Reference

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Comparative biomechanical evaluation of two technologically different microprocessor-controlled prosthetic knee joints in safety-relevant daily-life situations

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Products

C-Leg 4, Rheo Knee XC

Major Findings

→ Rheo Knee XC reliably switches into the swing phase during small steps (default swing) in every trial observed; C-Leg 4 in approximately 90% of all trials (default stance)

→ Walking backwards is safer with C-Leg 4 due to a reliable and stable flexion resistance

- The joint remains in stance phase mode throughout the gait cycle
- Due to the "default swing" concept used in the Rheo Knee XC, walking backwards may lead to an uncontrolled knee flexion and thus to a fall

→ C-Leg 4 offers a reliable and stable load bearing while descending stairs and slopes, due to:

- engaging stance phase flexion resistance before ground contact; increasing resistance progressively up to the end of the yielding phase

- significantly higher knee flexion moment ($p < 0.05$) and thus higher load bearing capacity on the prosthetic side compared to the Rheo Knee XC; also leading to less compensation on the contralateral side

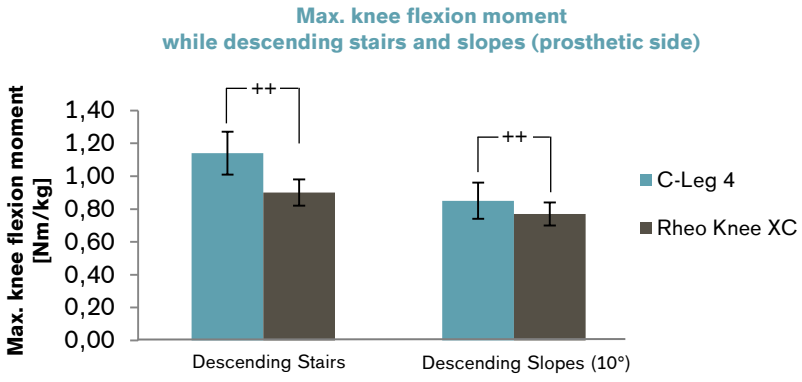
- knee joint extension position remains constant at the end of every swing phase, leading to a more precise positioning of the foot

→ Higher knee flexion during swing phase with C-Leg 4 when ascending slopes, which may lead to greater ground clearance

→ Swing phase perturbations are better compensated by C-Leg 4

- Knee joint extension after perturbation executed up to a flexion angle of approximately 46° at ground contact (11° more than Rheo Knee XC)

- Higher flexion resistance leads to slower knee flexion and enhanced load bearing capacity, enabling more time to prevent a fall

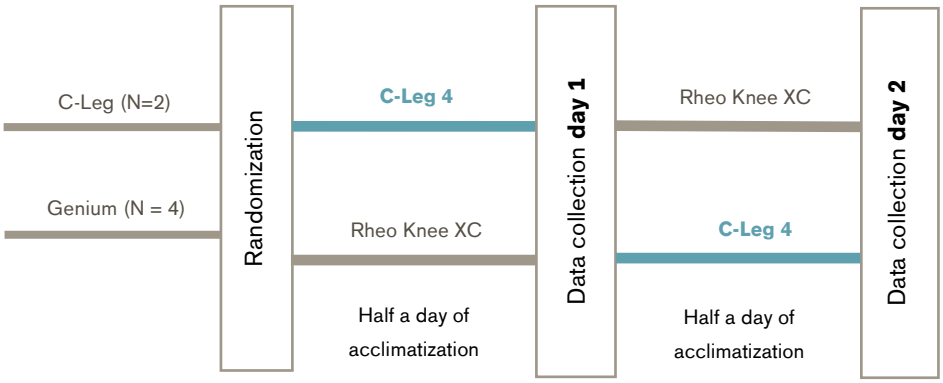


Population

Subjects:	6 active, unilateral transfemoral amputees
Previous prosthesis:	Genium (N = 4), C-Leg 3 (N = 2)
Amputation causes:	Trauma (all subjects)
Mean age:	42.5 ± 8.7 years
Mean time since amputation:	25.8 ± 6.0 years
MFCL:	K3+ and K4

Study Design

Interventional, randomized, crossover study



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	C-Leg 4	Rheo Knee XC	Sig.*
Level Walking	Successful release of swing phase with small steps	on slightly flexible surface: 85.4% on solid surface: 91.7%	on slightly flexible surface: 100% on solid surface: 100%	n.a. n.a.
	Maximum knee flexion angle in swing phase with small steps	46.2 ± 7.9°	44.8° ± 4.7°	0
	Tripping (swing phase); Contact angle < 40°	Compensatory movements needed for subsequent step?		
		No Compensation: 58.3% Compensation: 41.7% Fall: 0%	No Compensation: 37.5% Compensation: 62.5% Fall: 0%	n.a.
	Tripping (swing phase); Contact angle > 40°	No Compensation: 33.3% Compensation: 60% Fall: 6.7%	No Compensation: 0% Compensation 26.7% Fall: 73.3%	n.a.
	Walking backwards - General behavior of the prosthesis	Reliable load bearing for all backwards steps.	Undesirable knee flexion occurred sometimes during the swing phase.	n.a.
Stairs	Descending:			
	Gait velocity	0.27 ± 0.02 m/s	0.25 ± 0.03 m/s	0

