaries of categories researched in several studies (e.g. level walking, stairs, etc.). At the end of each summary you will find a list of reference studies contributing to the content of the particular summary.

Level Walking

Major Findings

With Genium compared to C-Leg:

→ **Increased toe clearance with more consistent maximum knee angle at 64° across different walking velocities**

→ **Step length symmetry is improved by up to 60%**

→ **Increased toe clearance when walking with small steps**

Maximum knee flexion angle in swing phase is increased by 11%

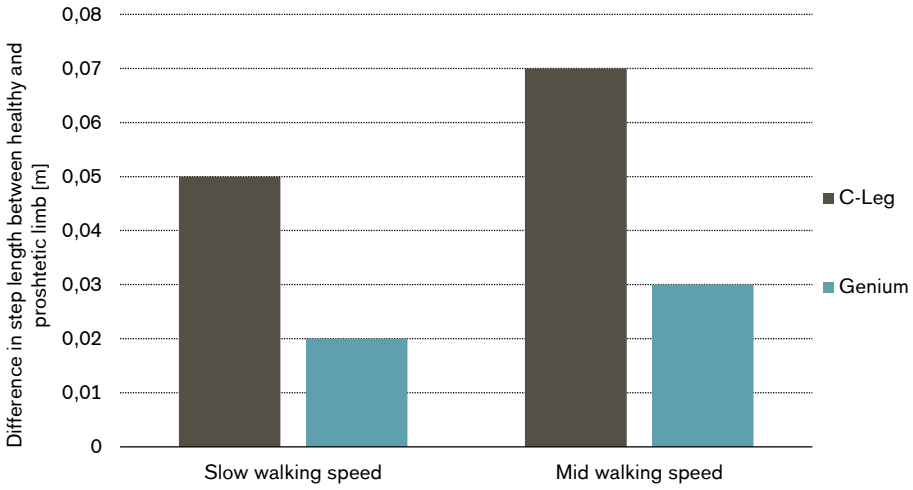
→ **Reliable swing phase release even when walking with small steps**

Swing phase is reliably released in 95% of all small steps

→ **Difficulty of walking backwards is improved by 26%**

Safe loading when stepping backwards was in all tests possible

Reduced asymmetry of step length with Genium compared to C-Leg



Bellmann et al. (2012)

Clinical Relevance

The main aim of a prosthesis is the restoration of function. For lower extremities the most important function is ambulation. It has influence on the mobility grade of the subject, the participation of life and, therefore, general quality of life. Furthermore, a natural gait pattern is pursued, since it prevents the sound side from higher or inappropriate loads due to compensatory movements. Gait asymmetries can contribute to secondary diseases such as osteopenia or arthritis.

Summary

Walking velocities were investigated by Bellmann et al. (2012) as well as by Highsmith et al. (2014) at varying speeds and varying distances. No differences between Genium and C-Leg could be observed. However, subjects had the tendency to rate the perceived exertion lower with Genium compared to C-Leg (Highsmith et al. 2014).

Regarding biomechanical gait analysis, several improvements with Genium were documented. The maximum knee angle in swing phase is not influenced by gait speed and stays constant at 64° (Bellmann et al. 2012 & Blumentritt et al. 2012). Therefore, adequate toe clearance is ensured even when walking slowly. Over the range from very slow to normal walking velocities, peak knee flexion angle in swing phase is increase by up to 7° with Genium compared to C-Leg. In stance phase, peak knee flexion angle is increased by 2°during slow and normal speed with Genium compared to C-Leg. Knee angles are due to accommodation, training and use

of Genium closer to the intact limb and therefore a more physiological gait pattern is achieved (Lura et al. 2015). Furthermore, it was observed that, with Genium, the prosthetic knee is in a pre-flexed position of 4° at heel strike. The pre-flex leads to reduced breaking forces which was proved by a decreased ground reaction force on the prosthetic side (Bellmann et al. 2012 & Blumentritt et al. 2012). In conclusion the improved gait characteristics of Genium resulted in a more normalized, anatomic movement pattern.

Walking with small steps is improved with Genium; not only is the maximum knee angle in swing phase increased compared to C-Leg, but also the swing phase is reliably released with Genium in 95% of all steps. With C-Leg, swing phase is released in 75% of all the steps (Bellmann et al. 2012 and Blumentritt et al. 2012).

When walking backwards, safe loading of the prosthesis is possible with Genium (Blumentritt et al. 2012). Moreover, subjects rated walking backwards as less difficult to perform with Genium than with C-Leg (Kannenberg et al. 2013).

In a retrospective, cross-sectional cohort analysis from Hahn et al. 2016, clinically important factors on performance using Genium were analysed based on 899 trial fittings. Variation of gait speed exhibit the highest number of sensitive confounders in the functional benefits category. However, the investigated variables failed to exhibit classifying power (e.g. variation of gait speed impacted by mobility grade presented a high significance ($p < 3x10^{-26}$) but a very low r^2 (0.13)).

References of summarized studies

Bellmann, M., Schmalz, T., Ludwigs, E., & Blumentritt, S. (2012). Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. Archives of physical medicine and rehabilitation, 93(3), 541–549. doi:10.1016/j.apmr.2011.10.017

Blumentritt, S., Bellmann, M., Ludwigs, E., & Schmalz, T. (2012). Zur Biomechanik des mikroprozessorgesteuerten Prothesenkniegelenks Genium. Orthopädie-Technik, 01(12), 24–35.

Hahn, A., Lang, M., Stuckart, C. (2016). Analysis of clinically important factors on the performance of advanced hydraulic, microprocessor-controlled exo-prosthetic knee joints based on 899 trial fittings. Medicine, 95 (45):e5386.

Highsmith, M. J., Kahle, J. T., Lura, D. J., Lewandowski, A. L., Quillen, W. S., & Kim, S. H. (2014). Stair ascent and ramp gait training with the Genium knee. Technology & Innovation, 15(4), 349–358. doi:10.3727/194982413X13844488879267

Kampas, P., & Seyr, M. (2011). Technologie und Funktionsweise des Genium-Prothesenkniegelenks. Orthopädie-Technik, 12(11), 898–903.

Kannenberg, A., Zacharias, B., Mileusnic, M., & Seyr, M. (2013). Activities of Daily Living: Genium Bionic Prosthetic Knee Compared With C-Leg. JPO Journal of Prosthetics and Orthotics, 25(3), 110–117. doi:10.1097/JPO.0b013e31829c221f

Lura, D. J., Wernke, M. M., Carey, S. L., Kahle, J. T., Miro, R. M., & Highsmith, M. J. (2015). Differences in knee flexion between the Genium and C-Leg microprocessor knees while walking on level ground and ramps. Clinical Biomechanics, 30(2), 175–181. doi:10.1016/j.clinbiomech.2014.12.003

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Stairs

Major Findings

With Genium compared to C-Leg:

→ **Difficulty of ascending and descending stairs is decreased by 34% and 10%**

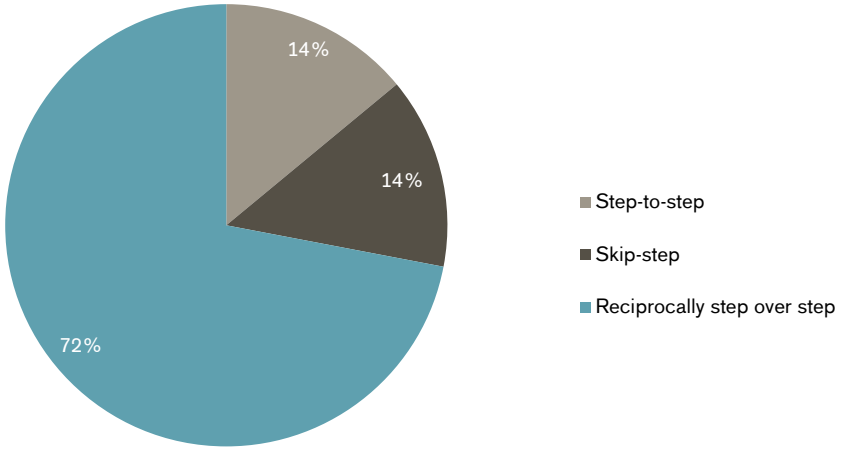
→ **70 – 80% of subjects are able to ascend stairs with a reciprocal step-over-step strategy**

→ **Loading of sound side is reduced by 10% during ascent**

→ **Movement of sound side is within range of healthy subjects during ascent**

Movement of hip and knee joints on sound side are reduced by 34% and 33%

Percent of subjects by stair ascent strategy with Genium



Stair ascent strategy was assessed observing 14 subjects (Aldridge Whitehead et al. 2014).

Clinical Relevance

Stair ambulation is an activity that is important for amputees with an activity level ranging from K2 to K4. Being able to ascend and descend stairs is a requirement to participate in daily life. Evaluation of stair ascent includes stair ascent strategy, use of handrail and/or use of an assistive device. Biomechanical assessment is conducted to determine load on the joints and joint angles and to compare them to values measured in healthy subjects.

Summary

The assessment of stair ascent strategy was conducted by multiple groups. Bellmann et al. (2012) reported that 80% of subjects were able to ascend stairs reciprocally after only one day of using Genium. These findings were confirmed by Highsmith et al. (2014), reporting 70% of subjects, and by Aldridge Whitehead et al. (2014), reporting 72%. Lura et al. (2017) found that from the subjects who were able to use a reciprocally step-over-step strategy to ascend stairs, 41 % preferred it over step-to-step strategies, compared to C-Leg users in which preference was only 5%. Furthermore, an improvement of the Stair Assessment Index (SAI) from 5 to 11 points (Aldridge Whitehead et al. 2014) respectively from 6 to 11 points (Highsmith et al. 2016) was achieved by switching from C-Leg or an NMPK to Genium. A score of 11 points represent a reciprocal stair ascent strategy with hand rail or assistive device use on a scale where a score of 13 points is the maximum. The reciprocal stair ascent strategy is accomplished with Genium by means of on an additional function, activated by a backward movement of the prosthesis after lifting the foot (Kampas et al. 2011).

Although the duration of a stride during stair ascent is longer with Genium than with C-Leg, a clear approximation to the movement pattern of healthy subjects was observed when using Genium. The movements of the knee and hip joints on the contralateral side were decreased and the loading of the contralateral knee joint was reduced with Genium compared to C-Leg (Bellmann et al. 2012 & Blumentritt et al. 2012). Moreover, hip and knee flexion during swing phase were increased and therefore toe clearance during stair ascent increased (Aldridge Whitehead et al. 2014). The peak flexion angle and swing period increased significantly with Genium (Lura et al. 2017). All these changes led overall to a decreased between-limb difference with Genium compared to C-Leg.

Besides improvement in stair ascent strategy and gait characteristics, subjects reported that ascending and descending stairs was perceived as less difficult with Genium than with C-Leg (Kannenberg et al. 2013).

In a retrospective, cross-sectional cohort analysis from Hahn et al. 2016, clinically important factors on performance using Genium were analysed based on 899 trial fittings. Descent and ascent from stairs presented a very clear responsiveness in 38.3% and 63.10% of subject's perception category, respectively. Reciprocal stair ascent exhibit the highest number of sensitive confounders (25) for the advanced manoeuvres category. However, none of the factors qualified as predictor for performance.

References of summarized studies

Aldridge Whitehead, J. M., Wolf, E. J., Scoville, C. R., & Wilken, J. M. (2014). Does a Microprocessor-controlled Prosthetic Knee Affect Stair Ascent Strategies in Persons With Transfemoral Amputation? Clinical Orthopaedics and Related Research®. doi:10.1007/s11999-014-3484-2

Bellmann, M., Schmalz, T., Ludwigs, E., & Blumentritt, S. (2012). Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. Archives of physical medicine and rehabilitation, 93(3), 541–549. doi:10.1016/j.apmr.2011.10.017

Bellmann, M., Schmalz, T., Ludwigs, E., & Blumentritt, S. (2012). Stair ascent with an innovative microprocessor-controlled exoprosthetic knee joint. Biomedizinische Technik. Biomedical engineering, 57(6), 435–444. doi:10.1515/bmt-2011-0029

Blumentritt, S., Bellmann, M., Ludwigs, E., & Schmalz, T. (2012). Zur Biomechanik des mikroprozessorgesteuerten Prothesenkniegelenks Genium. Orthopädie-Technik, 01(12), 24–35.

Hahn, A., Lang, M., Stuckart, C. (2016). Analysis of clinically important factors on the performance of advanced hydraulic, microprocessor-controlled exo-prosthetic knee joints based on 899 trial fittings. Medicine, 95 (45):e5386.

Highsmith, M. J., Kahle, J. T., Lura, D. J., Lewandowski, A. L., Quillen, W. S., & Kim, S. H. (2014). Stair ascent and ramp gait training with the Genium knee. Technology & Innovation, 15(4), 349–358. doi:10.3727/194982413X13844488879267

Highsmith, M.J., Klenow, T.D., Kahle, J.T., Wernke, M.M., Carey, S.L., Miro, R.M., Lura, D.J. (2016). Effects of the Genium microprocessor knee system on knee moment symmetry during hill walking. Technology & Innovation, 18: 151-157.

Kampas, P., & Seyr, M. (2011). Technologie und Funktionsweise des Genium-Prothesenkniegelenks. Orthopädie-Technik, 12(11), 898–903.

Kannenberg, A., Zacharias, B., Mileusnic, M., & Seyr, M. (2013). Activities of Daily Living: Genium Bionic Prosthetic Knee Compared With C-Leg. JPO Journal of Prosthetics and Orthotics, 25(3), 110–117. doi:10.1097/JPO.0b013e31829c221f

Lura, D. J., Wernke, M. M., Carey S. L., Kahle, J. T. Miro, R. M. & Highsmith, M. J. (2017). Crossover study of amputee stair ascent and descent biomechanics using

Genium and C-Leg prostheses with comparison to non-amputee control. Gait & Posture, 58, 103-107.

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Ramps / Hills

Major Findings

With Genium compared to C-Leg:

→ **Ease of ascending and descending ramps is improved by 24% and 17%**

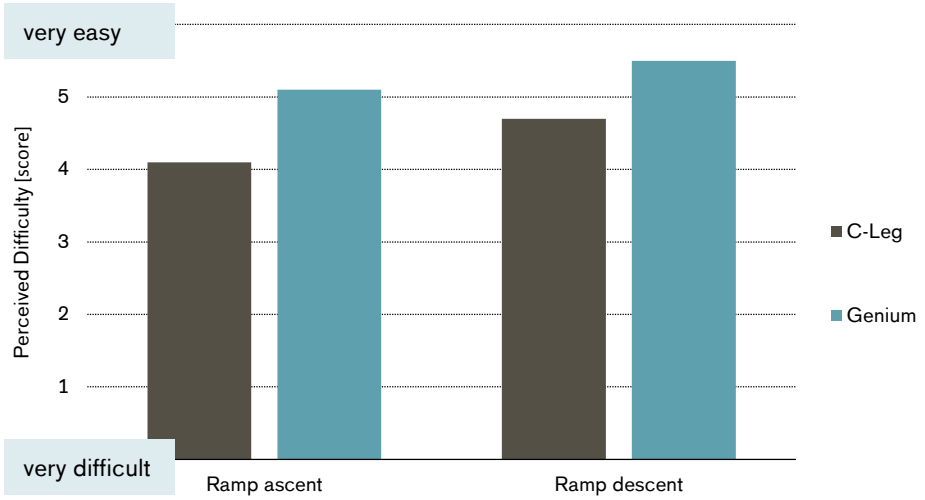
→ **Improved toe clearance during ramp ascent and descent**

Knee angle in swing phase increased by 14° during ramp ascent
Knee angle in swing phase increased by 13° during ramp descent

→ **Improved symmetry of knee moment while ascending and descending ramps**

Ascent: significantly lower at slow and fast walking speed
Descent: significantly lower at slow and self-selected walking speed

Ramp ambulation is perceived as less difficult with Genium



Kannenberg et al. (2013)

Clinical Relevance

Similar to stairs, ramps and hills need to be navigated by amputees with a wide range of activity levels to be able to participate in daily life. Biomechanical assessment is conducted to determine joint angles. The maximum knee flexion angle in swing phase was of special interest. To minimize the risk of stumbling, it is required to have an increased maximum flexion angle relative to level walking to ensure an adequate foot clearance.

Summary

Maximum knee angle was increased by 7° when ascending and by 8° when descending a ramp with Genium compared to C-Leg (Bellmann et al. 2012 and Blumentritt et al. 2012). Increased maximum knee angle in swing phase leads to an increased foot clearance which further decreases the risk of stumbling.

Besides increased safety, patients reported that ascending and descending ramps is less difficult to perform with Genium than with C-Leg (Kannenberg et al. 2013) and also that it´s more comfortable. When ascending ramps, less focal pressure near the anterior aspect of the hip was experienced (Highsmith et al. 2014).

Highsmith et al. (2014) observed that when subjects with Genium descended a ramp with only a slight decline such as 5°, a walking pattern similar to level walking characterized by two knee flexion peaks was facilitated. This feature of Genium is enabled through an adapted resistance in stance phase; it allows for a flexion angle which is higher than the maximum knee angle when level walking (17°). In comparison to C-Leg, peak knee flexion angle during descending a slope of 5° was with Genium in swing phase increased by up to 8° and during stance phase increased by up to 4° over a variety of gait velocities from slow to fast. Peak knee flexion an-

gles of the prosthetic side are therefore closer to peak knee flexion angles of the intact leg and therefore a more normalized, anatomic movement pattern is achieved with Genium (Lura et al. 2015). Similar results were reported by Bell et al. (2016) where additionally more knee flexion at initial heel strike and swing phase were observed as well as faster walking speed by 0.1 m/s compared to other MPKs. Also the knee moment while ascending and descending ramps was more symmetrically with Genium (Highsmith et al. 2016). The values were significant at slow and fast walking speed when ascending a ramp and at slow and self-selected walking speed when descending.

