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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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Abstract: Safety-relevant gait situations (walking on stairs and slopes, walking backwards, walking with small steps, simulated perturbations of swing phase extension) were investigated in a motion analysis laboratory with six unilateral transfemoral amputees using two different microprocessor-controlled prosthetic knee joints (Rheo Knee XC, C-Leg). A randomized crossover design was chosen. The study results imply that the performance and safety potential of a microprocessor-controlled knee joint can be associated with the individual control algorithms and the technological concepts that are implemented to generate motion resistances for controlling flexion and extension movements. When walking with small steps, advantages of the "default swing" concept used in the Rheo Knee XC were identified due to a highly reproducible swing phase release. However, when walking backwards, this concept may lead to an uncontrolled knee flexion which partly resulted in falls. When walking down stairs, walking on slopes or while recovering from a stumble after perturbations of the swing phase extension, the C-Leg demonstrated a reliable prosthetic side load-bearing capacity resulting in reduced loading on the residual body. In contrast, the Rheo Knee XC required increased compensatory movements of the remaining locomotor system in order to compensate for reduced load-bearing and safety reserves.

Keywords: amputee; knee joint; microprocessor-control; prosthesis; safety.

Introduction

A successful rehabilitation of transfemoral amputees requires a reliable and safe functionality of exoprosthetic components, especially knee joints. In all standing and walking situations, the amputee must be able to use all knee joint functions without special cognitive abilities and motor compensation. These functions are provided by technological features of the prosthetic knee joint. Walking on uneven or tilted surfaces such as stairs and slopes as well as unpredictable perturbations of the movement patterns are a major challenge for preventing an uncontrolled flexion of the prosthetic knee joint.

Some microprocessor-controlled knee joints detect movements and loads of the prosthesis via implemented sensors [1–4]. The necessary joint resistance is then provided by adjustable damping elements to ensure a controlled movement. Therefore, linear hydraulics as well as magnetorheological concepts are well-established technologies. In essence, technological platforms and software control algorithms of the joints determine the functional quality and the safety to avoid an uncontrolled knee flexion. Reliable and safe functionality has been proven to significantly reduce the frequency of falls in amputees, resulting in a lower attention demand and thus an improved divided attention. This results in a higher confidence in the reliability of the assistive device, which enables amputees to expand their range of daily activities [5–13].

The functional quality and safety of microprocessor-controlled knee joints have been shown to differ remarkably [14–18]. Furthermore, few biomechanical studies have compared the safety potentials of microprocessor-controlled knee joints. However, these studies have not been conducted with the currently available technological standard of these knee joints [15, 17, 19–21].

Daily-life situations of transfemoral amputees resulting in a fall have been reported [17]. With the magnetorheological concept of the Rheo Knee, a sudden stop on the prosthetic side during level walking led to compensatory movements in the upper body. After perturbation of the extension movement in the swing phase, the C-Leg was able to compensate for greater knee flexion angles at initial ground contact. With initial contact on the stair, the knee angle and stance phase flexion resistance of the previous version of the Rheo Knee varied, which significantly impeded a reproducible positioning of the prosthetic foot on stairs and a controlled knee flexion.

Due to the non-reproducible knee extension position of the former Rheo Knee, the amputees had to extend the

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knee joint before initial contact on the stairs by compensatory movement of the thigh segment [15]. Similarly, the maximum flexion resistance and thus the load-bearing capacity of the prosthesis appeared comparatively low. With perturbed swing phase extension and subsequent loading of the flexed prosthesis, the former C-Leg was shown to be superior [15]. The latter required more compensatory movements to avoid falls.

The descent on a slope was investigated with former versions of the Rheo Knee and the C-Leg [21]. An "inhomogeneous" flexion pattern or slight buckling was detected in the first half of the stance phase for the Rheo Knee. Compared to C-Leg, the stance phase duration of the unaffected side was longer with the Rheo Knee, which was associated with its slower extension speed during the swing phase.

