

C-Leg 4

Initial Clinical Results



Quality for life



First introduced in 1997 ...

C-Leg is the most widely used and studied microprocessor-controlled knee in the market. Around the globe, people rely on the C-leg to help them reclaim their determination and live the life they desire.



C-Leg 4

is the latest release and has been extensively observed in real user environments. In addition to being smaller in size, C-Leg 4 offers several new functionalities. Those include an easier transition from stance to swing phase and improved stumble recovery.

The objective of documenting the first routine fittings was to gain initial clinical results and experiences with C-Leg 4.¹

Methods

More than 30 C-Leg 4 devices were fitted by over 20 practitioners.

Data from routine fittings was collected in Canada as well as in European countries in order to assess the first impression of C-Leg 4 by users in an everyday environment. Over 20 orthopaedic workshops were involved in data collection.

Market	Number of users	Percentage of users relative to total amount of users
Canada	7	20%
Europe	28	80%
Total	35	

Responses were retrieved by standardized questionnaires at the day of the C-Leg 4 fitting and also after users have gained experiences for at least 4 weeks with C-Leg 4.

97% of the users wore a microprocessor-controlled knee prosthesis prior to the fitting of C-Leg 4. The remaining 3% of participants had used a mechanically controlled knee joint previously.

By the time the final questionnaire was due, users had worn C-Leg 4 for an average of 17 weeks and walked an average of 3,564 ($\pm 1,911$) steps per day.

Users	unilateral transfemoral and knee disarticulated amputees
Previous prosthesis	94% C-Leg, 3% C-Leg Compact, 3% 3R60
Amputation causes	54% trauma, 26% tumor, 20% others
Mean age	51 years (range from 27 to 71 years)
Mean time since amputation	23 years (range from 5.4 to 60 years)
Mobility grade (MG)	11% MG2, 63% MG3, 26% MG4
Gender	77% male, 23% female
Weight	81 kg/175 lbs (range from 44 to 120 kg/97 to 265 lbs)





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Results

Fitting process

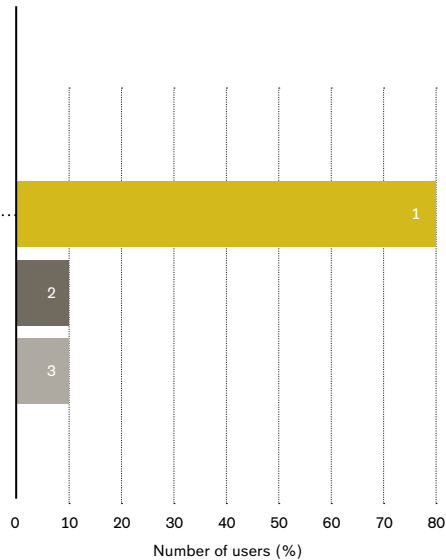
▶ Simplified fitting process

Required appointments to successfully fit C-Leg 4

Satisfying prosthetic alignment and setting was achieved after only one appointment in **80%** of the cases.

Practitioners particularly liked:

- Omitted sensors in the tube adapter
- Very user friendly software

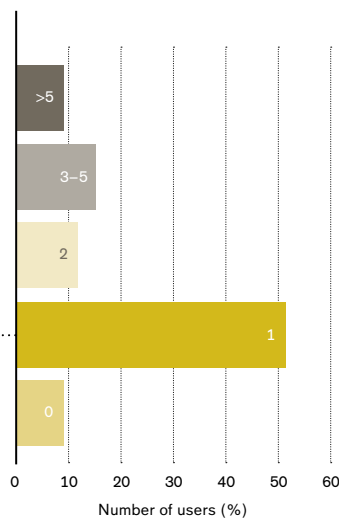


▶ Short acclimatization period

Number of days user needed to acclimate

Even though C-Leg 4 offers new functionality compared to previous C-Leg versions, users adapted fast according to their feedback:

Acclimatization period lasted one day or less for **61%** of the users.