Furthermore, when walking on ramps swing phase release occurs even when the prosthesis is in a flexed and loaded position (Kampas et al. 2011). Overall, a more natural gait pattern on ramps is achieved with Genium.

In a retrospective, cross-sectional cohort analysis from Hahn et al. 2016, clinically important factors on performance using Genium were analysed based on 899 trial fittings. Descent from ramps presented a very clear responsiveness in 59 %of subject's perception. Ascent (57.4%) and standing on ramps (76.4 %) presented also a very clear responsiveness as performance indicators. However, none of the factors qualified as predictor for performance.

References of summarized studies

Bell, E.M., Pruziner, A.L., Wilken, J.M., Wolf, E.J. (2016). Performance of conv tional and X2® prosthetic knees during slope descent. Clin Biomech, 33: 26–31.

Bellmann, M., Schmalz, T., Ludwigs, E., & Blumentritt, S. (2012). Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. Archives of physical medicine and rehabilitation, 93(3), 541–549. doi:10.1016/j.apmr.2011.10.017

Blumentritt, S., Bellmann, M., Ludwigs, E., & Schmalz, T. (2012). Zur Biomechanik des mikroprozessorgesteuerten Prothesenkniegelenks Genium. Orthopädie-Technik, 01(12), 24–35.

Hahn, A., Lang, M., Stuckart, C. (2016). Analysis of clinically important factors on the performance of advanced hydraulic, microprocessor-controlled exo-prosthetic knee joints based on 899 trial fittings. Medicine, 95 (45):e5386.

Highsmith, M.J., Klenow, T.D., Kahle, J.T., Wernke, M.M., Carey, S.L., Miro, R.M., Lura, D.J. (2016). Effects of the Genium microprocessor knee system on knee moment symmetry during hill walking. Technology & Innovation, 18: 151-157.

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Kampas, P., & Seyr, M. (2011). Technologie und Funktionsweise des Genium-Prothesenkniegelenks. Orthopädie-Technik, 12(11), 898–903.

Kannenberg, A., Zacharias, B., Mileusnic, M., & Seyr, M. (2013). Activities of Daily Living: Genium Bionic Prosthetic Knee Compared With C-Leg. JPO Journal of Prosthetics and Orthotics, 25(3), 110–117. doi:10.1097/JPO.0b013e31829c221f

Lura, D. J., Wernke, M. M., Carey, S. L., Kahle, J. T., Miro, R. M., & Highsmith, M. J. (2015). Differences in knee flexion between the Genium and C-Leg microprocessor knees while walking on level ground and ramps. Clinical Biomechanics, 30(2), 175–181. doi:10.1016/j.clinbiomech.2014.12.003

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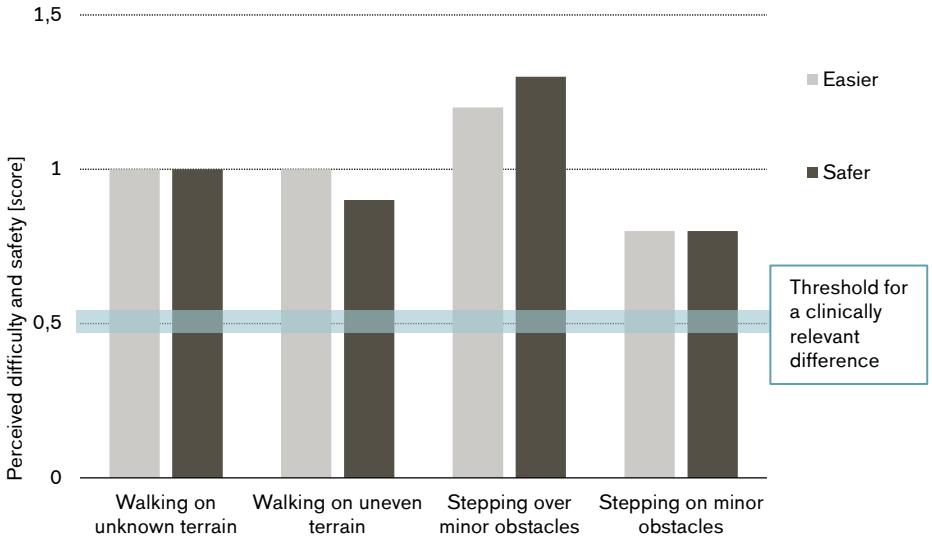
Uneven Ground / Obstacle Course

Major Findings

With Genium compared to C-Leg:

→ **Clinically relevant increase in perceived ease for walking on unknown or uneven terrain.**
→ **Clinically relevant increase in perceived ease for stepping over or stepping on minor obstacles.**
→ **Stair climbing training improves the ability to cross obstacles since same unique function is applied**

Differences in perceived ease and safety on uneven ground for Genium compared to C-Leg



Perceived difficulty and safety was rated by experienced C-Leg users after 3 months of Genium use (Kannenberg et al. 2013).

Clinical Relevance

Besides ambulating on stairs and ramps, overcoming obstacles and walking on different types of terrain are requirements to be able to participate in life. These activities are together with level walking a solid base for an amputee to ambulate independently. The ability to walk on uneven terrain is usually measured by the time required to complete a course and the perceived exertion.

Summary

Highsmith et al. (2014) studied the impact of different prostheses when amputees completed a course on sloping terrain over trimmed grass, sand, rocks and small roots. They could not observe any difference in gait speed between Genium and C-Leg; however, amputees showed a trend to rate perceived exertion lower when using Genium. When asked about the difficulty in an additional study, amputees rated walking on uneven and unknown terrain as clinically relevant less difficult and safer with Genium than with C-Leg. Furthermore, clinically relevant increase in perceived ease for stepping over and stepping on minor obstacles was reported (Kannenberg et al. 2013).

In a study which investigated stair ascent training using Genium, subjects believed that stair climbing practice improved their ability to cross obstacles (Highsmith et al. 2014). It is confirmed in a technical report that obstacles can be crossed with the same function as used for ascending stairs, activated by a backward movement of the prosthesis after lifting the foot. Using this function, the obstacle is crossed with the prosthetic limb first. Conventionally, crossing an obstacle is only possible through either stepping with the sound limb first or through a circumduction movement (Kampas et al. 2011).

In a retrospective, cross-sectional cohort analysis from Hahn et al. 2016, clinically important factors on performance using Genium were analysed based on 899 trial fittings. Crossing obstacles presented a very clear responsiveness in 65.9 %of subject's perception. However, none of the factors qualified as predictor for performance.

References of summarized studies

Hahn, A., Lang, M., Stuckart, C. (2016). Analysis of clinically important factors on the performance of advanced hydraulic, microprocessor-controlled exo-prosthetic knee joints based on 899 trial fittings. Medicine, 95 (45):e5386.

Highsmith, M. Jason; Kahle, Jason T.; Lura, Derek J.; Dubey, Rajiv V.; Carey, Stephanie L.; Quillen, William S.; Mengelkoch, Larry J. (2014): Short and Mid-Distance Walking and Posturography With a Novel Microprocessor Knee. In: Technology & Innovation 15 (4), S. 359–368. DOI: 10.3727/194982413X13844488879302.

Highsmith, M. J., Kahle, J. T., Lura, D. J., Lewandowski, A. L., Quillen, W. S., & Kim, S. H. (2014). Stair ascent and ramp gait training with the Genium knee. Technology & Innovation, 15(4), 349–358. doi:10.3727/194982413X13844488879267

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Safety

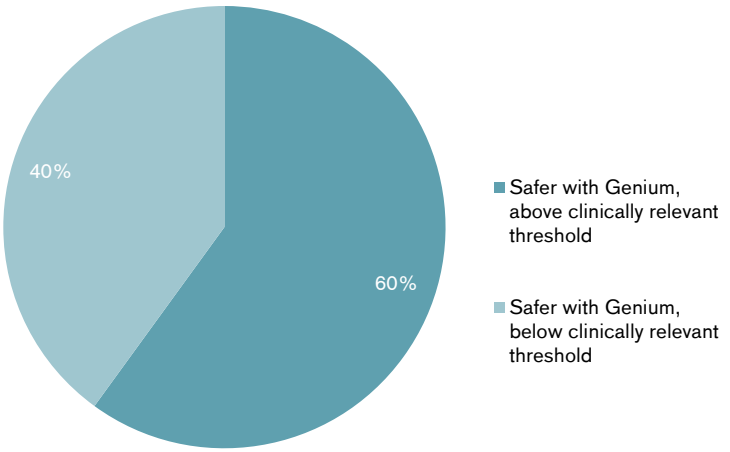
Major Findings

With Genium compared to C-Leg:

→ **60% of the examined activities of daily living (ADLs) are rated as safer above a threshold considered to be clinically relevant**

→ **Movement control in all three backward directions improved by up to 10%**

Clinically relevant improvment in safety of activities of daily living with Genium



Safety was assessed for 45 activities (Kannenberg et al. 2013).

Clinical Relevance

Safety aspects of the prosthesis are highly relevant for the patients. Since the fear of falling can have a negative impact on activities of daily living as well as on participation, perceived safety is regarded as an important factor for quality of life of an amputee. Information about perceived safety when performing different activities is gathered through a questionnaire. Balance tests are conducted to obtain objective information about the patients' ability to react in potential falling situations.

Summary

The results of an activity of daily living (ADL) questionnaire show, that 60% of the examined ADLs were rated as safer with Genium compared to C-Leg with a comparative rating above the threshold considered to be a clinically relevant difference (25% of the maximum possible difference). The other 40% of the examined ADLs also showed improved safety, but below this threshold. Especially the category 'Family and Social Life' with 83% of ADLs rated as safer, and 'Mobility and Transportation' with 63% of ADLs rated as safer were clearly in favour for Genium (Kannenberg et al. 2013).

Highsmith et al. examined 2016 the safety with the four square step test, a test of dynamic balance that clinically assesses the person's ability to step over objects forward, sideways, and backwards. The test could be finished by 9% faster with Genium than with C-Leg.

Other studies tested the influence of Genium when standing on a decline. It was observed that with Genium not only was the body weight evenly distributed on both legs, but also the body posture was more relaxed than with C-Leg. The latter can most likely be explained by the reduced activity required to keep up the posture and the decreased hip moments which were found in patients using Genium. Furthermore, observed that the postural sway on the prosthetic side is reduced when standing on a decline using Genium compared to C-Leg (Bellmann et al. 2012 and Blumentritt et al. 2012).

Highsmith et al (2014) investigated postural stability measured by a balance system. They could show that posterolateral directional stability over the sound side is improved with Genium compared to C-Leg.

In a retrospective, cross-sectional cohort analysis from Hahn et al. 2016, clinically important factors on performance using Genium were analysed based on 899 trial fittings. The category Safety within Functional Benefits presented a very clear responsiveness of 49.94%. However, none of the factors qualified as predictor for performance.

References of summarized studies

Bellmann, M., Schmalz, T., Ludwigs, E., & Blumentritt, S. (2012). Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. Archives of physical medicine and rehabilitation, 93(3), 541–549. doi:10.1016/j.apmr.2011.10.017

Blumentritt, S., Bellmann, M., Ludwigs, E., & Schmalz, T. (2012). Zur Biomechanik des mikroprozessorgesteuerten Prothesenkniegelenks Genium. Orthopädie-Technik, 01(12), 24–35.

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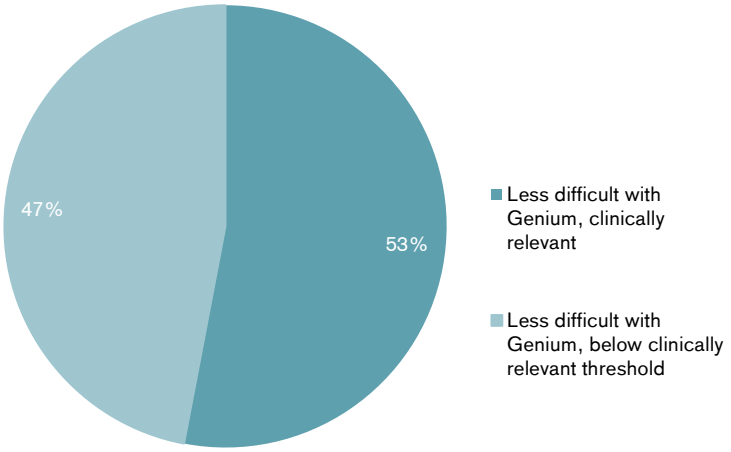
Activity / Mobility / Activity of daily living (ADL)

Major Findings

With Genium compared to C-Leg:

- → **53% of the examined activities of daily living (ADLs) show a clinically relevant decrease in difficulty**
- → **75% of ADLs in category 'Family and Social Life' show a clinically relevant decrease in difficulty**
- → **58% of ADLs in category 'Mobility and Transportation' show a clinically relevant decrease in difficulty**
- → **Mobility increased by 5%**
- → **Physical functional performance scores significantly higher with Genium**

Clinically relevant decrease in difficulty to perform acitivities of daily living with Genium



Perceived difficulty was assessed for 45 activities (Kannenberg et al. 2013).

Clinical Relevance

With an Activity of daily living (ADL) questionnaire, information is gathered about self-care activities such as functional mobility, dressing, eating and personal hygiene, as well as activities for living independently in a community, such as shopping, housework and transportation. The questionnaire is used as a tool to measure the general independence of patients.

Summary

The results of an activity of daily living (ADL) questionnaire demonstrate that 53% of the examined ADLs were rated to show a clinically relevant decrease in perceived difficulty with Genium compared to C-Leg. The other 47% of examined ADLs showed a trend to be rated as less difficult. Especially in the categories, 'Family and Social Life' and 'Mobility and Transportation', the results were clearly in favour of Genium: 75% and 58% of the examined ADLs, respectively, were rated as less difficult to perform (Kannenberg et al. 2013). This improvement in the activities of daily living was confirmed by a study by Highsmith et al. (2016). The Perceived function and safety in three of five ADL domains improved significantly. The other two domains showed no difference. This study group also showed that the overall mobility increased by 5%, as measured with the Amputee Mobility Predictor.

In a case study, a bilateral transfemoral amputee was fitted with Genium with osseointegrated prosthesis fixation (OPF). Compared to the situation before OPF, the patient was able to perform four more activity categories of daily living listed in lower extremity functional scale (LEFS) (any of your usual work, housework, etc; usual hobbies, recreational or sporting; getting into or out the bath; walking between rooms) (Schalk et al. 2015).

Functional performance differences were assessed between Genium, C-Leg and intact knees by Highsmith et al. 2016 (b) using the Continuous-Scale Physical Functional Performance-10 (CS-PFP10). Subjects with Genium presented a significant ($p<0.05$) score improvement for upper-body flexibility, balance and endurance, compared to C-Leg users. Compared to non-amputees, Genium users presented a significantly lower score only for endurance domain.

In a retrospective, cross-sectional cohort analysis from Hahn et al. 2016, clinically important factors on performance using Genium were analysed based on 899 trial fittings. While none of the factors qualified as predictor for performance, toileting was found to be the most responsive indicator for subjects' perception. The complexity of the task may have been insufficiently considered so far.

References of summarized studies

Hahn, A., Lang, M., Stuckart, C. (2016). Analysis of clinically important factors on the performance of advanced hydraulic, microprocessor-controlled exo-prosthetic knee joints based on 899 trial fittings. Medicine, 95 (45):e5386.

Highsmith, M. J. Kahle, J. T., Miro, R. M. Cress, M. E., Lura, D. J., Quillen, W. S. Carey, S.L., Dubei, R. V., Mengelkoch, L. J. (2016)(b). Functional performance differences between the Genium and C-Leg prosthetic knees and intact knees. J Rehabil Res Dev. 2016;53(6):753–66.

Highsmith, M.J., Klenow, T.D., Kahle, J.T., Wernke, M.M., Carey, S.L., Miro, R.M., Lura, D.J. (2016). Effects of the Genium microprocessor knee system on knee moment symmetry during hill walking. Technology & Innovation, 18: 151-157.

Kannenberg, A., Zacharias, B., Mileusnic, M., Seyr, M. (2013). Activities of Daily Living: Genium Bionic Prosthetic Knee Compared With C-Leg. JPO Journal of Prosthetics and Orthotics, 25(3), 110–117. doi:10.1097/JPO.0b013e31829c221f

Schalk, S.A.F., Jonkergouw, N., van der Mer, F., Swaan, W.M., Aschoff, H.H., van der Wurff, P. (2015). The Evaluation of Daily Life Activities after Application of an Osseointegrated Prosthesis Fixation in a Bilateral Transfemoral Amputee: A Case Study. Medicine (Baltimore), 94(36): e1416.

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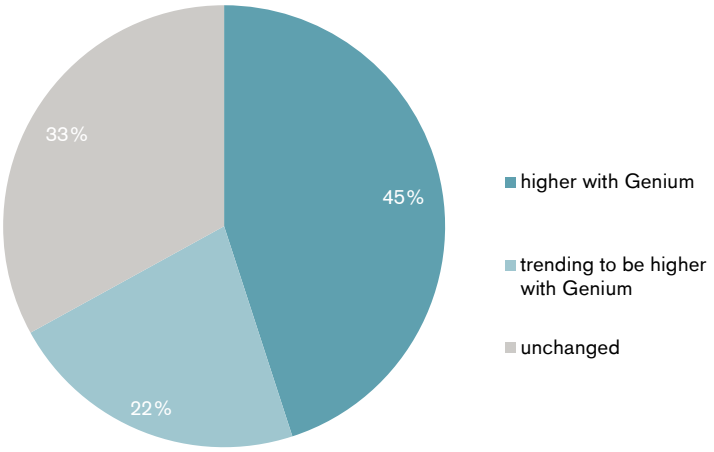
Preference / Satisfaction / Quality of Life (QoL)

Major Findings

With Genium compared to C-Leg:

→ **Improved prosthesis-related quality of life**
→ **45% of prosthetic-related scales are improved**
→ **70% of activities, relevant to the physical performance aspects of Genium, are improved**
→ **80% preferred Genium**

Percent of scales showing improvement in prosthetic function and quality of life with Genium



In total 41 items divided in 9 scales were assessed (Highsmith et al. 2014).