The aim of this study was to investigate the functional performance of the current standard of two technologically different representatives of microprocessor-controlled knee joints in safety-relevant daily-life situations using biomechanical methods. Besides other microprocessor-controlled knee joints existing in the market, these two concepts differ in their technological designs to generate motion resistances as well as the default setting of their resistances most. We examined whether certain characteristics are able to differentiate between these two concepts, with clinical relevance for the rehabilitation of transfemoral amputees focusing on safety and performance.

Materials and methods

Subjects

Six active unilateral transfemoral amputees (mobility grade 3+ to 4) participated in this study (Table 1). During the measurements, they had no further comorbidities, no problems in socket fit or temporary diseases. All were highly experienced with using different microprocessor-controlled prosthetic knee joint concepts. The subjects were informed about the scope and requirements for the upcoming study and gave their written consent to voluntarily participate in this study. Ethics approval was granted by the Ethics Committee of the Medical University of Göttingen (no. 7/10/16).

Prosthetic components

The currently available versions of the Rheo Knee XC and the C-Leg were selected as representative examples of the two most different technological concepts chosen for resistance generation and default setting of these resistances in microprocessor-controlled prosthetic knee joints. Both prosthetic knees were tested in combination with the Triton 1C60 foot.

Rheo Knee XC: In 2016, the Rheo Knee XC (Össur, Reykjavik, Iceland) was introduced as a version with extended functionalities. It is based on the same design and sensor principle as the Rheo Knee 3, but has expanded functionality for alternating stair climbing, cycling or running.

A magnetorheological principle is used to generate movement resistances in the direction of flexion and extension (Figure 1, top). Thin plates are alternately arranged around the axis of rotation of the knee joint, which are connected to the housing or the inner part of the joint. The gaps (approximately 20 μm) are filled with a magnetorheological fluid consisting of oil and small magnetic particles. Application of a magnetic field forces the particles to form chains between the opposing discs and thus form a connection between the inner and outer part of the joint head. Changing the knee angle causes a relocation of the plates against each other, creating shear forces and thus generating a torque around the knee joint axis. The generated resistance is controlled by the strength of the applied magnetic field. Due to the underlying principle, the resistance simultaneously acts in the direction of flexion and extension [14, 23]. The Rheo Knee XC is equipped with a knee angle sensor and strain gauges to measure the axial load and the bending moment of the shank. The sampling rate and operating frequency are 1000 Hz [23] and 200 Hz, respectively.

Generally, the knee joint is set to a default swing mode and thus a low resistance is applied. Depending on the axial loading at ground contact, a higher resistance is generated, varying with the extent of the applied load. The higher the loading, the higher the resistance and vice versa [14, 22]. To switch into a lower swing phase resistance

Table 1: Individual subjects' characteristics.

Subject	1	2	3	4	5	6	Mean
Age (years)	43	32	50	46	52	32	42.5
Height (cm)	182	179	178	186	178	182	180.8
Body mass (kg)	91.5	84	75	74.5	83	64	78.7
Time since amputation (years)	35	27	27	22	27	17	25.8
Cause of amputation	Trauma	Trauma	Trauma	Trauma	Trauma	Trauma	
Socket system everyday prosthesis	ischium containment	ischium containment	ischium containment	ischium containment	ischium containment	ischium containment	
Knee joint type everyday prosthesis	Genium	Genium	C-Leg 3	C-Leg 3	Genium	Genium	
Foot type everyday prosthesis	Triton 1C62	Triton 1C60	Triton 1C60	C-Walk 1C40	Triton 1C64	Triton 1C60	

while walking, the knee must be extended and a defined shank bending moment must be applied at the same time, or the prosthesis must be unloaded almost completely [23].