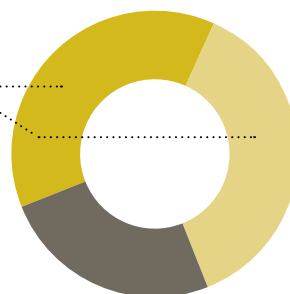
Level walking

► Easier swing phase initiation

Swing phase initiation with C-Leg 4 compared to previous prosthesis

72% of the users rated the transition from stance to swing phase as much better or better with C-Leg 4 compared to their previous prosthesis (94% previous C-Leg version).

Note: These findings were confirmed by biomechanical analysis^{2,3}; Hip moments in terminal stance phase were decreased with C-Leg 4 compared to the previous C-Leg version and Plié.

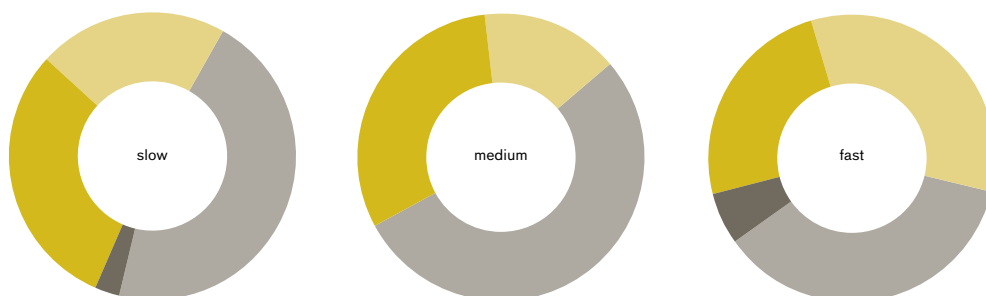


■ much better
■ better
■ same

► Improved adaptation to changes in walking speed

The majority of test users reported improved walking at all walking speeds with C-Leg 4 compared to their previous prosthesis (94% previous C-Leg version): slow walking speed by 52%, medium by 67% and fast by 58%.

Adaptation to changes in walking speed was experienced as reliable by **97%** of the users.



■ much better
■ better
■ same
■ worse

Note: Biomechanical analysis showed that with C-Leg 4 the maximum knee angle in swing phase is more constant over a variety of gait speeds compared to other microprocessor controlled knees and therefore better swing control is provided³. The same biomechanical analysis was conducted with Genium compared to C-Leg; maximum knee flexion angle in swing phase is with Genium nearly constant at 64° across walking velocities⁴. Therefore the provided swing control with Genium is even superior compared to C-Leg resulting in a nearly natural, physiological gait pattern.

Results

Level walking

► Smoother, more harmonic and easier walking

Level walking, as well as **walking on uneven surfaces**

were rated as improved by **58%** of the users compared to their previous prosthesis (94% previous C-Leg version).

Effort of walking

was rated as decreased by **59%** of all users with C-Leg 4 compared to their previous prosthesis.

Walking was rated **more harmonic** by **73%** of all users with C-Leg 4 compared to their previous prosthesis.

37% of practitioners ranked **gait pattern improvement** to be a major benefit of C-Leg 4.

Smoother and easier gait

was noted as a major benefit of C-Leg 4 by **45%** of the users.

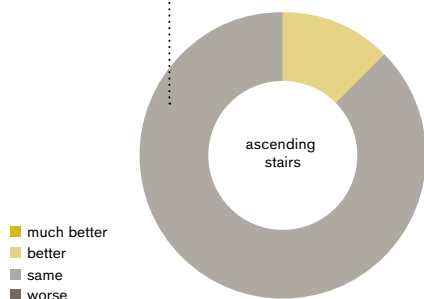


Stairs and slopes

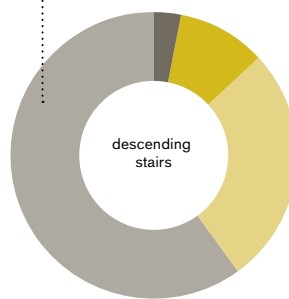
► Stairs and slopes functionality similar to previous prosthesis

Ascending stairs using step-by-step or skip-step strategy was rated by

88% of the users as unchanged ...