Definition/Clinical Relevance

Satisfaction and quality of life can be measured to determine the general well-being of a person. They are all very meaningful parameters to investigate, since they have the most direct impact on the amputee's well-being. They are influenced by other categories and can therefore be seen as a summary of possible activities, independence and perceived safety. A common outcome measure in prosthetic research is the Prosthesis Evaluation Questionnaire (PEQ), a questionnaire with a total of 84 items. Several selected items are further used in 9 subscales.

Summary/Discussion

Comparing all items of the Prosthesis Evaluation Questionnaire (PEQ) in aggregate, the Genium was rated to be improved compared to C-Leg. 4 out of 9 scales were rated as improved, namely perceived response, social burden, utility, and well-being. In addition, the scales appearance and sounds, showed a trend to be improved with Genium. Furthermore, 10 items of special interested were looked at separately. 7 out of these 10 were improved with Genium compared to C-Leg; comfort standing, ability to walk in close spaces, go down stairs, walking up and down steep hills, walk on slippery surfaces and satisfaction with walking (Highsmith et al. 2014). In one publication by Highsmith et al. (2016) the preference for Genium was 80%.

In a case study, a bilateral transfemoral amputee was fitted with Genium with osseointegrated prosthesis fixation (OPF). Life habits were recorded with LIFE-H questionnaire for daily activities and social roles and showed increases in five and eight respectively out of 12 categories in comparison to the situation before OPF (Schalk et al. 2015).

References of summarized studies	Highsmith, M.J., Klenow, T.D., Kahle, J.T., Wernke, M.M., Carey, S.L., Miro, R.M., Lura, D.J. (2016). Effects of the Genium microprocessor knee system on knee moment symmetry during hill walking. Technology & Innovation, 18: 151-157. Highsmith, M. J., Kahle, J. T., Miro, R. M., Lura, D. J., Dubey, R. V., Carey, S. L., . . . Mengelkoch, L. J. (2014). Perceived differences between the Genium and the C-Leg microprocessor prosthetic knees in prosthetic-related function and quality of life. Technology & Innovation, 15(4), 369–375. doi:10.3727/194982413X13844489091297 Schalk, S.A.F., Jonkergouw, N., van der Mer, F., Swaan, W.M., Aschoff, H.H., van der Wurff, P. (2015). The Evaluation of Daily Life Activities after Application of an Osseointegrated Prosthesis Fixation in a Bilateral Transfemoral Amputee: A Case Study. Medicine (Baltimore), 94(36): e1416.

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3 Summaries of individual studies

On the following pages you find summaries of studies that researched Genium. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of each summary you also can read the original study authors' conclusions.

Reference

Lura DJ, Wernke MM, Carey SL, Kahle JT, Miro RM, Highsmith MJ.

School of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, FL, USA.

Crossover study of amputee stair ascent and descent biomechanics using Genium and C-Leg prostheses with comparison to non-amputee control

Gait & Posture 2017; 58: 103-107.

Products

Genium vs C-Leg

Major Findings

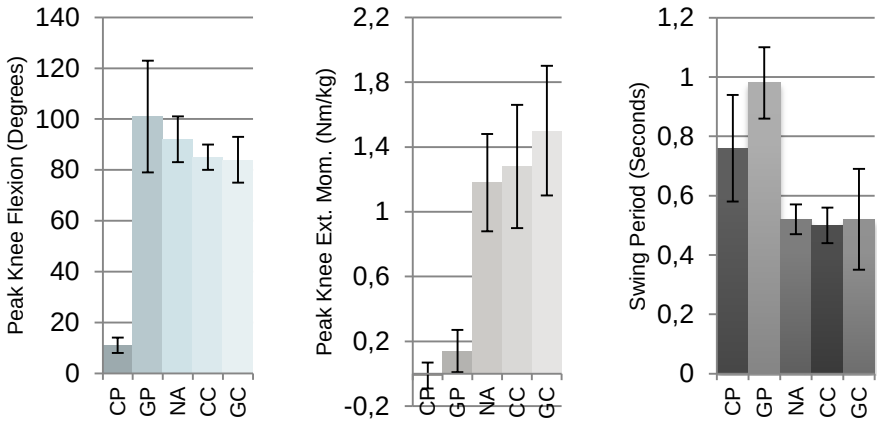
With Genium compared to C-Leg:

- → **Deficiency in gait patterns for stair ascent decreased overall (peak flexion angle and swing period increased significantly).**
- → **Ability and preference to use a step-over-step gait increased significantly.**
- → **With Genium, 41% of subjects who were able to use a step-over-step (SOS) pattern prefer it to step-to-step (ST); with C-Leg, only 5% subjects would prefer step-over-step (SOS), likely due to comfort and stability of their previous gait pattern.**

Stair ascent step-over-step (SOS)* gait, mean values

Genium (GP) and contralateral (GC, n=17); C-Leg (CP) and contralateral (CC, n=4); non-amputees (NA, n=10)

(n = subjects who were able to use SOS gait).



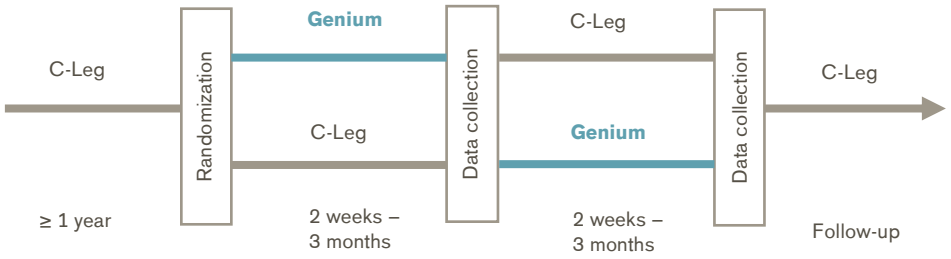
*"[…] since participants were not asked to perform the ST gait if they preferred the SOS gait, and not all participants were able to perform the SOS gait, each grouping did not have the same number of trials. For the descent trials, since only one participant preferred the ST gait for descent with the Genium there was not a sufficient sample to perform statistical analysis with for study outcomes for ST descent" (Lura et al., 2017)

Population

Subjects:	20 unilateral, transfemoral amputees, 5 non-amputees
Previous prosthesis:	C-Leg
Amputation causes:	70% trauma, 20% malignancy, 10% vascular disease
Mean age:	Patients: 46.5 yrs (±14.2 yrs), Controls 57.2 (±15.7 yrs)
Mean time since amputation:	17.7 yrs (±15.6 yrs)
MFCL:	K3

Study Design

Interventional, randomized crossover design:



Results

Activities								Participation	Environment
Level walking	**Stairs**	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Metabolic energy consumption	Safety	Activity, Mobility, ADLs	Preference, Satisfaction, QoL	Health economics

Category	Outcomes	Results (compared to non-amputees)	
		C-Leg	Genium
Stairs	Descent		
	Peak flexion angle		
	prosthetic to contralateral side	--	--
	contralateral side to non-amp.	--	--
	Peak extension moment		
	contralateral to prosthetic side contra-	++	++
	lateral side to non-amp.	++	++
	Prosthetic side to non-amp.	0	0
	Swing duration		
	prosthetic to contralateral side	+	+
	prosthetic side to non-amp.	+	+
	contralateral side to non-amp.	+	+
	C-Leg to Genium	+	
	Ascent (step-over-step pattern)		
	Peak flexion angle		
	prosthetic to contralateral side	--	++
	prosthetic side to non-amp.	--	0
	contralateral side to non-amp.	0	0
	Genium to C-Leg		++

Category	Outcomes	Results (compared to non-amputees)	
		C-Leg	Genium
	Peak extension moment		
	prosthetic to contralateral side	--	--
	prosthetic side to non-amp.	--	--
	Genium to C-Leg prosthetic		+
	Genium to C-Leg contralat.		+
	Swing duration		
	prosthetic to contralateral side	**++**	**++**
	prosthetic side to non-amp.	**++**	**++**
	contralateral side to non-amp.	0	0
	Genium to C-Leg		**++**

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"Use of the Genium knee enabled the majority of the participants to use a reciprocal SOS gait pattern for stair ascent, increased knee flexion during swing phase of stair ascent, and generally contributed to a more symmetric gait. However, there was not a significant change in gait parameters for participants while descending stairs, and the swing duration while using the Genium for stair ascent was marginally longer than while using the C-Leg." (Lura et al., 2017)

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Reference

Hahn A, Lang M, Stuckart C.

Analysis of clinically important factors on the performance of advanced hydraulic, microprocessor-controlled exo-prosthetic knee joints based on 899 trial fittings

Medicine (Baltimore), 2016, 95(45)e5386.

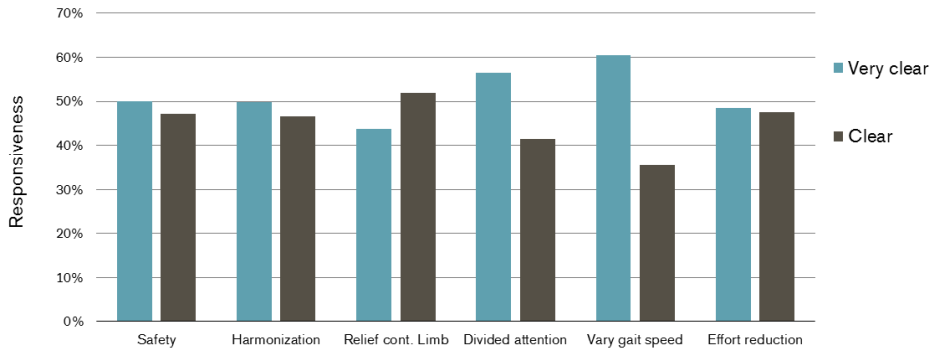
Products

Genium®, C-Leg®, mechanical knee joints

Major Findings

- → **Overall responsiveness exceeded 90%** after 1 week trial fitting**.** Genium responders span a wide range of demographic and epidemiologic characteristics.
- → **Investigated variables failed to exhibit classifying power.** Eligibility decisions for the patient based on such variables only (e.g. mobility grade, comorbidities, BMI and over 50 more) might thus be unjustified.
- → **Single and multiple regression models** detected influences of mobility grade, residual limb conditions, socket type, use of liners, vacuum technology, dynamic foot and others on likelihood to improve performance indicators.
- → **Trial fittings** may pose a very appropriate method to investigate individuals' potential to benefit from Genium. Bias in the sample is estimated to be below 5%.
- → Trial outcomes vary in sensitivity**. Variation of gait speed, perception of toileting and reciprocal stair ascent** exhibit the highest number of sensitive confounders in their respective categories (functional benefits (FB), subject perception (SP) and advanced maneuvers (AM), respectively).
- → **C-Leg walkers profit from an upgrade to Genium** in advanced maneuvers and subjects' perception categories**.**

Responsiveness to Functional Benefits (FB) variable subgroup

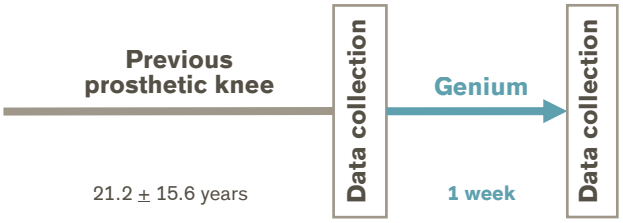


Population

Subjects:	899
Previous prosthetic knee:	C Leg (689), mechanical hydraulic knees (38), pneumatic knees(22), other polycentric (19), 4-bar knees (15), brake knees (9), locked knees (2).
Amputation causes:	68.9% trauma, 15.4% tumor, 6% vascular disease.
Amputation level:	80.1% TF, 18.9% KD.
Mean age:	49.0 ± 12.9 y.
First prosthesis since:	21.2 ± 15.6 y.
MFCL:	12.5% K2, 64.1% K3, 22.8% K4.

Study Design

Retrospective, cross-sectional cohort analysis.



Data from routine trial fittings was retrieved from customer support service, from 272 prosthetic clinics between 2011 and 2015. Influence of clinical variables (i.e. mobility grade) on performance indicators (functional befits (FB), subjects perception (SP), advanced manoeuvring (AM)) were analysed using single and multiple linear and logistic regression modelling. FB by prosthetist and SP by patient were assessed on 5 point Likert scales. The upper two ratings of the Likert scale were defined as being respondent. Advanced manoeuvres were categorized by the prosthetist non-ordinally and dichotomized for analysis. The number of statistically relevant confounders were identified in each performance-indicating category. Clinical significance was derived by regression estimate (e).

Results

Functions and Activities						Participation			Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Energy	Safety	Activity, Mobility, ADLs	Preference, Satisfaction, QoL	Health Economics

Category	Outcomes	Results for Genium®	Sig.*
Level walking	Harmonization of gait pattern (FB)	FB total responsiveness: 96.36% very clear: 49.76% clear: 46.6 % # of detected sensitive confounders: 10	++
	Capability to vary gait speed (FB, SP)	FB total responsiveness: 96.05% very clear: 60.57% clear: 35.48% # of detected sensitive confounders: 22	++
		SP total responsiveness: 83.20% very clear: 52% clear: 31.2% # of detected sensitive confounders: 11	++
		Impacted by mobility grade e: 0.36, $p < 3x10^{-26}$, $r^2 = 0.13$	++
	Reduction of overall effort (FB)	FB total responsiveness: 96.03% very clear: 48.45% clear: 47.58% # of detected sensitive confounders: 13	++
	Walking backwards (SP, AM)	SP total responsiveness: 90.78% very clear: 64.90% clear: 25.88 % # of detected sensitive confounders: 5	++
		AM responsiveness safety: 92.28% # of detected sensitive confounders: 16	++
	"Door Test" (AM)	AM responsiveness safety: 88.35 %	++

Category	Outcomes	Results for Genium®	Sig.*
	Abrupt change of walking direction	# of detected sensitive confounders: 13	
Stairs	Descent (SP, AM)	SP total responsiveness: 66.82 % Very clear: 38.30 % Clear: 28.52% # of detected sensitive confounders: 13	++
		AM responsiveness safety: 70.52 % # of detected sensitive confounders: 20	++
	Ascent (reciprocal) (SP, AM)	SP total responsiveness: 88.64% very clear: 63.10% clear: 25.54 % # of detected sensitive confounders: 12	++
		AM responsiveness safety: 32.81 % # of detected sensitive confounders: 25	++
Ramps, Hills	Descent (SP, AM)	SP total responsiveness: 85.78% very clear: 59% clear: 26.78 % # of detected sensitive confounders: 6	++
		AM responsiveness safety: 70.86 % # of detected sensitive confounders: 21	++
	Ascent (SP, AM)	SP total responsiveness: 86.03% very clear: 57.40% clear: 28.63 % # of detected sensitive confounders: 9	++
		AM responsiveness safety: 74.53 % # of detected sensitive confounders: 14	++
	Standing (SP)	SP total responsiveness: 95.69% very clear: 76.60% clear: 19.09 % # of detected sensitive confounders: 11	++
Uneven ground, Obstacles	Crossing Obstacles (SP, AM)	With prosthetic side first SP total responsiveness: 92.36% very clear: 65.90% clear: 26.46% # of detected sensitive confounders: 8	++
		With contralateral side first SP total responsiveness: 85.32% very clear: 54% clear: 31.32% # of detected sensitive confounders: 5	++
	Stepping on Obstacles (SP)	# detected sensitive confounders: 10	++
Cognitive Demand	Divided Attention (FB)	FB total responsiveness: 98.05% very clear: 56.57% clear: 41.48% # of detected sensitive confounders: 18	++
	Dual Tasking (SP)	# detected sensitive confounders: 14	++
Metabolic Energy Consumption	Carrying objects with visual obstruction (SP, AM)	SP total responsiveness: 82.83% very clear: 51.30% clear: 31.53%	++

Category	Outcomes	Results for Genium®	Sig.*
		# detected sensitive confounders: 9	
		AM responsiveness safety: 87.74% # detected sensitive confounders: 11	++
	Carrying heavy loads (SP, AM)	SP total responsiveness: 82.40% very clear: 51% clear: 31.40% # detected sensitive confounders: 6	++
		AM responsiveness safety: 72.73% # detected sensitive confounders: 14	++
Safety	Safety (FB)	FB total responsiveness: 97.04% very clear: 49.94% clear: 47.10% # detected sensitive confounders: 14	++
Activity, Mobility, Activities of Daily Living (ADLs)	Change of mobility grade	FB total responsiveness: 96% very clear: 57.10% clear: 38.90% # detected sensitive confounders: 14	++
	Toileting (SP)	# detected sensitive confounders: 18	++

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"Responders to Genium trial fittings span a wide range throughout the entire investigated variables. **None of those variables nor their combination seem to qualify as predictor for an individual response to a performance indicator**. This is confirmed for mobility grade and further includes age, etiology, residual limb conditions, and comorbidities. BMI fails to exhibit statistical significance. Decision making processes that rely on those variables without appropriately considering the subjects' individual potential and capabilities do not seem to be supported by these findings. As no data is available supporting such approaches, the denial of access to advanced technology based on such variables may indeed be questionable. **A threshold value for walking capacity cannot be excluded and may pose a component of a possible predictor**. Future research may consider a minimum walking capacity as a component of a predictive instrument.