C-Leg 4: The current version of the C-Leg was launched in 2015 by Otto Bock (Duderstadt, Germany). It is based on a linear hydraulic system that independently generates resistance in the direction of flexion or extension (Figure 1, bottom). The resistance is adjusted by means of two microprocessor-controlled servo valves, both in the stance and swing phases. A spring (a) and a hydraulic channel produce a progressive extension resistance (b), which generates an imperceptible extension stop for the amputee [18]. Major changes were implemented concerning the sensors. Instead of using the bending moment of the tube adapter, the knee flexion moment is detected via a knee moment sensor. Furthermore, an inertial measurement unit (IMU) was incorporated to measure the position and rotation in space, and the acceleration of the knee joint in all three spatial dimensions. A knee angle sensor detects the flexion angle and angular velocity [24]. The C-Leg is in a default stance mode with high stance phase flexion resistance. The following conditions result in a switching of the joint into low swing phase flexion resistance in terminal stance:

1. Forward tilt (position in space)
2. Forward movement (rotation in space, acceleration of the knee joint)
3. Ground contact of the prosthetic foot
4. Knee extension moment (knee moment sensor, knee angle sensor)

The swing phase control was optimized by an enhanced processor performance (100 Hz) and a new sensor technology in order to control the swing phase flexion and extension resistance in real time [24]. A specifically developed stumble recovery mode closes the flexion valve in swing phase extension to a greater extent compared to the basic setting of flexion resistance in stance. Thus, in case of perturbation of the swing phase