Category	Outcomes	C-Leg 4	Rheo Knee XC	Sig.*
	Prosthetic side			
	Flexion at stair contact	2 ± 0.6 °	4 ± 4.3 °	n.a.
	Max. knee angular velocity during stance phase flexion	176.4 ± 12.7 °/s	203.4± 33.0 °/s	0
	during extension in swing phase**	**323.4 ± 33.8** °/s	**188.5 ± 40.7** °/s	**++**
	Max. knee flexion moment	**1.14 ± 0.13 Nm/kg**	**0.90 ± 0.08 Nm/kg**	**++**
	Contralateral side			
	Stance phase duration	**68.9 ± 2.8 %**	**72.3 ± 2.1 %**	**--**
	Max. knee flexion (first half of stance phase)	14.4 ± 4.8°	17.5 ± 3.4°	0
	Max. vertical ground reaction force	157.3 ± 15.1 %BW	169.4 ± 16.2 %BW	0
	Max. knee flexion moment	**0.19 ± 0.24 Nm/kg**	**0.52 ± 0.18 Nm/kg**	**--**
Ramps, Hills	Descending:			
	Gait velocity	0.59 ± 0.02 m/s	0.50 ± 0.06 m/s	0
	Prosthetic side			
	Stance phase duration	**57.3 ± 1.5 %**	**58.7 ± 2.2 %**	**--**
	Max. knee flexion velocity	145.1 ± 16.2 °/s	160.9 ± 16.5 °/s	0
	Max. knee flexion angle	**67.8 ± 5.9** °	**63.0 ± 1.0** °	**+**
	Knee extension velocity in swing phase	**373.1 ± 48.6 °/s**	**291.6 ± 36.9 °/s**	**++**
	Extension of thigh segment (75% to 100% of gait cycle)	**4.4 ± 2.7** °	**6.8 ± 2.0** °	**--**
	Knee flexion moment (30% to 100% of gait cycle)	**0.85 ± 0.11 Nm/kg**	**0.77 ± 0.07 Nm/kg**	**++**
	Contralateral side			
	Max. vertical ground reaction force	122.1 ± 5.4 N	117.2 ± 4.1 N	0
	Ascending:			
	Gait velocity	**0.56 ± 0.04 m/s**	**0.52 ± 0.04 m/s**	**+**
	Prosthetic side			
	Stance phase duration	62.4 ± 3.0 %	60.7 ± 2.6 %	0
	Max. knee flexion angle	**54.7 ± 5.7** °	**61.7 ± 8.4** °	**--**
	Max. knee flexion velocity	**406.5 ± 63.9 °/s**	**367.1 ± 50.8 °/s**	**++**

Category	Outcomes	C-Leg 4	Rheo Knee XC	Sig.*
	Max. knee extension velocity	**377.9 ± 91.1 °/s**	**314.6 ± 69.5 °/s**	**++**

* no difference (0), positive trend (+), negative trend (–), significant (++/––), not applicable (n.a.)
** At the end of the motion cycle, the Rheo Knee XC was still in extension movement (angular velocity at 100% was 44.6 ± 24.3°/s).

Author's Conclusion

"Safety against uncontrollable knee flexion and an overall reliable functionality of prosthetic knee joints is the basis for a successful clinical rehabilitation of transfemoral amputees. Safety and performance are the clinically relevant parameters that have been in the scope of this study. The objective biomechanical data measured in this context imply functional and safety-related advantages and disadvantages which can be attributed to the unequal technological concepts. The "default swing" principle used in the Rheo Knee XC offers slight advantages in the reproducibility of the swing phase release when walking with small steps, but at the disadvantage for walking backwards safely. This may lead to an uncontrolled flexion of the knee joint and thus to a fall. The C-Leg provides a reliably stable loadbearing prosthesis. Furthermore, the Rheo Knee XC shows lower safety reserves and requires increased compensation of the remaining locomotor system when walking down stairs, walking on slopes or while recovering from a stumble. These findings suggest that the technological concept used in C-Leg 4 provides an enhanced functional quality and advantages in daily-life situations compared to the technology used in Rheo Knee XC, especially concerning safety-relevant aspects." (Bellman et al., 2018)