Toileting was identified as the most responsive indicator in the subject's perception. Difficulties associated with this specifically demanding task may be insufficiently considered and may play a more important role when deciding upon the appropriate prosthetic components. Future protocols for trial fittings may consider limiting the number of performance indicators to those with high differentiating power. Subjects having previously been fitted with C-Leg show benefits when fitted with Genium. Most of these benefits can be found in perception and advanced manoeuvres among which is stairs ascent. Liners and the use of a higher dynamic response foot further contribute to a better utilization of functional benefits." (Hahn et al., 2016).

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Reference

Highsmith MJ, Kahle JT, Miro RM, Cress ME, Lura DJ, Quillen WS.

School of Physical Therapy and Rehabilitation Sciences, University of South Florida, Tampa, FL.

Functional performance differences between the Genium and C-Leg prosthetic knees and intact knees

Journal of Rehabilitation Research and Development 2016; 53(6): 753-766.

Products

Genium vs C-Leg (vs Nonamputees)

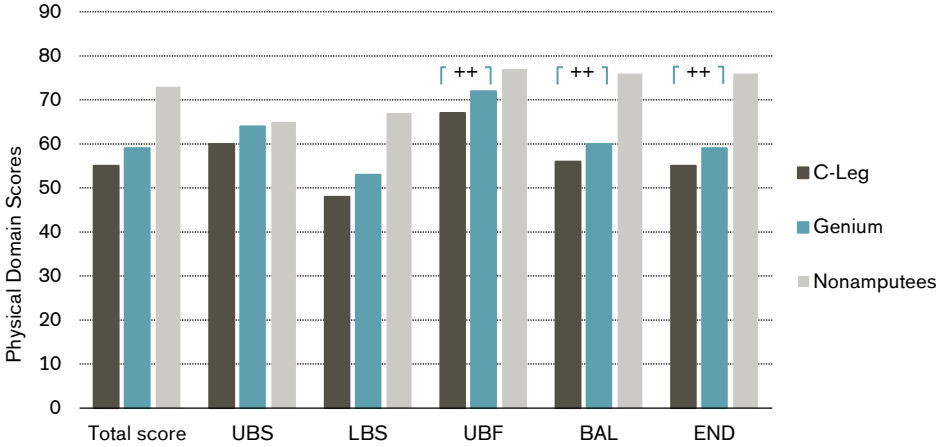
Major Findings

With Genium compared to C-Leg:

→ **Genium scores significantly higher than C-Leg**
in the upper-body flexibility (UBF), balance(BAL) and endurance (END) domains

→ **Genium scores higher than C-Leg**
upper-body and lower-body strength scores

Genium scores higher than C-Leg in Physical Functional Performance



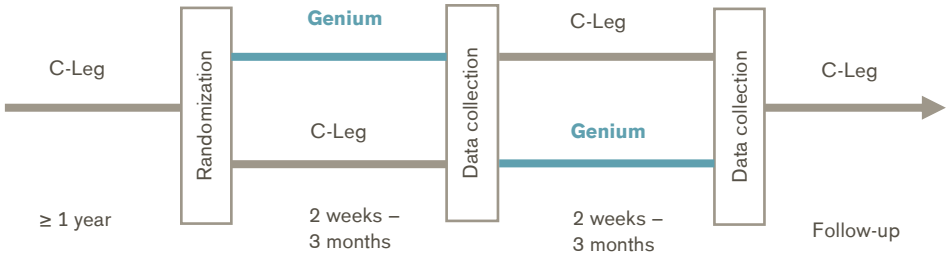
UBS = upper-body strength; LBS = lower-body strength; UBF = upper-body flexibility; BAL = balance; END = endurance; ++ $p < 0.05$ (significant)

Population

Subjects:	20 unilateral transfemoral amputees (AMP), 5 nonamputee controls (NAMP)
Previous prosthesis:	C-Leg
Amputation causes:	Trauma (75%), Malignancy (20%), PVD (5%)
Mean age:	46.5 ± 14.2 yrs (AMP); 57.2 ± 15.7 yrs (NAMP)
Mean time since amputation:	17.7 ± 15.6 yrs
MFCL:	MFCL 3

Study Design

Interventional, randomized crossover design:



Results

Functions and Activities						Participation			Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Energy	Safety	Activity, Mobility, ADLs	Preference, Satisfac-tion, QoL	Health Economics

Category	Outcomes	Results for Genium vs C-Leg	Sig.*
Activity, Mobility, Activities of Daily Living (ADLs)	CS-PFP10 (Continuous-Scale Physical Functional Perfor-mance 10)	The total score showed a trend of improvement by 7.4%.	+
		The upper-body flexibility score was significantly improved by 7%.	++
		The balance score was significantly improved by 7.6%.	++
		The endurance score was significantly improved by 8.4%.	++
		The upper-body and lower-body strength scores showed a trend of improvement (+5.4% and +8.1%).	+

Category	Outcomes	Results for Genium vs nonamputees	Sig.*
Activity, Mobility, Activities of Daily Living (ADLs)	CS-PFP10 (Continuous-Scale Physical Functional Perfor-mance 10)	Nonamputees scored higher in all five domains but **only significantly higher in the endurance domain (+22.4%).**	+ ++

Category	Outcomes	Results for C-Leg vs nonamputees	Sig.*
Activity, Mobility, Activities of Daily Living (ADLs)	CS-PFP10 (Continuous-Scale Physical Functional Perfor-mance 10)	**Nonamputees scored significantly higher in the total score (-24.4%) and lower-body strength (-27.6%), upper-body flexibility (-13.4%), balance (-27.1%) and endurance (-28.9%) do-mains** but not significantly higher in the domain upper-body strength**.**	-- -

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"There were no significant differences in functional UBS between nonamputees and persons with TFA regardless of knee condition. Compared with the C-Leg, Genium use improved the UBF, BAL, and END domains of functional performance, likely because of improved confidence, willingness to lift and carry greater mass, and

ability to move faster during activity. These benefits may be technologically due to the incorporation of a faster processing speed and axial load data assisting in regulating knee resistance and offering new functions such as stance locking and backward stepping. In the LBS, UBF, BAL, and END domains, C-Leg use resulted in significantly lower scores compared with nonamputees. Genium use significantly reduced the magnitude of impairment. The only domain in which persons with TFA performed significantly lower than nonamputees regardless of knee condition was the END domain. In terms of total CS-PFP10 performance, C-Leg use resulted in significantly lower function compared with nonamputees, whereas Genium use was not significantly different from nonamputees. Nonetheless, regardless of knee condition, persons with TFA did not equal or surpass nonamputees in any functional performance domain, suggesting room for improvements in TFA integrated functional performance. Further, the CS-PFP10 test was able to detect statistically significant differences of small effect size between prosthetic knee conditions, which should be interpreted with caution because the test has not been formally assessed in persons with TFA." (Highsmith et al., 2016)

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Reference

Highsmith MJ, Kahle JT, Wernke MM, Stephanie LC, Miro RM, Lura DJ, Sutton BS.

School of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, FL, USA.

Effects of the Genium knee system on functional level, stair ambulation, perceptive and economic outcomes in transfemoral amputees

Technology and Innovation 2016; 18: 139-150

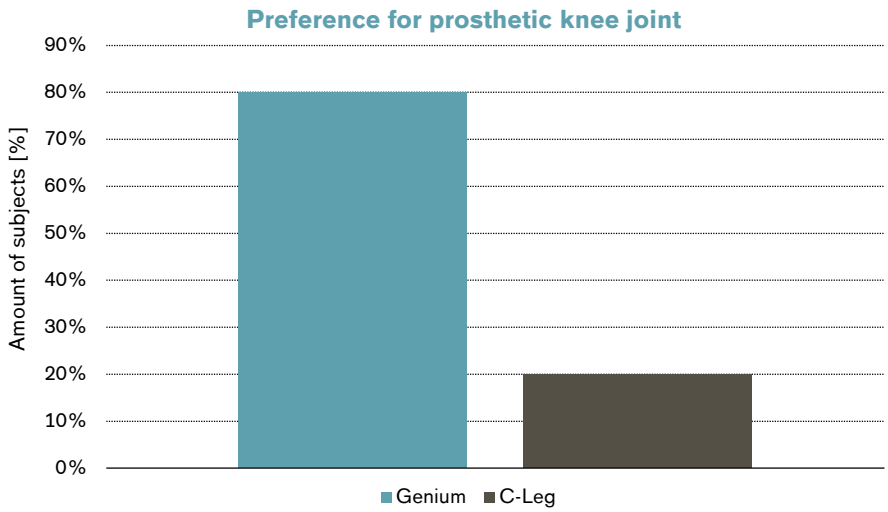
Products

Genium vs C-Leg

Major Findings

With Genium compared to C-Leg:

→ The quality of stair ascent and descent improved significantly
→ Mobility and functional level improved significantly
→ Perceived function and safety in ADLs was as good as with C-Leg or significantly better
→ 80% preferred Genium

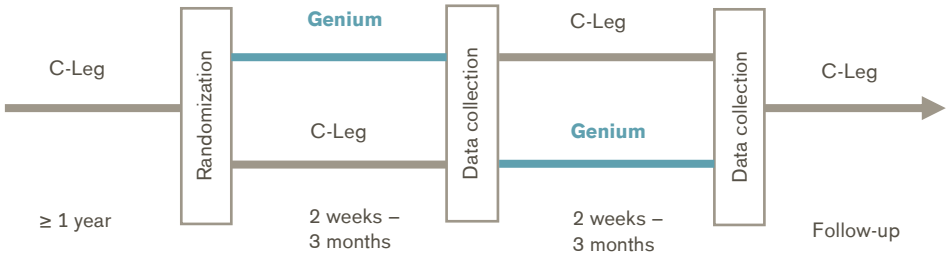


Population

Subjects:	20 unilateral, transfemoral amputees
Previous prosthesis:	C-Leg
Amputation causes:	70% trauma, 20% malignancy, 10% vascular disease
Mean age:	46.5 ± 14.2 yrs
Mean time since amputation:	17.7 yrs ± 15.6 yrs
MFCL:	K3

Study Design

Interventional, randomized crossover design:



Results

Functions and Activities						Participation			Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Energy	Safety	Activity, Mobility, ADLs	Preference, Satisfac-tion, QoL	Health Economics

Category	Outcomes	Results for Genium	Sig.*
Stairs	SAI (Stair Assessment Index)	**SAI stair *ascent* score improved significantly from 6 to 11 points (median).**	++
		SAI stair *descent* median score was 11 for both knee joints. The mean score significantly improved by 9%.	++
		Stair ascent and descent completion time did not differ significantly.	0
Safety	Four Square Step Test	**Time to complete the test significantly decreased by 9%.**	--
Activity, Mobility, Activities of Daily Living (ADLs)	AMP (Amputee mobility predictor)	**Mobility increased significantly by 5%.**	++
	Step activity derived functional level	**The functional level significantly increased by 6%.**	++
	ADL survey	**Perceived function and safety in three of five ADL domains improved significantly.** The other two domains showed no difference.	++
Preference, Satisfaction, Quality of Life (QoL)	Survey	**80% of the participants preferred Genium.**	++
Health Economics	ICER (Incremental cost-effectiveness ratio)	The ICER for reimbursing Genium ranges from $6,000 to $6,522 per unit of functional increase assuming a $30,000 intervention cost difference.	n.a.

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"Accommodation and use of the Genium knee system compared with C-Leg improved stair walking performance, multi-directional stepping, functional level, and perceived function. Genium was also preferred compared to C-Leg in this group of high functioning community ambulators with unilateral transfemoral amputation. Finally, Genium is a more costly microprocessor knee system but, in this group of patients, is worth funding due to significant differences in functional performance with activities of daily living." (Highsmith et al., 2016).

Back to overview table

Reference

Highsmith MJ, Klenow TD, Kahle JT, Wernke MM, Carey SL, Miro RM, Lura DJ.

School of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, FL, USA.

Effects of the Genium microprocessor knee system on knee moment symmetry during hill walking.

Technology and Innovation 2016; 18: 151-157.

Products

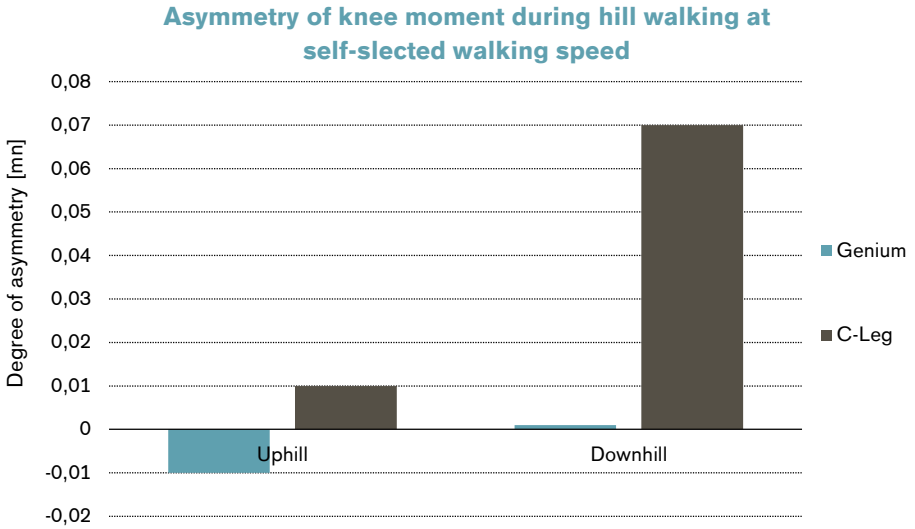
Genium vs C-Leg

Major Findings

With Genium compared to C-Leg:

→ The degree of asymmetry for knee moment during hill walking is lower with Genium

Uphill: significantly lower at slow and fast walking speed
Downhill: significantly lower at slow and self-selected walking speed



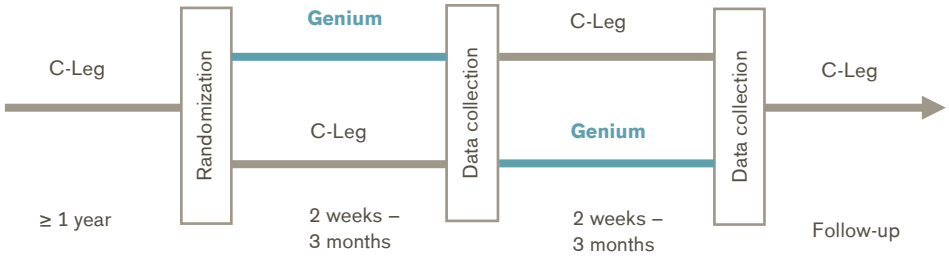
A positive value indicates a greater knee moment on the sound side when ascending ramps, a negative value a greater knee moment on the prosthetic side and a value of zero perfect symmetry.

Population

Subjects:	20 unilateral, transfemoral amputees
Previous prosthesis:	C-Leg
Amputation causes:	70% trauma, 20% malignancy, 10% vascular disease
Mean age:	46.5 ± 14.2 yrs
Mean time since amputation:	17.7 ± 15.6 yrs
MFCL:	K3

Study Design

Interventional, randomized crossover design:



Results

Functions and Activities						Participation			Environment
Level walking	Stairs	**Ramps, Hills**	Uneven ground, Obstacles	Cognitive demand	Energy	Safety	Activity, Mobility, ADLs	Preference, Satisfac-tion, QoL	Health Economics

Category	Outcomes	Results for Genium	Sig.*
Ramps, Hills	Motion analysis Ramp ascent	**The degree of asymmetry for knee moment was significantly lower at slow and fast walking speed** and not significantly different at self-selected walking speed.	--
	Motion analysis Ramp descent	**The degree of asymmetry for knee moment was significantly lower at slow and self-selected walking speed** and not significantly different at fast walking speed.	--

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"Accommodation and use of the Genium knee system, compared with C-Leg, improved knee moment symmetry in slow speed walking up and down a five degree ramp. Additionally, the Genium improved knee moment symmetry when walking downhill at comfortable speed. At fast walking speed, variance in knee moment symmetry was lower when using Genium. These results were found in a sample of high functioning persons with unilateral transfemoral amputation; however, the results likely have application in other patients who could benefit from more consistent knee function, such as older patients and others who have slower walking speeds." (Highsmith et al., 2016)

↑ Back to overview table

Reference

Huppert L, Mileusnic M, Hahn A.

Otto Bock Healthcare Products GmbH; Brehmstraße 16, 1110 Vienna.

Das Genium-Prothesenkniegelenk – ein Überblick über die wissenschaftliche Evidenz

(Genium prosthetic knee joint–Overview of scientific evidence)

Orthopädie Technik 2016. 4: 44-49.