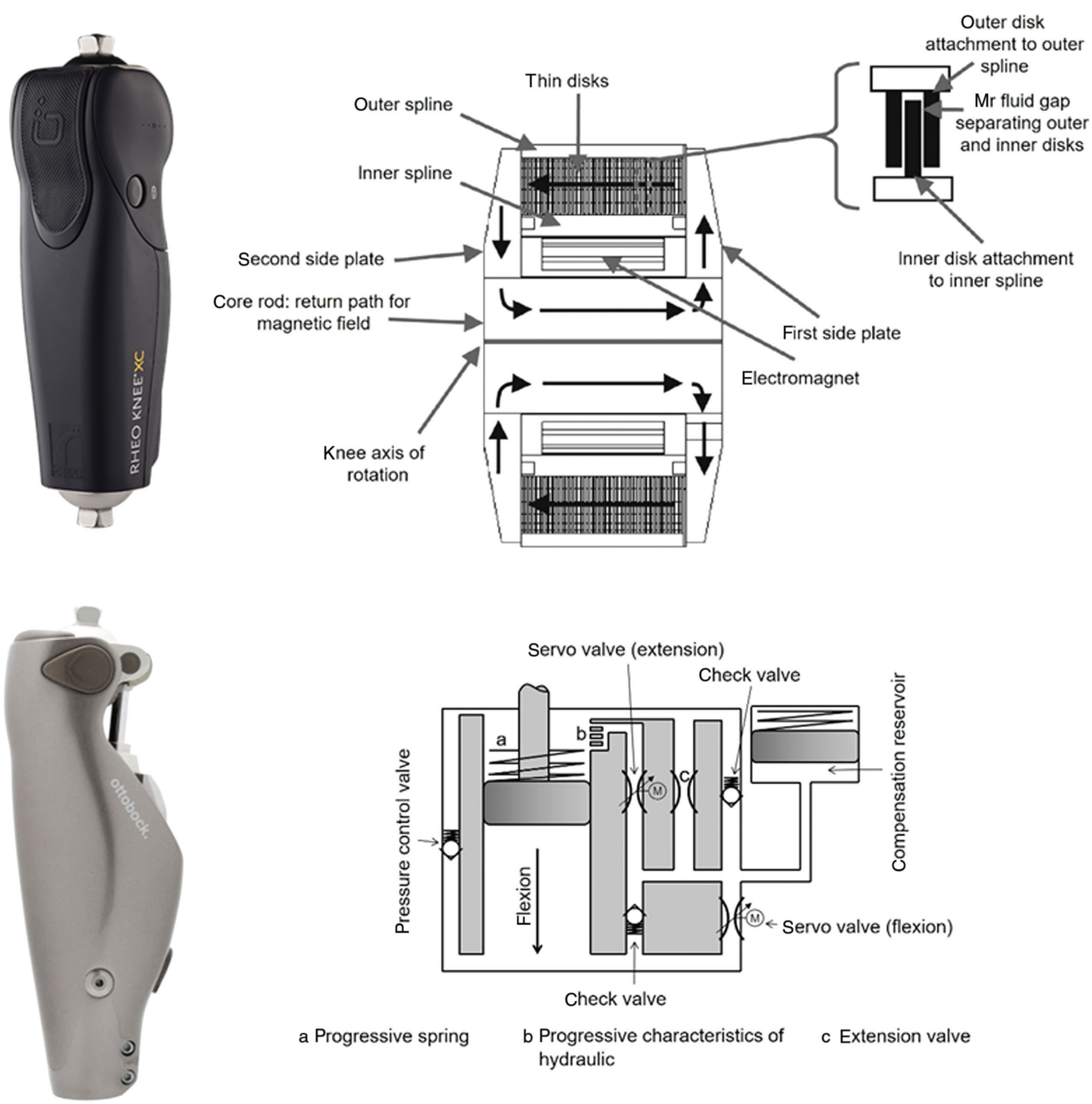

Figure 1: Top left: Rheo Knee XC [3], top right: schematic representation of the magnetorheological principle, according to [22], bottom left: C-Leg 4 [4], bottom right: schematic representation of the hydraulic system, according to [18].

extension and loading of the flexed prosthesis, a higher flexion resistance is instantly generated. At the same time, the extension resistance is low to enable the extension of the prosthetic knee joint [24].

Prosthetic foot Triton 1C60: The Triton (Ottobock SE & Co. KGaA, Duderstadt, Germany) is a carbon spring foot, designed for mobility grades 3–4.

Measuring systems

Prosthetic alignment: The L.A.S.A.R. Assembly (Laser Assisted Static Alignment Reference) was used to align the socket position of the test prosthesis identical to the everyday prosthesis. The L.A.S.A.R. Posture (both Ottobock SE & Co. KGaA, Duderstadt, Germany) was used to check and optimize the static alignment in accordance with established recommendations [25, 26].

Motion analysis: The gait lab is equipped with a 12-m walkway and two piezoelectric force plates embedded in the center (Type 9287A, Kistler Instrumente AG, Winterthur, Switzerland). A 12-camera optoelectronic system (Vicon MX, Vicon Motion Systems Ltd., Oxford, UK) was used to measure the kinematic parameters. To determine joint positions in space, reflective markers were attached to the following anatomical reference points: fifth metatarsal-phalangeal joint, prominence of the lateral malleolus, knee center as defined by Nietert (prosthetic side knee axis), greater trochanter, acromion, lateral epicondyle of the humerus and styloid process of the ulna.

Synchronously, video recordings (Panasonic, 50 Hz) were taken from every trial.

Experimental procedure

The measurements with the two prosthetic knee joints were performed in random order on 2 separate days. The test sequence was also randomized.

For the tests, the subjects' everyday sockets were used. The test prosthetic alignment for both joints was in accordance with the manufacturer's recommendations, which are identical in both cases [27, 28]. The socket position was copied from the everyday prosthesis. An identical lace-up shoe in the test person's individual size was used. The effective heel height was 10 mm. Static prosthetic alignment was optimized using the L.A.S.A.R Posture and then documented. Joint settings were adjusted according to the manufacturer's specifications. A certified prosthetist-orthotist (CPO) performed the alignment and settings. The subjects were given half a day to familiarize with the functioning of the knee joints [29].

Small steps: To limit stride length, markers were attached to the measuring range of the force plates and the adjacent wooden floor at a distance of approximately 40 cm. This wooden floor slightly yields under load, allowing investigation of the effects on a slightly flexible surface. With both, the prosthetic and contralateral side, three trials with four steps were recorded contacting either the force plate or the wooden floor areas, respectively.