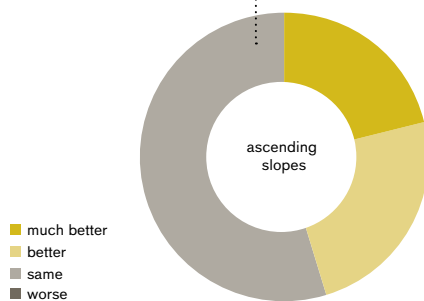


... and **descending stairs** was rated by **60%** of the users as unchanged relative to their previous prosthesis (94% previous C-Leg version).

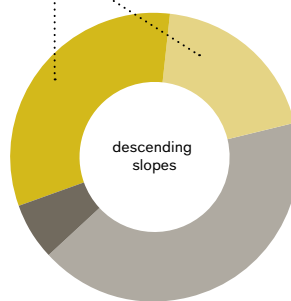


Note: Only Genium allows a prosthetic user to ascent stairs reciprocally, resulting in a clear approximation to the physiological movement pattern. The movements of the knee and hip joint on the contralateral side decrease and the loading of the contralateral knee joint decreases with Genium compared to C-Leg 4.

Ascending slopes was rated by **55%** of the users as unchanged ...



... and **descending slopes** was rated by the majority of **52%** of all users as improved compared to their previous prosthesis (94% previous C-Leg version).



Note: Due to Geniums' adaptive yielding control, stance phase flexion resistance is continuously adapted depending on the situation. This allows a physiological gait pattern even when walking on slopes as well as a fluent transition from slopes to even ground.

Results

Activities of daily living

► Improvements in regard to various activities of daily living

Some of the activities that were reported by users to be improved the most with C-Leg 4 compared to their previous prosthesis (94% previous C-Leg version) include:

- Walking in crowds
- Walking over gravel surface
- Walking across a slippery floor
- Picking up objects from the floor

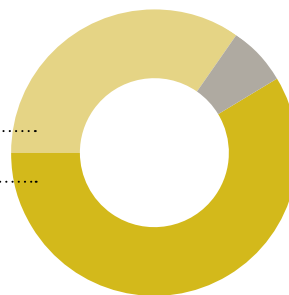
Stance Function

► Intuitive Stance Function brings major benefit

Activating Intuitive Stance

97% of the users experienced the Intuitive Stance Function as useful.

- Intuitive Stance Function was the major benefit noted by 70% of users.
- 93% of the users rated the activation of Intuitive Stance as very easy or easy.
- Standing on slopes, comfort while standing and perceived safety while standing were rated as improved by 70% of the users.