Products

Genium vs C-Leg

Major Findings

With Genium compared to C-Leg:

→ **Level walking:**

- → **More physiological walking due to increased knee flexion angle during standing and swing phase while walking on level ground and ramps.**
- → **Reduced impact forces through 4° "Preflex" at initial heel contact**
- → **Reduction of step length gait asymmetry while level walking by 40-60%.**
- → **Correct swing initiation of 95% of the subjects when walking with small steps with Genium instead of 75% with C-Leg.**

→ **Safe detection of walking backwards and therefore reliable blocking of the swing phase release.**

→ **Improved stair ambulation:**

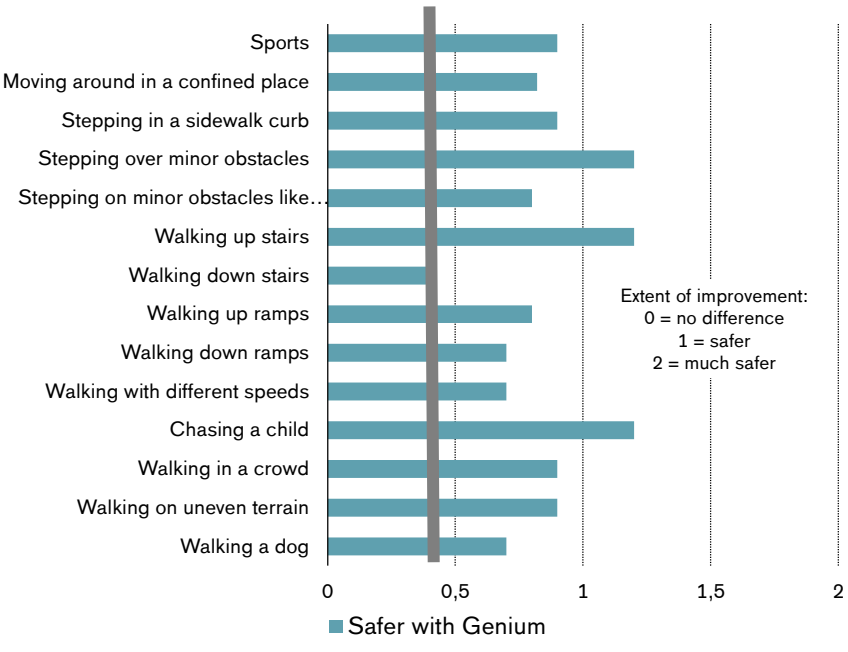
- → 70-80% of the patients used step-over-step strategy for stair ascent.
- → Range of motion (ROM) of the hip and knee joint of the sound side was reduced by one third and is nearly equivalent to able bodied persons.

→ **More balanced and safer standing on ramps.**

→ **Activities of daily living (ADLs) showed a clinically relevant decrease in perceived difficulty (53% of ADLS) and gain in safety (60% of ADLS).**

→ **Quality of life (QoL) is significantly improved including 4 out of 9 scales of Prosthetic Evaluation Questionnaire (PEQ)**

Genium makes activities of daily living safer



Kannenberg et al., 2013.

Study Design

Systematic review:

Nine publications were identified comparing Genium to C-Leg with each including on average between 10 and 20 transfemoral participants. The following table lists topics that were reviewed in this overview including the number of supporting studies:

Results	Number of studies
Level walking	4
Stairs	3
Ramps, Hills	3
Safety	4
ADLs	1
Quality of Life (QoL)	1
Health	4

Results

Functions and Activities						Participation			Environment
Level walking	**Stairs**	**Ramps, Hills**	**Uneven ground, Obstacles**	**Cognitive demand**	**Energy**	**Safety**	**Activity, Mobility, ADLs**	**Preference, Satisfaction, QoL**	**Health Economics**

Category	Outcomes	Results for Genium vs C-Leg	References
Level walking	Forces at initial heel contact	The 4° "Preflex" at initial heel contact reduces impact forces, thus protecting the body.	[1,2]
	Knee flexion during standing phase	Increased knee flexion angle during stance phase up to 2° with Genium while walking very slow, slow or fast.	[5]
	Adaptive swing phase control	Maximum knee flexion angle was 64°, which ensures toe clearance at different gait velocities.	[1,2]
		With Genium, the knee flexion increased significantly at very slow, slow and fast walking speed compared to C-Leg. These angles are nearly equivalent to those of able bodied persons.	[5]
		Adding more weight on the prosthetic foot (like heavy shoes), led to higher knee flexion angles.	[3]
		At 95% of small steps, swing was initiated correctly through adaptive swing phase control of Genium. With C-Leg the percentage was only 75%.	[1,2]
	Asymmetry of step length	Asymmetry of step length was reduced by 40-60%, depending on gait velocity.	[1,2]
Stairs	Stair ascent strategy	70-80% of the patients could use step-over-step strategy to ascent stairs with Genium.	[4,6,7]
	Range of motion (ROM)	Compensations in terms of ROM of the hip and knee joint on the sound side were reduced by about one third, which is nearly equivalent to an able bodied person.	[6]
Ramps, Hills	Maximum knee flexion during stance phase	During ramp descent at slow and fast walking speed the knee flexion angle increased significantly with Genium.	[5]

Category	Outcomes	Results for Genium vs C-Leg	References
	Maximum knee during swing phase	7° to 8° higher knee flexion angle during ramp ascent and descent with Genium compared to C-Leg.	[1,2,5]
	Standing on a 10 degree ramp for 3 minutes	• Higher loading of the affected side up to 86%. • Sagittal knee flexion moment on the prosthetic side increased by 92%. • Reduction of postural sway of the prosthetic side.	[1,2]
Safety	Stumbles and falls	The risk for stumbling or falling can be reduced through: • Better toe clearance through higher knee flexion. [1,2,5] • Initiation of the swing phase, while making small steps. [1,2] • Walking backwards detection, thus blocking the swing phase release. [2]	[1,2,5]
	ADL questionnaire	60% of ADLs showed a clinically relevant gain in safety.	[8]
Activity, Mobility, Activities of Daily Living (ADLs)	ADL questionnaire	53% of ADLs showed a clinically relevant decrease in perceived difficulty. Especially ascending and descending stairs and ramps as well as walking backwards improved significantly.	[8]
Preference, Satisfaction, Quality of Life (QoL)	Prosthetic Evaluation Questionnaire (PEQ)	4 out of 9 scales were rated significantly higher: • Perceived Response • Social Burden • Utility • Well-being "Appearance" and "Sounds" had the tendency to be rated higher, but not significantly. 3 out of 9 scales were unchanged: • Ambulation • Frustration • Residual Limb Health	[9]

Author's Conclusion

"Erste wissenschaftliche Studien, welche die Leistungsversprechungen des Genium biomechanisch, funktionell und hinsichtlich des subjektiven Zugewinns an Sicherheit und Einfachheit in der Durchführung von Aktivitäten des täglichen Lebens sowie den Einfluss auf die Lebensqualität überprüften, liefern Hinweise darauf dass mit dem Genium selbst im Vergleich zum C-Leg weitere Gebrauchsvorteile realisiert werden können. Von Bedeutung sind diese Ergebnisse insbesondere im Hinblick auf die Sicherheit des Anwenders sowie deren Schutz ihres gesamten Bewegungsapparates." (Huppert, 2016)

↑ Back to overview table

Reference

Bell EM, Pruziner AL, Wilken JM, Wolf EJ.

Department of Rehabilitation, Walter Reed National Military Medical Center, Bethesda, MD, 20889, USA.

Performance of conventional and X2® prosthetic knees during slope descent.

Clin Biomech, 2016; 33: 26–31.

Products

Genium X2®

Major Findings

With **Genium X2®** (X2) compared to

- Mechanical knee (**MECH**) (Total Knee & Mauch, Össur) and
- Standard microprocessor controlled knee (**MPK**) (C-Leg, Otto Bock & Rheo Knee, Össur):

→ Walking speed is faster by 9.6% (+0.1 m/s) compared to MPK.

→ Step length is longer with X2 by 1.6-16.9% and leads to a more harmonized movement in slope descent.

→ Through the stance flexion resistance, walking with the X2 was more comparable to able-bodied individuals.

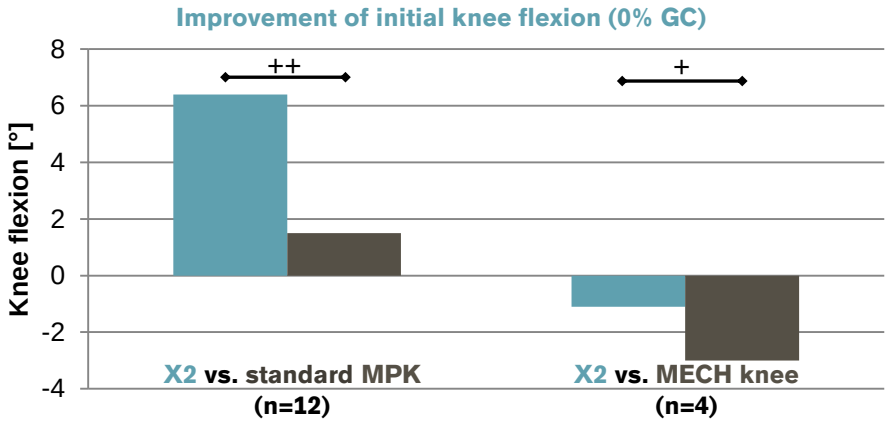
Initial knee flexion (0% GC): 326.7% more flexion
Max knee swing flexion (50-100% GC): 21.2% more flexion

→ A heightened use of the intact limb for support in descent could be indicated by the significant increase of the max. support moment flexion with X2 compared to MPK:

0% GC: 26.3% higher
35-75% GC: 21.2% higher

→ With X2, the prosthetic limb was utilized and loaded more normative. Therfore, the first vertical impact maximum (0-30%) increased up to 13.2%.

Please note: The percentage differences were calculated between the published Median values.

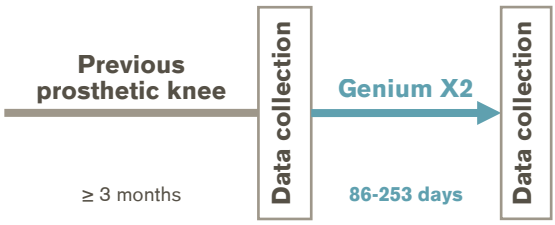


Population

Subjects:	21 unilateral, transfemoral amputees	
Previous prosthetic knee:	Mechanical knee (n=8)	→ Total Knee (Össur) → Mauch (Össur)
	Standard MPK (n=13)	→ C-Leg (Otto Bock) → Rheo Knee (Össur)
Amputation causes:	Trauma	
Mean age:	32.7 yrs (± 5.3 yrs)	
Time since amputation:	≥ 2 years	
MFCL:	K4	

Study Design

Interventional, pre- to post-test design:



Use of handrails influenced what data were available for biomechanical analysis. As such, data from participants who self-selected to use handrails for support were not included in temporal-spatial, kinematic, or kinetic analyses.

	Temporal-spatial	Kinematic	Kinetic
MECH	n=4	n=4	n=3
MPK	n=12	n=12	n=11

Results

Functions and Activities						Participation			Environment
Level walking	Stairs	**Ramps, Hills**	Uneven ground, Obstacles	Cognitive demand	Energy	Safety	Activity, Mobility, ADLs	Preference, Satisfac-tion, QoL	Health Economics

Category	Outcomes	Results for Genium X2	
Ramps, Hills	Temporal-spatial	**Walking speed is faster:**	
		X2 vs. MPK **9.6% faster** **++**	X2 vs. MECH 8.2% faster +
		Step length is longer with X2:	
		X2 vs. MPK **16.9% longer** **++**	X2 vs. MECH 1.6% longer +
		No significant differences were found for stance time.	
	Kinematic	**The initial knee flexion (0% GC) increased with X2 compared to MPK (significantly) and MECH:**	
		X2 vs. MPK **326.7% higher** **++**	X2 vs. MECH 63.3% higher +

Category	Outcomes	Results for Genium X2	
		The max. knee swing flexion (50-100% GC) increased:	
		X2 vs. MPK **21.2% higher** **++**	X2 vs. MECH 8.83% higher +
		No significant differences were found for: • Ankle excursion (0-100% GC) • Hip excursion (0-100% GC)	
	Kinetic	**The max. support moment (0-30% GC) increased with X2 compared to the previous knee:**	
		X2 vs. MPK **26.3% higher** **++**	X2 vs. MECH 240.6% higher +
		The max. support moment (35-75% GC) increased:	
		X2 vs. MPK **21.2% higher** **++**	X2 vs. MECH 147.5% higher +
		Due to more prosthetic limb utilization and normative loading, the first vertical impact maximum (0-30%) increased:	
		X2 vs. MPK **13.2% higher** **++**	X2 vs. MECH 12.3% higher +
		No significant differences were found for: • Max. braking force (0-30%) • Max. propulsive force (35-75%) • Second vertical impact maximum (35-75%)	

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"The aim of the current study was to determine if use of the X2® improves overall slope descent mechanics by assessing self-selected technique of decent, and subsequent changes in temporal-spatial outcomes and joint mechanics. Although this analysis finds normalization of some temporal-spatial outcomes and joint mechanics were likely achieved due to the use of stance flexion resistance with the X2® device allowing for improved control lowering the body when both leading and trailing, some values continued to deviate from those of able-bodied individuals. Nevertheless, decreased reliance on handrail use as MECH users descended in the X2® suggest improved function and perhaps greater confidence in the device possibly reducing the risk of falling. Furthermore, overall reductions in intact limb loading and more symmetric loading at impact could indicate more normative loading patterns and a possible reduction of intact limb overuse during downslope walking. Reducing compensatory gait strategies during slope descent, perhaps through use of the X2®, could thus play a role in mitigating longer-term overuse injuries commonly associated with TFA." (Bell et al., 2016)

↑ Back to overview table

Reference

Schalk SAF, Jonkergouw N, van der Mer F, Swaan WM, Aschoff HH, van der Wurff P.

Military Rehabilitation Centre Aardenburg, Korte Molenweg 3, 3941 PW, Doorn, The Netherlands.

The Evaluation of Daily Life Activities after Application of an Osseointegrated Prosthesis Fixation in a Bilateral Transfemoral Amputee: A Case Study

Medicine (Baltimore) 2015. 94(36): e1416.

Products

Genium with osseointegrated prosthesis fixation (OPF)

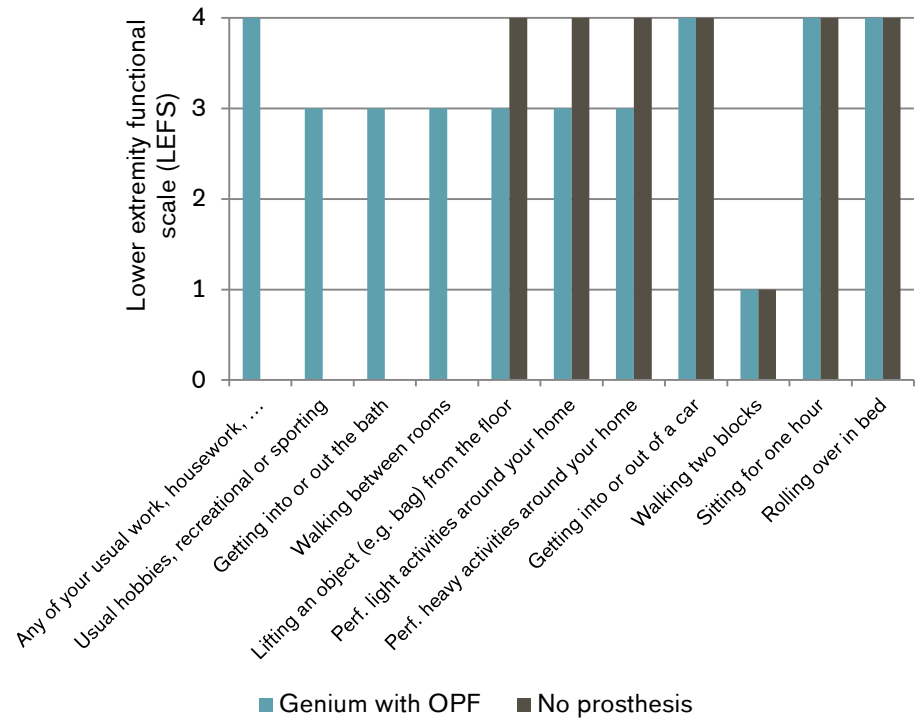
Major Findings

With Genium with OPF compared to previous situation without a prosthesis:

→ **The patient was able to perform four more activities (in total 11 out of 20) of Lower extremity functional scale (LEFS)**

→ **LIFE-H (life habits questionnaire) increased in daily activities and social roles in five and eight respectively out of 12 categories.**

More activities possible with Genium with OPF

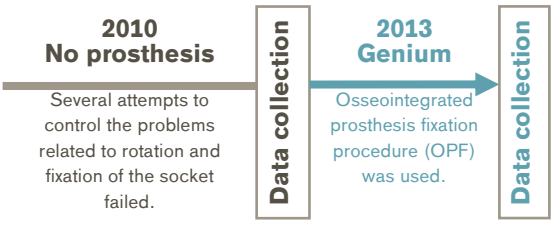


Population

Subjects:	One bilateral, transfemoral amputee (male)
Previous:	No prosthesis, because several attempts to control the problems related to rotation and fixation of the socket failed.
Amputation causes:	Trauma (injured by an improvised explosive device (IED) during a military mission)
Stump length:	13 cm (right), 19 cm (left)
Age:	21 years
Time since amputation:	4 years

Study Design

Case study:



Results

Functions and Activities						Participation			Environment
Level walking	Stairs	Ramps, Hils	Uneven ground, Obstacles	Cognitive demand	Energy	Safety	Activity, Mobility, ADLs	Preference, Satisfac-tion, QoL	Health Economics

Category	Outcomes	Results for Genium with OPF	Sig.*
Activity, Mobility, Activities of Daily Living (ADLs)	Lower extremity functional scale (LEFS)	The LEFS is a questionnaire containing 20 activities which subject ranks according to difficulty (0 - extreme difficulties to 4 - no difficulties).	
		The subject was capable of performing four more activities with Genium with OPF compared to no prosthesis. • Any of your usual work, housework, … • Usual hobbies, recreational or sporting • Getting into or out the bath • Walking between rooms	+
		Three activities were rated to be easier without prosthesis (LEFS-score = 4) than with Genium (LEFS-score = 3) • Lifting an object (e.g. bag) from the floor • Performing light activities around your home • Performing heavy activities around your home As statement about this trend, the patient admitted that he may have overestimated the expected capabilities of OPF.	-
		No differences between Genium with OPF and no prosthesis for four activities that are capable: • Getting into or out of a car • Walking two blocks • Sitting for one hour • Rolling over in bed	0
Preference, Satisfaction, Quality of Life (QoL)	LIFE-H (life habits questionnaire)	This LIFE-H questionnaire is divided in two domains (“daily activities” and “social role”) and 12 categories (whereby education was not applicable for this patient).	
		Daily activities: LIFE-H increased with Genium with OPF in five categories (recreation, community life, mobility, housing and fitness).	+

Category	Outcomes	Results for Genium with OPF	Sig.*
		LIFE-H decreased with Genium with OPF in three categories (work, relationships, personal care). This could be a result of the social change in 2013, when the patient moved from his parent's house to his own place.	-
		Social roles: LIFE-H increased with Genium with OPF in eight categories (recreation, community life, mobility, housing, communication, personal care, fitness and nutrition).	+
		The patient rated the situation without prosthesis as being better than with Genium in two categories (work, relationships). This could again be a result of the social change in 2013, when the patient moved from his parent's house to his own place.	-

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"In conclusion, although several studies clearly demonstrate the benefits of using an OPF, studies describing the long-term effects are lacking. In this specific case we conclude that the quality of life improved through the use of an OPF. However, OPF might not be the appropriate device for every individual with TFA, due to varying bone compositions and co-morbidities." (Schalk, 2015)

↑ Back to overview table

Reference

Lura DJ, Wernke MM, Carey SL, Kahle JT, Miro RM, Highsmith MJ.