Walking on stairs and slopes: Measurements were performed while descending the stairs as well as descending and ascending a 10° inclined slope, respectively. The ground reaction forces were measured on the third step of the stair case from the top and in middle of the ramp. The experimental set-up has been presented by Schmalz et al. [30, 31]. An optional handrail was provided. In each of the walking situations, nine trials were measured for the prosthetic and contralateral side.

Walking backwards: The subjects were asked to walk backwards alternately at a self-selected speed along a walking distance of 4 m. For this purpose, the first step was performed from a standing position. Three trials with the prosthetic and the contralateral side were measured, respectively. For safety reasons, the subjects were equipped with a special harness, which was mounted on a height-adjustable rail system under the ceiling. The gait of the subjects was not influenced by this system [32].

Tripping during the swing phase: The experimental procedure was performed according to Blumentritt et al. [32]. Toe tripping of the prosthetic side due to perturbations in the swing phase extension was simulated by a slight tug on a string attached to the ankle adapter during level walking. This perturbation occurred in 4–7 out of 25–30 total trials per subject. The subjects were not previously informed in which of the trials the perturbation was applied. For safety reasons, the subjects were secured by the harness to avoid falls (see Walking backwards).

Data analysis and statistics

For small steps, walking on stairs and slopes, two whole gait cycles from each trial were evaluated. Means of the individual normalized gait cycles were calculated from the single trials of the subjects. Group means and standard deviations were then calculated.

The following parameters were investigated:

1. Time-distance parameters: walking speed, stride length, stance phase duration.
2. Kinematics: knee and hip joint angle, angular velocity of the joints.
3. Kinetics: ground reaction forces, external joint moments.

The Wilcoxon test was used to identify significant differences between the mean group values of recorded parameters. The level of significance was defined as $p < 0.05$. For the "small steps", trials with the joint not switching correctly into low resistance at the beginning of the swing phase (four steps per trial) were identified. The percentage of failures across all six subjects was determined.

For "walking backwards", all single trials were analyzed based on biomechanical parameters and video recordings to characterize the performance of the knee joints of this specific situation. Averaging did not appear to be appropriate here.

Single trial analysis was performed for "tripping" trials. The following parameters and characteristics were investigated:

1. Sagittal knee angle of the prosthetic side at ground contact of the prosthesis after perturbation of the swing phase extension.
2. Knee joint fully extended after ground contact? Yes/No.

Each trial was assigned to one of the three categories:

1. No compensation: The subsequent step was completed without or with only minimal deviations from a normal movement pattern.

2. Compensation: The subsequent step could only be executed with compensatory movements of the upper body or a long anterior contralateral step.
3. Fall: The patient was not able to perform the subsequent step and was saved from falling by the harness.

Results

Static alignment of the prosthesis

The mean sagittal distance from the load line and the center of gravity line to the reference points (greater trochanter, knee joint axis of rotation and lateral malleolus for the prosthetic side) was below 3.2 mm and not statistically significant (Table 2).

Small steps

The Rheo Knee XC switched reliably into the swing phase for all investigated small steps. The C-Leg triggered the swing phase for 89.9% of all steps. With 91.7%, the percentage of successful swing phase release on the solid surface was 6.3% higher than on the slightly flexible surface (85.4%).

Kinematics

For the C-Leg, the maximum knee flexion angle in the swing phase was 1.4° greater than that for the Rheo Knee XC (C-Leg: 46.2 ± 7.9°; Rheo Knee XC: 44.8 ± 4.7; p = 0.345). Extension of the knee joint in the late swing phase was delayed for the Rheo Knee XC.

Walking down stairs

Time-distance parameter

The speed while descending stairs was comparable for both knee joints (C-Leg 0.27 ± 0.02 m/s; Rheo Knee XC 0.25 ± 0.03 m/s; p = 0.463).

For the Rheo Knee XC, the contralateral stance phase duration was 3.4% longer compared to the C-Leg (C-Leg 68.9 ± 2.8%; Rheo Knee XC 72.3 ± 2.1%; p = 0.028).