Safety

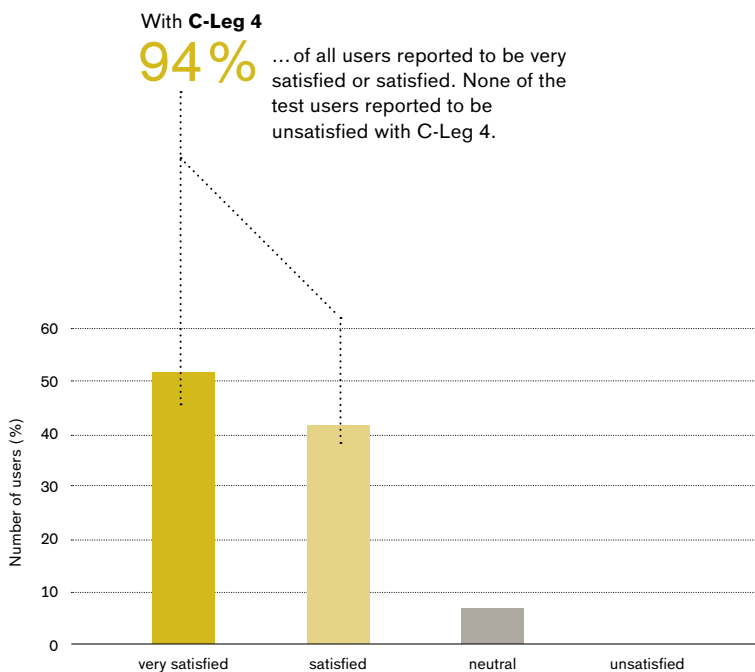
► Greater safety

Perceived safety measured by grading of stumble recovery was rated

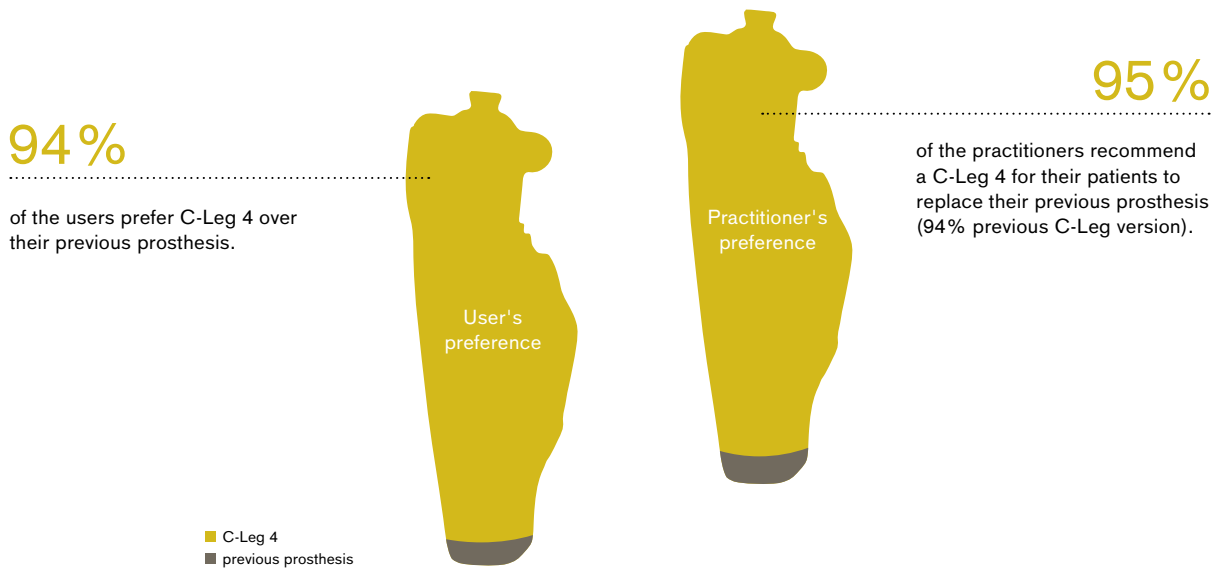
by **39%** of the users as improved with C-Leg 4 compared to their previous prosthesis (94% previous C-Leg version).

Preference and satisfaction

► High satisfaction with C-Leg 4



► High preference for C-Leg 4 by users and practitioners



Conclusion

Users and practitioners show a high preference for C-Leg 4. They reported improvements regarding a variety of activities of daily living. High satisfaction with C-Leg 4 was observed due to improved and additional functionality offered by the knee.

In particular, users praised the smoother, easier and more harmonic walking due to an improved swing phase initiation pattern. Moreover, improved safety and stability, Intuitive Stance and adaptation to changing gait speed were well received by the users.



Reference

- ¹ Wismer, N., Mileusnic, M., Sreckovic, I., & Hahn, A. (2016). First results on next generation C-Leg. Poster presentation at OTWorld, Leipzig, Germany.
- ² Thiele, J., Westebbe, B., Bellmann, M., & Kraft, M. (2014). Designs and performance of microprocessor-controlled knee joints. *Biomedizinische Technik/Biomedical Engineering*, 59(1), 65–77.
- ³ Kraft, M., Thiele, J., Bellmann, M. (2015). Functional differences between various MPKs – are they all alike? Presentation at ISPO World Congress Symposium, Over 20 Years of Microprocessor-Controlled Knees – What's the State of the Science? Lyon, France.
- ⁴ 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.
- ⁵ 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.