School of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, FL, USA.

Differences in knee flexion between the Genium and C-Leg microprocessor knees while walking on level ground and ramps

Clinical Biomechanics 2015; 30(2): 175-181.

Products

Genium vs C-Leg

Major Findings

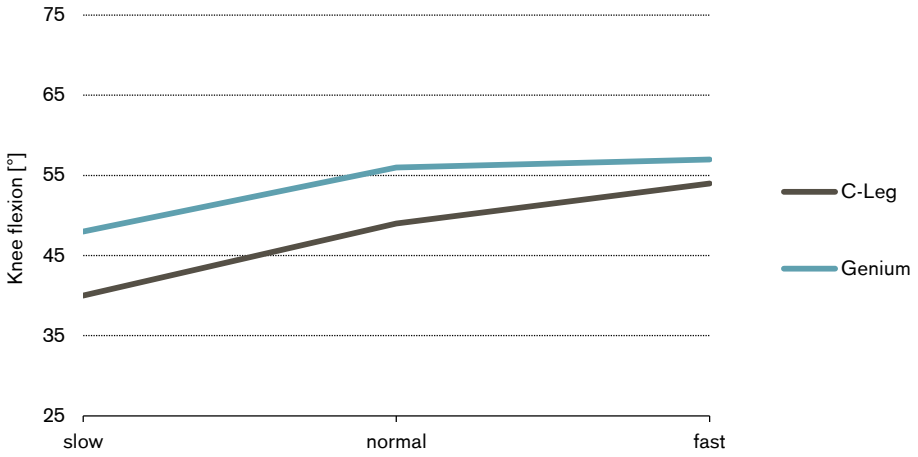
With Genium compared to C-Leg:

→ **More physiological movement pattern**

→ **Increased knee flexion angle in both stance and swing phase due to accommodation, training and use of Genium during level walking and walking on ramps**

by up to 7° during swing phase when level walking
by up to 2° during stance phase when level walking
by up to 8° during swing phase when descending a ramp
by up to 4° during stance phase when descending a ramp
by up to 9° during swing phase when ascending a ramp

Increased swing phase knee flexion angle during 5° ramp ascent



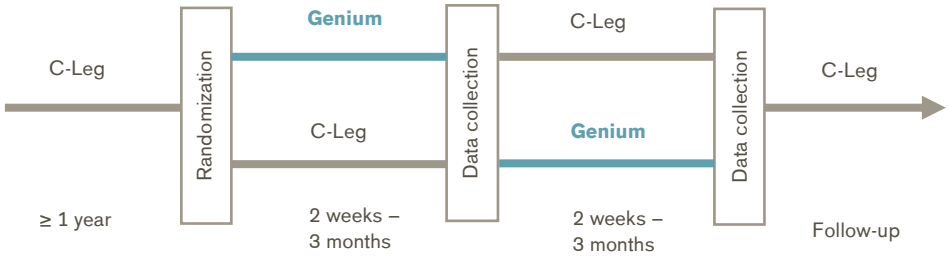
Peak knee flexion angle was measured at slow, normal and fast walking speed.

Population

Subjects:	20 unilateral, transfemoral amputees
Previous prosthesis:	C-Leg
Amputation causes:	70% trauma, 20% malignancy, 10% vascular disease
Mean age:	46.5 yrs (±14.2 yrs)
Mean time since amputation:	17.7 yrs (±15.6 yrs)
MFCL:	K3

Study Design

Interventional, randomized crossover design:



Results

Activities								Participation	Environment
Level walking	**Stairs**	**Ramps, Hills**	**Uneven ground, Obstacles**	**Cognitive demand**	**Metabolic energy consumption**	**Safety**	**Activity, Mobility, ADLs**	**Preference, Satisfaction, QoL**	**Health economics**

Category	**Outcomes**	**Results for Genium compared to C-Leg**			
		Very slow	**Slow**	**Normal**	**Fast**
Level Walking	Peak knee flexion angle in swing phase	**++ 7°**	**++ 6°**	**++ 6°**	+
	Peak knee flexion angle in stance phase	+	**++ 2°**	**++ 2°**	+
	0.5 kg ankle weight attached to each leg Peak knee flexion angle in swing phase	**++ 6°**	**++ 5°**	**++ 4°**	**++ 3°**
	0.5 kg ankle weight attached to each leg Peak knee flexion angle in stance phase	**++ 1°**	+	+	**++ 2°**
Ramps, Hills	5° slope Descent Peak knee flexion angle in swing phase		**++ 8°**	**++ 7°**	**++ 3°**
	5° slope Ascent Peak knee flexion angle in swing phase		+	**++ 9°**	–
	5° slope Descent Peak knee flexion angle in stance phase		**++ 3°**	+	**++ 4°**
	5° slope Ascent Peak knee flexion angle in stance phase		+	+	+

Category	Outcomes	Results for Genium compared to C-Leg			
		Very slow	**Slow**	**Normal**	**Fast**
	10° slope Descent Peak knee flexion angle in swing phase		+	+	+
	10° slope Ascent Peak knee flexion angle in swing phase		+	**++ 8°**	0
	10° slope Descent Peak knee flexion angle in stance phase		+	+	+
	10° slope Ascent Peak knee flexion angle in stance phase		+	+	+

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"Accommodation, training and use of the Genium were found to produce increased knee flexion compared with the C-Leg in both the stance and swing phases of gait. This increased knee flexion is clinically significant as it better recreates a normalized, anatomic movement pattern. The knee flexion angle of the non-amputated leg was not significantly affected by use of the Genium relative to the C-leg. Control subjects typically had the greatest knee flexion, followed by the amputees' sound side, and then prosthetic side of the subjects with the Genium and C-Leg respectively. This shows that Genium use increases stance and swing knee flexion angles compared with the C-Leg, but improvements are still possible, especially in certain walking conditions such as when walking uphill." (Lura et al., 2014)

↑ Back to overview table

Reference

Aldridge Whitehead JM, Wolf EJ, Scoville CR, Wilken JM.

Extremity Trauma and Amputation Center of Excellence, Department of Orthopaedics and Rehabilitation, Brooke Army Medical Center, Ft Sam Houston, TX, USA.

Does a Microprocessor-controlled Prosthetic Knee Affect Stair Ascent Strategies in Persons with Transfemoral Amputation?

Clinical Orthopaedics and Related Research 2014; 472(10):3093-3101

Products

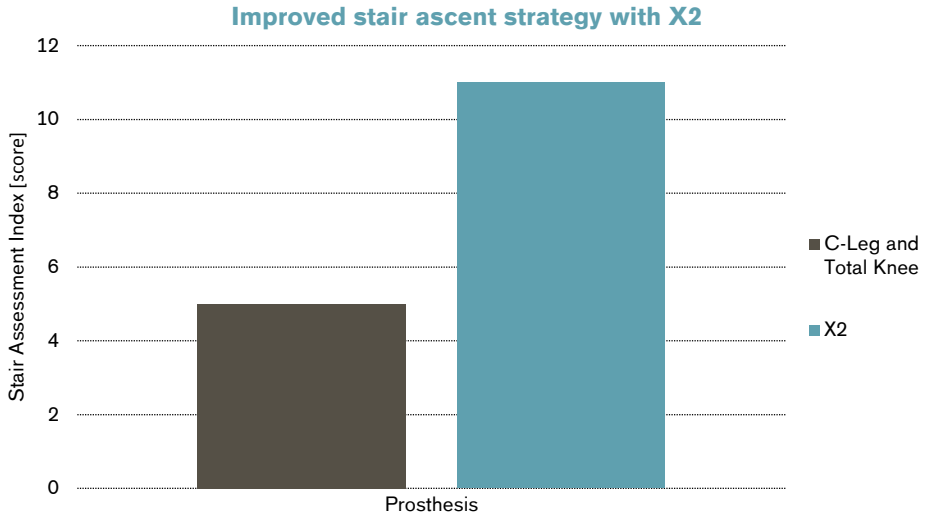
X2 vs C-Leg and Total Knee

Major Findings

With X2 compared to C-Leg:

→ Stair ascent strategy improved significantly
→ 10 times more subjects were able to ascent stair using step-over-step strategy
→ Greater range of motion (ROM) on prosthetic side throughout gait cycle of stair ascent:

62° more knee flexion during swing phase
30° more knee flexion at initial contact
22° more hip flexion during swing phase

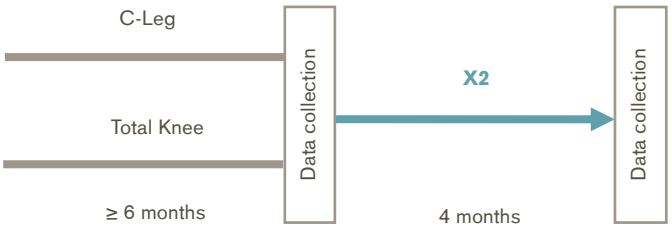


Population

Subjects:	14 transfemoral amputees
Previous prosthesis:	12 C-Leg (MPCK), 2 Total Knee (NMPCK)
Amputation causes:	not reported
Mean age:	31.1 yrs
Mean time since amputation:	≥ 6 months
MFCL:	K3 – K4 (independent ambulators)

Study Design

Interventional, pre- to post-test design:



Results

Activities								Participation	Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Metabolic energy consumption	Safety	Activity, Mobility, ADLs	Preference, Satisfaction, QoL	Health economics

Category	Outcomes	Results				Sig.*
		for X2 compared to C-Leg and Total Knee				
Stairs	Self-selected stair ascent strategy		Step-to	Skip-step	Step-over	
		X2	14.25%	14.25%	71.5%	n.a.
		C-Leg and Total Knee	71.5%	21.5%	7%	n.a.
	Stair Assessment Index (SAI)	SAI score improved from 5 to 11 points (median). While using X2 during step-over-step stairs ascent 60% of subjects used two handrails, 30% used one handrail and 10% did not use the handrails.				n.a. n.a.
		for X2 (stair function) compared to C-Leg (no stair function)				**Sig.***
	Motion Analysis	**62° more prosthetic knee flexion during swing phase.**				**++**
		22° more prosthetic limb hip flexion during swing phase.				**++**
		30° more prosthetic knee flexion at initial ground contact.				**++**
		Prosthetic limb peak hip power generated during push-up was increased by 143%.				**– –**

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"Stair ascent can be difficult for individuals with transfemoral amputation because of the loss of knee function. Most individuals with transfemoral amputation use either a step-to- step or skip-step strategy because it allows the leading intact limb to do the majority of work. A new microprocessor-controlled knee (X2®) uses flexion/extension resistance to allow step-over-step stair ascent. We compared stair ascent strategies and joint mechanics as individuals with transfemoral amputation ascended stairs using their conventional prosthetic knee and the novel X2® device. Most participants self-selected a step-to-step stair ascent strategy while using their conventional device and a step-over-step strategy while using the X2® device. Participants were

more symmetrical while using the X2® than the conventional device to include more similar peak knee and hip flexion during swing and peak hip power generation during push-up when comparing between limbs. Although the X2® resulted in greater prosthetic knee ROM and fewer between-limb differences than the conventional knee, stair ascent gait deviations still persisted compared to individuals without amputation. Peak knee flexion during swing while using the X2® device was the only prosthetic limb measure that was not different from individuals without amputation. Correlational analysis revealed that greater X2® knee flexion during initial contact and swing was associated with greater prosthetic limb hip power during pull-up and push-up/early swing, respectfully [sic]." (Aldridge Whitehead et al., 2014)

↑ Back to overview table

Reference

Highsmith MJ, Kahle JT, Miro RM, Lura DJ, Dubey RV, Carey SL, Quillen WS, Mengelkoch LJ.

School of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, FL, USA.

Perceived differences between the Genium und the C-Leg microprocessor prosthetic knees in prosthetic-related function and quality of life

Technology and Innovation 2014; 15(4):269-375.

Products

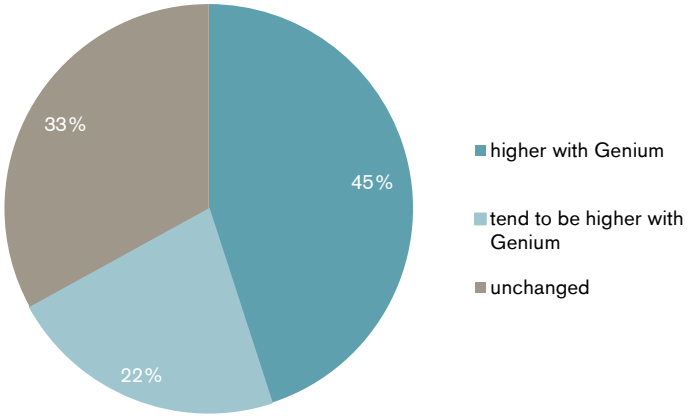
Genium vs C-Leg

Major Findings

Genium compared to C-Leg:

→ Prosthesis-related quality of life is improved
→ 45% of prosthetic-related scales are improved
→ 70% of activities, relevant to the physical performance aspects of Genium, are improved

Percent of scales showing improvement in prosthetic function and quality of life with Genium

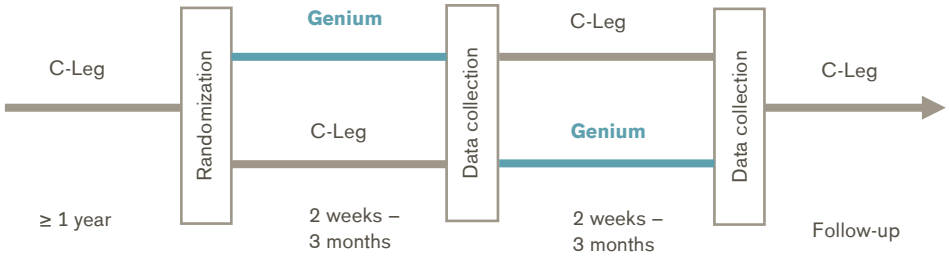


Population

Subjects:	20 unilateral, transfemoral amputees
Previous prosthesis:	C-Leg
Amputation causes:	70% trauma, 20% malignancy, 10% vascular disease
Mean age:	46.5 yrs (±14.2 yrs)
Mean time since amputation:	17.7 yrs (±15.6 yrs)
MFCL:	K3 - K4 (ambulate without assistive device within community)

Study Design

Interventional, randomized crossover design:



Results

Activities								Participation	Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Metabolic energy consumption	Safety	Activity, Mobility, ADLs	Preference, Satisfaction, QoL	Health economics

Category	Outcomes	Results for Genium compared to C-Leg	Sig.*
Preference, Satisfaction, Quality of Life (QoL)	Prosthesis Evaluation Questionnaire (PEQ)	Comparing all 41 items:	
		Genium was rated to be improved	**++**
		4 out of 9 scales were rated higher:	
		Perceived Response	**++**
		Social Burden	**++**
		Utility	**++**
		Well-Being	**++**
		2 out of 9 scales had the tendency to be rated higher:	
		Appearance	+
		Sounds	+
		3 out of 9 scales were unchanged:	
		Ambulation	0
		Frustration	0
		Residual Limb Health	0
		7 out of 10 chosen items, relevant to the physical performance aspects of Genium, were improved:	
		Comfort standing	**++**
		Ability to walk in close spaces	**++**
		Go down stairs	**++**
		Walk up steep hill	**++**
		Walk down steep hill	**++**
		Walk on slippery surfaces	**++**
		Satisfaction with walking	**++**

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"In this sample, several PEQ scales were rated as being significantly improved following Genium use. These included Perceived Response, Social Burden, Utility, and Well-Being. Movement analysis data from other studies may explain improvements in the Perceived Response scale. Further, the Genium was rated as improving specific mobility activities including walking on stairs, slopes, and slippery surfaces as well as increasing comfort during standing. The entire PEQ, which represents patient-perceived prosthetic-related function and quality of life, was rated

as a significant improvement when participants utilized the Genium MPK. This study presents additional data to make future comparisons in persons with lower limb amputation who are assessed utilizing the PEQ in its ordinally scaled format. Further research is needed to more emphatically confirm the perceived improvements with objective functional and movement analyses. Finally, the PEQ does not assess perceived differences in nonambulatory functional tasks, preference, or safety." (Highsmith et al., 2014)

↑ Back to overview table

Reference

Highsmith MJ, Kahle JT, Lura DJ, Dubey RV, Carey SL, Quillen WS, Mengelkoch LJ.

School of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, FL, USA.

Short and mid-distance walking and posturography with a novel microprocessor knee

Technology and Innovation 2014; 15(4):259-368.