Kinematics

Prosthetic side

At stair contact, the group average was 4 ± 4.3° of flexion for the Rheo Knee XC and 2 ± 0.6° for the C-Leg (Figure 2). From approximately 25% of the motion cycle the Rheo Knee XC flexed much faster. The difference in maximum angular velocity of the knee during stance phase flexion was 27.0°/s (C-Leg 176.4 ± 12.7°/s; Rheo Knee XC 203.4 ± 33.0°/s; p = 0.116). Extension of the knee joint during swing was faster with the C-Leg. The maximum knee angular velocity was significantly faster by 134.9°/s (C-Leg 323.4 ± 33.8°/s; Rheo Knee XC 188.5 ± 40.7°/s; p = 0.028). 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).

Contralateral side

With the Rheo Knee XC, the knee flexion of the subject was increased by a maximum of 3.1° in the first half of the stance phase (C-Leg 14.4 ± 4.8°; Rheo Knee XC 17.5 ± 3.4°; p = 0.172). After the subsequent stronger extension movement of the unaffected side, flexion started later with the Rheo Knee XC (Figure 2).

Kinetics

Prosthetic side

The maximum knee flexion moment with the C-Leg was significantly higher (C-Leg 1.14 ± 0.13 Nm/kg, Rheo Knee XC 0.90 ± 0.08 Nm/kg; p = 0.028) (Figure 2).

Contralateral side

On the contralateral side, the maximum vertical ground reaction force for the C-Leg was 157.3 ± 15.1% body weight

Table 2: Results of prosthesis static analysis performed with L.A.S.A.R. Posture; distances between reference points and the load line and the center of gravity line, respectively; means and standard deviation, p-values.

Reference points	Load line			Center of gravity line		
	C-Leg	Rheo Knee XC	p-value	C-Leg	Rheo Knee XC	p-Value
Greater trochanter (mm)	17.2 ± 18.6	17.5 ± 17.9	0.83	2.7 ± 13.2	3.0 ± 17.3	0.89
Knee joint axis (mm)	29.2 ± 1.8	30.0 ± 2.1	0.18	16.2 ± 9.1	19.3 ± 7.8	0.60
Malleolus lateralis (mm)	66.0 ± 13.6	64.5 ± 13.3	0.69	55.8 ± 20.8	57.5 ± 12.8	0.83