Products

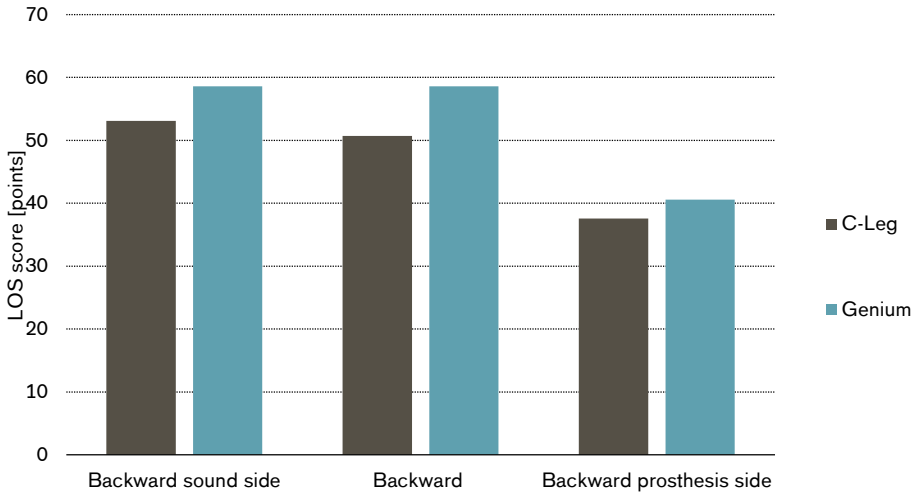
Genium vs C-Leg

Major Findings

With Genium compared to C-Leg:

→ Movement control in all three backward directions improved by up to 10%
→ Walking velocities during short- and mid-distance are maintained whereas levels of perceived exertion tend to decrease

Improved limits of stability with Genium



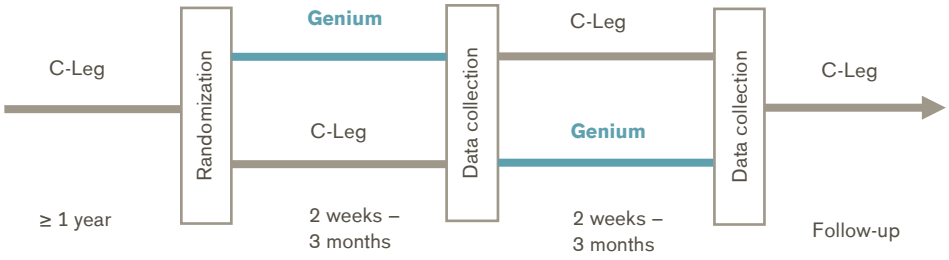
Limits of stability (LOS) was measured by Biodex Balance SD system.

Population

Subjects:	20 unilateral, transfemoral amputees
Previous prosthesis:	C-Leg
Amputation causes:	70% trauma, 20% malignancy, 10% vascular disease
Mean age:	46.5 yrs (± 14.2 yrs)
Mean time since amputation:	17.7 yrs (± 15.6 yrs)
MFCL:	K3 - K4 (ambulate without assistive device within community)

Study Design

Interventional, randomized crossover design:



Results

Activities								Participation	Environment
Level walking	**Stairs**	**Ramps, Hills**	**Uneven ground, Obstacles**	**Cognitive demand**	**Metabolic energy consumption**	**Safety**	**Activity, Mobility, ADLs**	**Preference, Satisfaction, QoL**	**Health economics**

Category	Outcomes	Results for Genium compared to C-Leg	Sig.*
Level Walking	75 m self-selected walking speed (SSWS)	Walking velocity increased by 2% (1.17 m/s vs 1.15 m/s).	+
		Perceived exertion was rated lower.	+
	75 m fastest possible walking speed (FPWS)	No difference in walking velocity.	0
		Perceived exertion was rated lower.	+
	6 m fastest possible walking speed (FPWS)	No difference in walking velocity.	0
		Perceived exertion was rated lower.	+
Uneven Ground, Obstacle Course	38 m fastest possible walking speed (FPWS), sloping terrain over trimmed grass, sand, rocks, and small roots	No difference in walking velocity.	0
		Perceived exertion was rated lower.	+
Safety	Postural stability and limits of stability (LOS) both measured by Biodex Balance SD system	No differences in postural stability.	0
		Movement control:	
		Improved by 10% in backward sound side direction	**++**
		Improved by 10% in backward direction	+
		Improved by 9% in backward amputated side direction	+
		Decreased by 6% in forward sound side direction	–
		Improved by 8% in forward direction	+
		Decreased by 12% in forward amputated side direction	**– –**
		Time to complete LOS test tended to be decreased by 2%.	**+**

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

'During short to mid-distances, the Genium knee sustains the walking speed improvements realized by the C-Leg with a trend toward decreased levels of perceived exertion. In terms of directional control, TFAs demonstrate multidirectional impairment compared with nonamputees. However, C-Leg use results in improved antero-

lateral directional control compared with Genium, possibly due to the toe load requirement needed to initiate swing phase knee flexion. Conversely, Genium use results in a trend of movement control improvements in all three rearward directions compared with the C-Leg., (Highsmith et al. 2014)

↑ Back to overview table

Reference

Highsmith MJ, Kahle JT, Lura DJ, Lewandowski AJ, Quillen WS, Kim HS.

School of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, FL, USA.

Stair ascent and ramp gait training with the Genium knee

Technology and Innovation 2014; 15(4):349-258.

Products

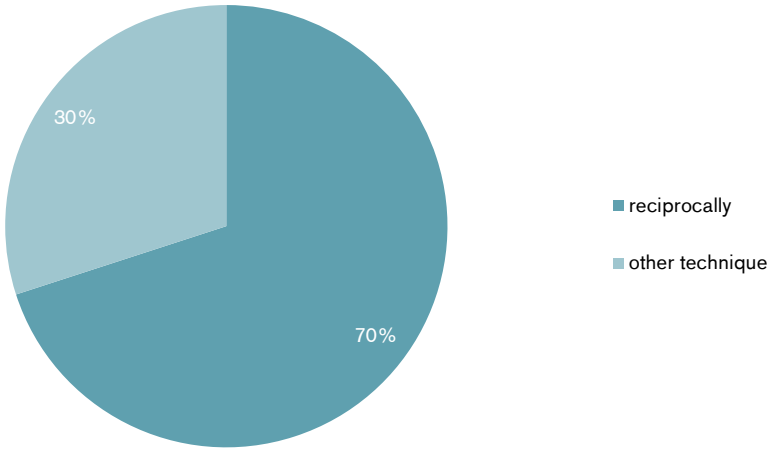
Genium

Major Findings

With Genium:

→ 70% of subjects are able to climb stairs reciprocally
→ Ability to cross obstacles improves when subject are able to climb stairs reciprocally
→ Focal pressure near the anterior aspect of the hip during ramp ascent is experienced as decreased compared to other prosthesis

Stair climbing technique with Genium



Population

Subjects:	20 transfemoral amputees
Previous prosthesis:	not reported
Amputation causes:	trauma
Mean age:	not reported
Mean time since amputation:	not reported
MFCL:	K3 – K4 (unlimited community ambulators)

Study Design

Technical report about stair ascent and ramp gait training with Genium

Results

Activities								Participation	Environment
Level walking	Stairs	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Metabolic energy consump-tion	Safety	Activity, Mobility, ADLs	Preference, Satisfac-tion, QoL	Health economics

Category	Outcomes	Results for Genium	Sig.*
Stairs	Observations	70% of subjects demonstrated ability to climb stairs reciprocally.	n.a.
Ramps, Hills	Observations	Ascent: less focal pressure was experienced by subjects near the anterior aspect of the hip.	n.a.
		Descent: On 5° declines, more active walkers utilized a stepping strategy similar to level walk-ing with two sagittal knee flexion peaks.	n.a.
Uneven Ground, Obstacle Course	Subject´s report	Subjects believe that stair climbing practice improved the ability to cross obstacles	n.a.

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"Technological developments in assistive devices continue to outpace rehabilitation strategies to maximize their utilization and implementation. Clinical rehabilitation techniques remain limited. This technical note presents strategies for training the patient with transfemoral amputation in how to utilize the reciprocal stair ascent and ramp gait functions of the Genium knee. Additional training suggestions for further advanced training with these skills are also discussed. Functional training strategies introduced here were specifically used with the Genium knee in high-functioning patients. Therefore, they may not be appropriate for all patients with transfemoral amputation based on component or functional level. Thus, clinical judgment and patient goals are vital in the decision of whether or not to include such training in the course of an amputee's therapy. We maintain that ramp and stair training in a broader context may be functionally important even if a patient indicates these obstacles are not often encountered in their usual routines. This training is important because it is difficult to determine when daily activities require out-of-the-ordinary settings or present unanticipated challenges. Supervised practice and familiarity may improve safety by decreasing fall risk, should the situation arise." (Highsmith et al., 2014)

↑ Back to overview table

Reference

Kannenberg A, Zacharias B, Mileusnic M, Seyr M.

Otto Bock HealthCare GmbH, Duderstadt, Germany.

Activities of Daily Living: Genium Bionic Prosthetic Knee Compared with C-Leg

Journal of Prosthetics & Orthotics 2013; 25(3):110–117.

Products

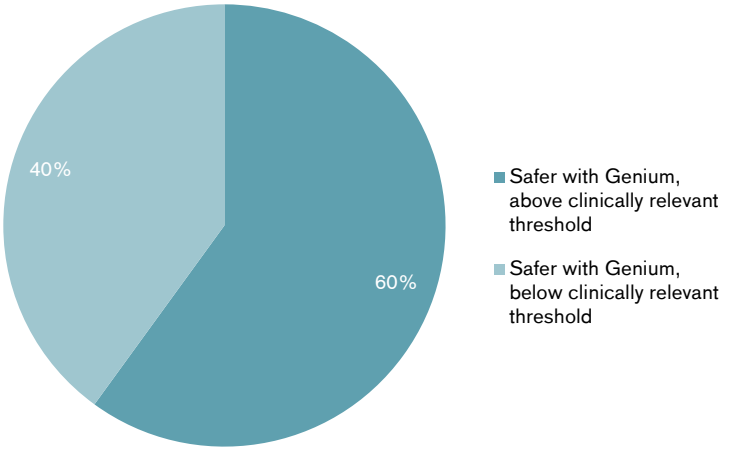
Genium vs C-Leg

Major Findings

With Genium compared to C-Leg:

→ 60% of Activities of Daily Living (ADLs) show a clinically relevant gain in safety
→ 53% of ADLs show a clinically relevant decrease in difficulty.
→ Ease of ascending and descending stairs is improved by 34% and 10%
→ Ease of ascending and descending ramps is improved by 24% and 17%
→ Ease of walking backwards is improved by 26%

Clinically relevant improvement in safety of activities of daily living with Genium



Safety was assessed for 45 activities.

Population

Subjects:	10 unilateral, transfemoral amputees
Previous prosthesis:	C-Leg
Amputation causes:	trauma
Mean age:	36.7 yrs (±10.2 yrs)
Mean time since amputation:	12.5 yrs (±9.6 yrs)
MFCL:	40% K3, 60% K4

Study Design

Interventional, pre- to post-test design:

Results

Activities								Participation	Environment
Level walking	**Stairs**	**Ramps, Hills**	**Uneven ground, Obstacles**	**Cognitive demand**	**Metabolic energy consumption**	**Safety**	**Activity, Mobility, ADLs**	**Preference, Satisfaction, QoL**	**Health economics**

Category	Outcomes	Results for Genium compared to C-Leg	Sig.*
Level Walking	ADL Questionnaire, separate for each MPCK	**Difficulty of walking backwards was decreased by 26%.** Walking at varying speeds tends to be rated as less difficult.	**++** +
Stairs	ADL Questionnaire, separate for each MPCK	**Difficulty of ascending and descending stairs was decreased by 34% and 10%.**	**++**
Ramps, Hills	ADL Questionnaire, separate for each MPCK	**Difficulty of ascending and descending slopes was decreased by 24% and 17%.**	**++**
Uneven Ground, Obstacle Course	ADL Questionnaire, separate for each MPCK	Walking on uneven and unfamiliar ground tends to be rated as less difficult.	+
Safety	ADL Questionnaire, comparative	**60% of ADLs showed a clinically relevant gain in safety.** 40% of ADLs showed a trend toward a clinically relevant gain in safety. **In the category 'Family and Social Life' 83% of ADLs showed a clinically relevant gain in safety.** **In the category 'Mobility and Transportation' 63% of ADLs showed a clinically relevant gain in safety.**	**n.a.**
Activity Mobility, Activities of daily living (ADLs)	ADL Questionnaire, comparative	**53% of ADLs showed a clinically relevant decrease in perceived difficulty.** 47% of ADLs showed a trend towards a clinically relevant decrease in perceived difficulty. **In the category 'Family and Social Life' 75% of ADLs showed a clinically relevant decrease in perceived difficulty.** **In the category 'Mobility and Transportation' 58% of ADLs showed a clinically relevant decrease in perceived difficulty.**	n.a.

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"This study showed that the new technological functions of the Genium Bionic Prosthetic Knee for transfemoral amputees of MFCL 3 and 4 lead not only to clear biomechanical benefits compared with the C-Leg but also to a further improvement in the subjective perception of safety and perceived difficulty of many ADLs." (Kannenberg et al., 2013)

↑ Back to overview table

Reference

Bellmann M, Schmalz T, Ludwigs E, Blumentritt S.

Department of Research, Otto Bock HealthCare, Duderstadt, Germany

Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation

Archives of physical medicine and rehabilitation 2012; 93(3):541–549.

Products

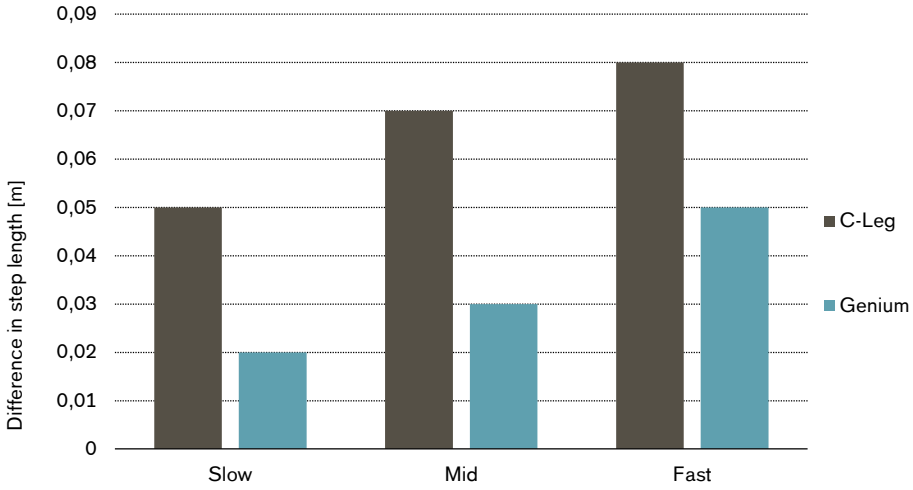
Genium vs C-Leg

Major Findings

With Genium compared to C-Leg:

- → **Step length symmetry is improved by up to 60%**
- → **Knee flexion angle in swing phase is nearly constant at 63.8° across walking velocities**
- → **Loading of sound side is reduced by 10% when climbing stairs**
- → **Knee flexion is increased by 14% during ramp ascent and descent, leading to an increased toe clearance**

More symmetrical step length with Genium



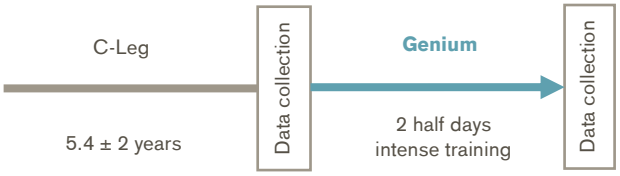
Asymmetry of step length was determined by measuring difference in step length between prosthetic limb and sound limb when subjects walked at slow, medium and fast velocities.

Population

Subjects:	11 unilateral, transfemoral amputees
Previous prosthesis:	C-Leg
Amputation causes:	91% trauma, 9% tumour
Mean age:	37 yrs (± 10.2 yrs)
Mean time since amputation:	12.5 yrs (range from 3 – 34 yrs)
MFCL:	45% K3, 55% K4

Study Design

Interventional, pre- to post-test design:



Results

Activities								Participation	Environment
Level walking	**Stairs**	**Ramps, Hills**	**Uneven ground, Obstacles**	**Cognitive demand**	**Metabolic energy consumption**	**Safety**	**Activity, Mobility, ADLs**	**Preference, Satisfaction, QoL**	**Health economics**

Category	Outcomes	Results for Genium	Slow v	Mid v	Fast v
Level Walking	Motion analysis	Mean walking velocity	0	0	0
		Asymmetry of step length	**decr ++**	**decr ++**	**decr +**
		External knee flexion moment at weight acceptance	incr +	incr +	**incr ++**
		External hip flexion moment at weight acceptance	incr –	0	decr +
		Vertical ground reaction forces on prosthetic side at weight acceptance			
		• With stance flexion movement	**incr – –**	decr +	decr +
		• Without stance flexion movement	0	decr +	**decr ++**
		Horizontal ground reaction forces on prosthetic side at weight acceptance			
		• With stance flexion movement	decr +	**decr ++**	**decr ++**
		• Without stance flexion movement	**decr ++**	decr +	**decr ++**

		Results for Genium	Sig*
		Maximum knee flexion angle in swing phase nearly constant at 63.8° with Genium at all walking velocities. With C-Leg the mean maximum knee flexion angle increased by 14.6° when the walking velocity increased by 1 m/s.	n.a.
	Motion analysis when walking with small steps	**Mean maximum knee flexion angle in swing phase increased by 11%.**	**++**
		Genium failed to switch into swing phase mode in 4.9% of steps, whereas C-Leg failed to switch into swing phase mode in 24.7% of steps.	n.a.

Category	Outcomes	Results for Genium	Slow v	Mid v	Fast v
Stairs	Motion analysis descending	**Mean sagittal external knee flexion moment on the prosthetic side at mid stance increased by 15°.**			**+ +**
	Motion analysis ascending	**The mean duration of a stride takes 31% longer with the Genium (using step-over-step method) than with C-Leg (using conventional method).**			**– –**
		A clear approximation to the movement pattern of healthy subjects was observed.			n.a.
		Range of motion (ROM) of the contralateral and prosthetic knee and hip joints was lower with Genium (step-over-step method) than ROM of the contralateral side with C-Leg (conventional method).			**++**
		Loading of the contralateral knee joint was reduced by 10%.			**++**
		Mean loading of the contralateral hip joint was slightly increased.			–
Ramps, Hills	Motion analysis descending and ascending a ramp (10° decline)	**Increased mean knee flexion angles when ascending (14% higher) and descending (14% higher) a ramp.**			**++**
		Sagittal external knee flexion moments on the effected side increased by 11% when descending.			**+ +**
		Decreased contralateral vertical ground reaction forces at weight acceptance when descending.			+
Safety	Motion analysis and sway measurements when standing on a ramp (10° decline)	**The affected side was able to bear 86% higher loads.**			**++**
		Sagittal external knee flexion moment on the prosthetic side increased by 92%.			**– –**
		Reduced moments of the hip centre of rotation by 69%.			+
		Reduced postural sway of the prosthetic side.			**++**

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"For the rehabilitation of lost lower limbs and the simulation of natural gait, increasingly complex technologies are required. The functions of the Genium knee, such as stance function, stairs function, and improved functionality for walking on level ground and ramps, provide further approximation to a more natural gait and physiologic loading pattern immediately after transition to this knee joint. This offers the user increased functionality and clinically relevant advantages in everyday situations like standing with an automatically lockable knee joint, walking on level ground at different velocities and step lengths, and walking up and down ramps and stairs. This increased functionality is represented in this study by direct comparison with the C-Leg, whose benefit has been demonstrated in numerous scientific studies. Additional investigations are indicated to evaluate if improvements in biomechanical parameters identified by this study can be confirmed after a longer period of adaptation to the Genium or if further advancements can be detected. It would also be of interest to evaluate if above-knee amputees with a lower activity level would benefit from the Genium functions." (Bellmann et al., 2012) ↑ Back to overview table

Reference

Bellmann M, Schmalz T, Ludwigs E, Blumentritt S.

Research Biomechanics, Otto Bock HealthCare GmbH, Göttingen, Germany.

Stair ascent with an innovative microprocessor-controlled exoprosthetic knee joint

Biomedizinische Technik 2012; 57(6):435–444.

Products

Genium vs C-Leg

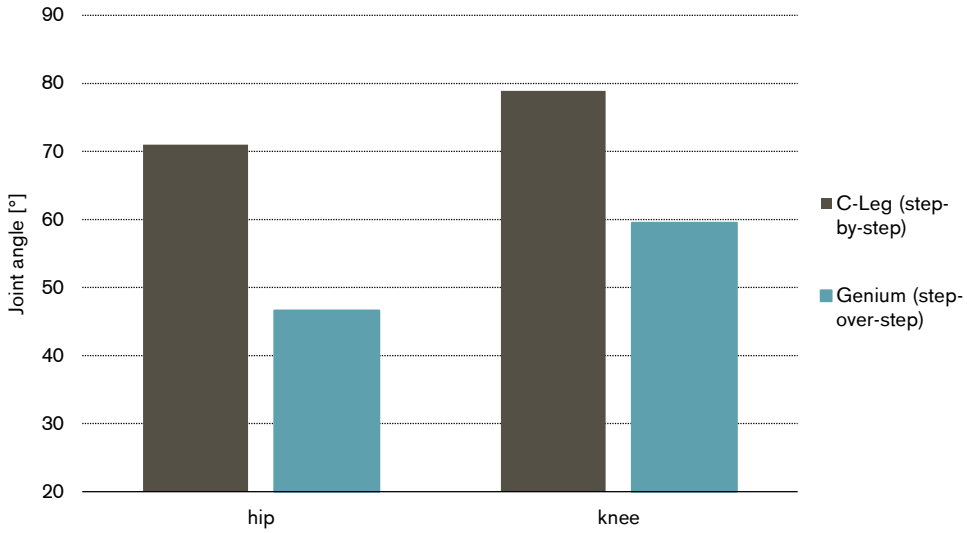
Major Findings

With Genium compared to C-Leg:

→ **80% of subjects were able to climb stairs with step-over-step pattern after using Genium for one day**

→ **Movements of hip and knee on the sound side are reduced by 34 and 33% and are within a normal range**

Decreased movement on sound side with Genium during stair ascent

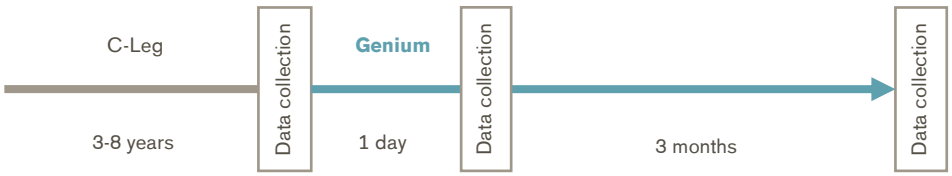


Population

Subjects:	10 unilateral, transfemoral amputees
Previous prosthesis:	C-Leg
Amputation causes:	90% trauma, 10% tumour
Mean age:	36 yrs (range from 22 – 54 yrs)
Mean time since amputation:	10.4 yrs (range from 3 – 24 yrs)
MFCL:	40% K3, 60% K4

Study Design

Interventional, pre-to post-test design:



Results

Activities								Participation	Environment
Level walking	**Stairs**	Ramps, Hills	Uneven ground, Obstacles	Cognitive demand	Metabolic energy consumption	Safety	Activity, Mobility, ADLs	Preference, Satisfaction, QoL	Health economics

Category	Outcomes	Results for Genium (step-over-step) compared to C-Leg (step-by-step)	Sig.*
Stairs	Motion analysis	80% of subjects were able to climb stairs with step-over-step pattern after one day using Genium. With C-Leg subjects ascended stairs using the step-by-step strategy.	n.a.
		Duration of step cycle was increased by 31%.	**– –**
		On the sound side, movement of the hip was decreased by 34% and movement of the knee was decreased by 33%.	**++**
		Decreased flexion angles of hip and knee on the prosthetic side when contact is made with the step.	**++**
		Increased extension in hip on the prosthetic side at the end of the extension phase.	**++**
		Joint power of the contralateral knee decreased by 14%.	+

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"The study shows that a definite approximation of a natural gait and reduction of stress to the residual musculoskeletal system is achieved with the Genium prosthetic knee joint. Movements and motion sequences are nearly normal on the prosthetic side as well as the contralateral side, and the stress acting on the contralateral knee joint also tends to be reduced. The stump can help support the motion sequence and can operate in its original function as hip joint extensor in this gait situation. These improvements are apparent after just a short adaptation phase to this function." (Bellmann et al., 2012)

↑ Back to overview table

Reference

Blumentritt S, Bellmann M, Ludwigs E, Schmalz T.

Otto Bock HealthCare, Research Department, Duderstadt, Germany.

Zur Biomechanik des mikroprozessorgesteuerten Prothesenkniegelenks Genium

(Biomechanics of the microprocessor controlled knee prosthesis Genium)

Orthopädie-Technik 2012; 01:24-35.

Products

Genium vs C-Leg

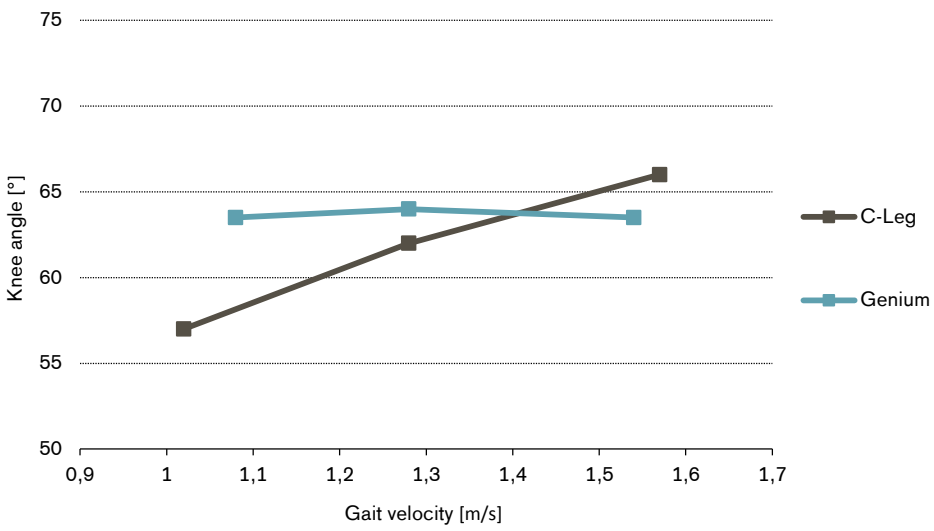
Major Findings

With Genium compared to C-Leg:

- → **Improved toe clearance based on a constant knee angle of 64° prevents stumbling and therefore the risk of falling is reduced**
- → **The safety potential when walking backwards as well as when walking with small steps is improved**
- → **Improved toe clearance during ramp ascent and descent**

  Knee angle in swing phase increased by 14% during ramp ascent
  Knee angle in swing phase increased by 13% during ramp descent

Knee flexion with Genium even more consistent

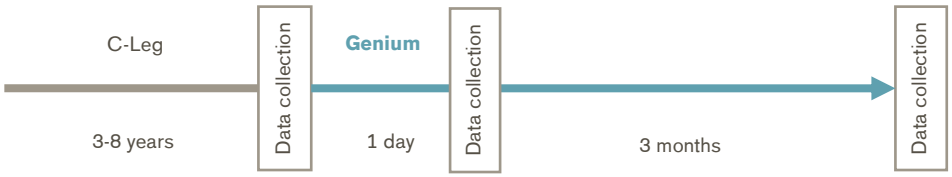


Population

Subjects:	11 unilateral, transfemoral amputees
Previous prosthesis:	C-Leg
Amputation causes:	not reported
Mean age:	36.7 yrs (± 10.2 yrs)
Mean time since amputation:	3 – 34 yrs
MFCL:	K3 – K4

Study Design

Interventional, pre- to post-test design:



Results

Activities								Participation	Environment
Level walking	**Stairs**	**Ramps, Hills**	**Uneven ground, Obstacles**	**Cognitive demand**	**Metabolic energy consumption**	**Safety**	**Activity, Mobility, ADLs**	**Preference, Satisfaction, QoL**	**Health economics**

Category	Outcomes	Results for Genium compared to C-Leg	Sig.*
Level Walking	Motion analysis when walking at slow, normal, and fast self-selected walking velocity	Maximum knee angle in swing phase is not influenced by walking velocity and stays constant at 64°, as physiological. Knee flexion at heel strike is constantly at 4°. More symmetrical step length. Decreased ground reaction force at the beginning of stance phase.	n.a.
	Motion analysis when walking with small steps	When walking with small steps, in 95% of all steps swing phase was released. With C-Leg swing phase was released in 75% of steps.	n.a.
	Walking backwards	Prosthesis never switched to swing phase resistance and therefore safe loading was always possible.	n.a.
Stairs	Motion analysis ascending	73% of subjects were able to ascend stairs reciprocally. With C-Leg subjects ascended stairs using the step-by-step strategy.	n.a.
	Motion analysis descending	All subjects descended stairs reciprocally with Genium and C-Leg. The motion cycle is similar.	n.a.
Ramps, Hills	Motion analysis ascending (10° decline)	Knee angle was increased by 14%.	n.a.
	Motion analysis descending (10° decline)	Knee angle was increased by 13%.	n.a.
Safety	Motion analysis and sway measurements when standing on a horizontal ground or ramp (10° decline)	Standing on horizontal ground: No difference. Standing on decline: Body weight was distributed evenly on both legs. Body posture was more relaxed. Reduced activity to keep up posture. Decreased hip moments by 76%.	n.a.

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"With the Genium knee prosthesis a new generation of microprocessor controlled knees is available to the supply team. This joint offers the technical requirements for the expansion of mobility for amputees in daily life and this is exceeding the dimensions known until now. Affected aspects are function as well as safety. The designed advantages of the specific functions – sitting, standing, walking – and the intuitive switch between these function states could be proved with measured data and were confirmed by patient reports. A reliable and precise switch between stance phase resistance and swing phase resistance plays the key role in safe functioning of the prosthesis. This switch in functionally is necessary and at the same time safety-critical. The high reliability of C-Leg could be proved for Genium too. The safety potential of Genium is even improved when amputees walk backwards or when they walk with small steps." (Blumentritt et al.. 2012)

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Reference

Kampas P, Seyr M.

Otto Bock Healthcare Products, Vienna, Austria.

Technologie und Funktionsweise des Genium-Prothesenkniegelenks

(Technology and functionality of the Genium knee prosthesis)

Orthopädie-Technik 2011; 12:898-903.

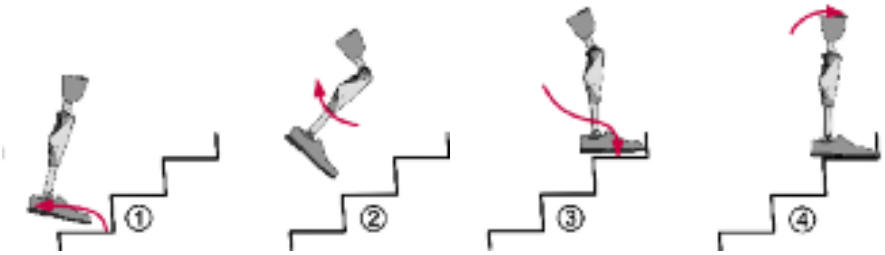
Products

Genium

Major Findings

With Genium:

→ Allows for a symmetrical and physiological gait pattern
→ Increased safety results from assured toe clearing at any walking velocity
→ Stair function enables reciprocally stair climbing strategy



Stair and Obstacle Function: (1) Release, (2) Knee flexion, (3) Unloaded extension movement, (4) Loaded extension movement. (Kampas *et al* 2011)

Population

Not applicable

Study Design

Technical Report

Results

Activities								Participation	Environment
Level walking	**Stairs**	**Ramps, Hills**	**Uneven ground, Obstacles**	**Cognitive demand**	**Metabolic energy consumption**	**Safety**	**Activity, Mobility, ADLs**	**Preference, Satisfaction, QoL**	**Health economics**

Category		
Level Walking	Pre-Flex	• Knee angle at heel strike in a 4° flexion position. • Facilitated yielding. • Full ground contact of the foot is reached in an earlier stage. • Peak force of heel-strike is converted into a forward movement which results in a shock absorption effect.
	Adaptive Yielding-Control	• Maximum knee flexion angle in stance phase is 17°. • When walking on a decline, maximum knee flexion angle higher than 17° possible.

Category		
	Swing phase release by dynamic stability control (DSC)	• Swing phase is released depending on the position of the point of applied force on the foot and not on the amount of load. → Swing phase is released even when the subject is carrying additional load or if he supports himself on a shopping cart. • Forward rotation of the prosthesis. → Release of swing phase when stepping backwards is avoided. • Straight knee joint. • Lower leg is in a forward tilted position. • Minimum load.
	Adaptive swing phase control	• Pre-setting of the maximum knee angle is 65° (adjustable). • Knee angle is constant even when walking at varying speeds. • If the maximum knee angle is not reached when walking slowly, the extension movement is slowed down and foot clearance is assured.
Stairs	Release of function	Through a backward movement of the prosthesis after lifting the foot.
	Knee flexion	A low flexion resistance of the prosthesis enables that knee flexion is initiated through a hip flexion movement.
	Extension before ground contact (unloaded)	Extension movement in swing phase is performed faster and therefore the foot can be put on the next step in a controlled way. Flexion resistance is blocked.
	Extension after ground contact (loaded)	Extension resistance is increased further, so that the knee reaches a straight position in a controlled manner. Flexion resistance stays blocked.
Ramps, Hills	Adapted resistance	Allows for an increased flexion angle in stance phase compared to level walking, where it is limited to 17° knee flexion.
	Release of swing phase	• Occurs even when the prosthesis is in a flexed and loaded position. • Flexion is opened only continuously so that the prosthesis allows only for smooth motion clearance. • Additional foot clearance is provided
Uneven Ground, Obstacle Course	Crossing Obstacles	Obstacles can be crossed using the same function as for stair ascent.
Safety	Dynamic stability control (DSC)	Allows for a safe switch between stand and swing phase resistance.
Activity, Mobility, Activities of daily living (ADLs)	Functions	• Activated intuitively through a motion pattern. • The joint is releasing, blocking or changing the resistance continuously between conditions. • After finishing conducting the activity the joint switches back automatically to base mode. • Following functions can be activated: Stair and obstacle

Category		
		Standing Sitting
	MyModes	• Activated through repeated bouncing or through remote control • Five MyModes for special activities can be programmed.

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)

Author's Conclusion

"The manufacturer is convinced that Genium prosthetic system has a significant impact on rehabilitation and disability compensation based on optimized physiological walking including dynamic stability control, implementation of functions and five MyModes, as well as other in the article mentioned improvements. The prior target is to minimize the difference between the natural body function of the sound locomotor system and the artificial replacement by the prosthesis during walking but also during other activities of daily living." (Kampas & Seyr 2011)

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