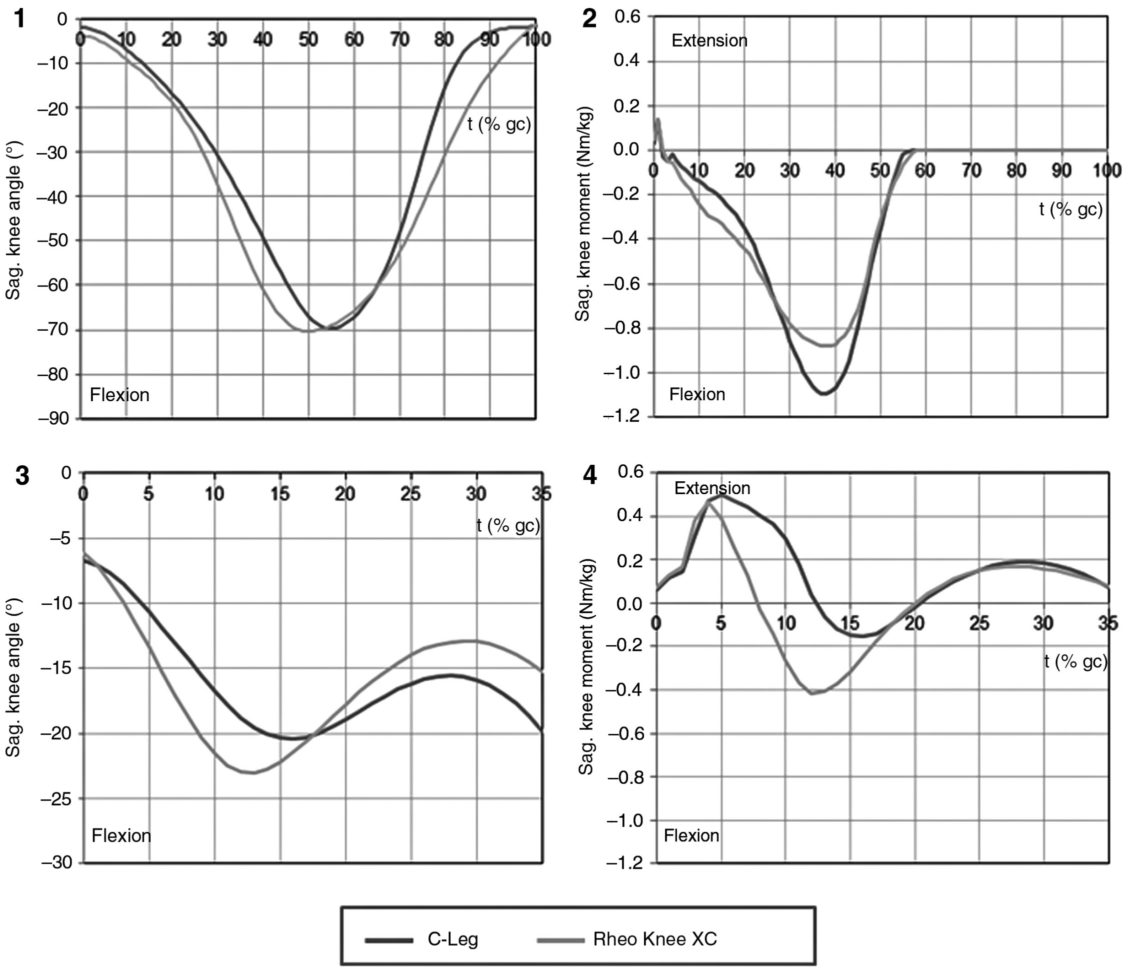

Figure 2: Descending stairs: mean sagittal knee angle (1) and mean sagittal knee moment (2) of the prosthetic side; mean sagittal knee angle (3) and mean sagittal knee moment (4) of the contralaeral side.

(BW) and for the Rheo Knee XC 169.4 ± 16.2% BW (p = 0.345). The contralateral maximum knee flexion moment during the first half of the stance phase differed significantly (C-Leg 0.19 ± 0.24 Nm/kg; Rheo Knee XC 0.52 ± 0.18 Nm/kg; p = 0.046) (Figure 2).

Walking on slopes

Descending

Time-distance parameter

Walking speed was 0.09 m/s faster with the C-Leg compared to the Rheo Knee XC (C-Leg 0.59 ± 0.02 m/s; Rheo Knee XC 0.50 ± 0.06 m/s; p = 0.028). The stance phase duration of the prosthetic side was 1.4% longer with Rheo Knee XC (C-Leg 57.3 ± 1.5%; Rheo Knee XC 58.7 ± 2.2%; p = 0.046).

Kinematics

Prosthetic side

In mid-stance, the Rheo Knee XC initially flexed slower but from approximately 34% of the motion cycle it flexed faster than the C-Leg. The maximum flexion velocity was 160.9 ± 16.5°/s for the Rheo Knee XC and 145.1 ± 16.2°/s for the C-Leg (p = 0.116). The maximum knee flexion angle of the Rheo Knee XC was 4.8° smaller compared to the C-Leg (63.0 ± 1.0° vs. 67.8 ± 5.9°; p = 0.075). The knee extension in the swing phase was faster for the C-Leg than for the Rheo Knee XC (C-Leg 373.1 ± 48.6°/s; Rheo Knee XC 291.6 ± 36.9°/s; p = 0.028) (Figure 3).

At heel strike and at the end of the swing phase, the thigh segment angle was slightly more extended with the Rheo Knee XC compared to the C-Leg. Between 75% and 100% of the gait cycle, the extension of the thigh segment differed significantly (Rheo Knee XC 6.8 ± 2.0°; C-Leg 4.4 ± 2.7°; p = 0.028) (Figure 3).

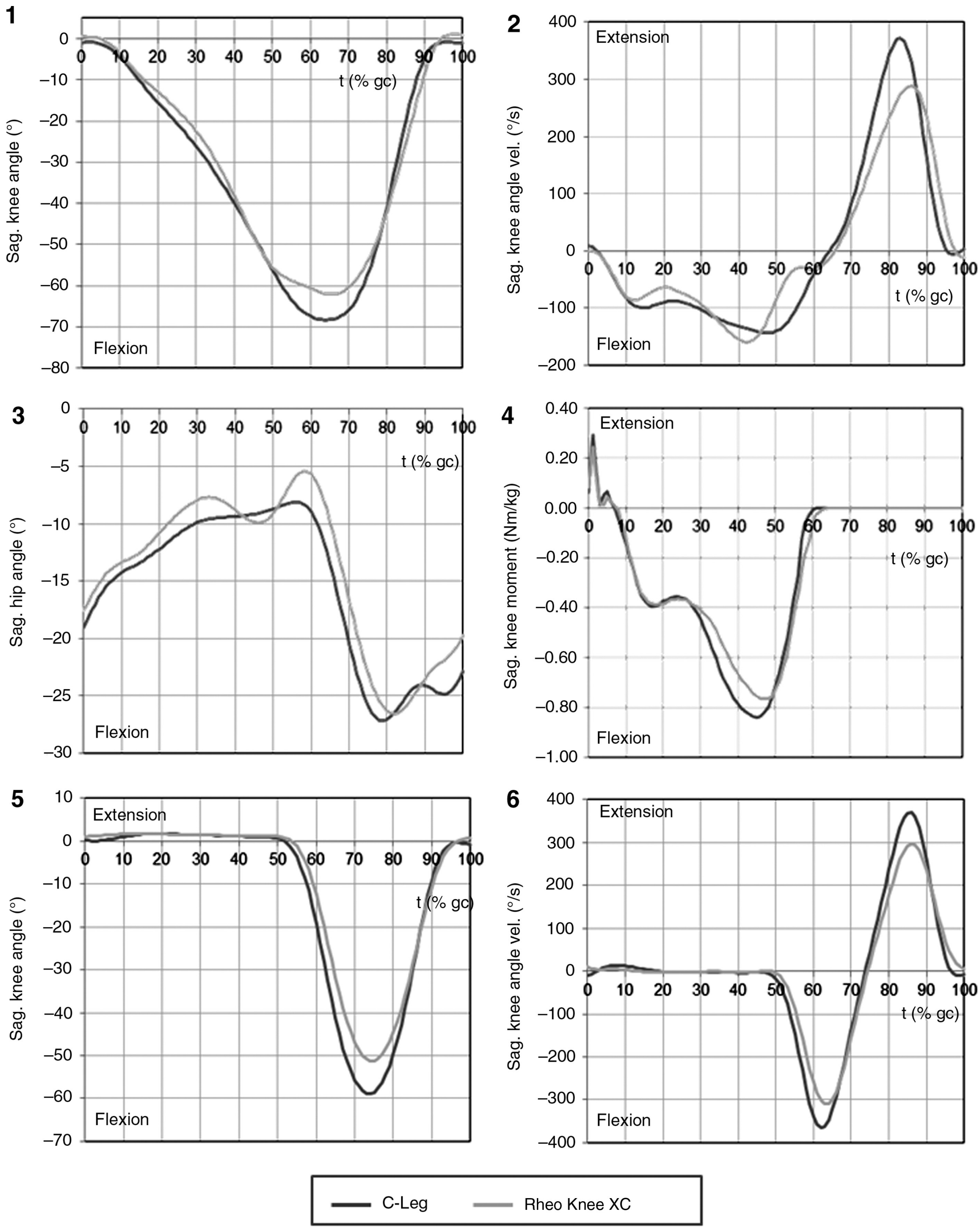

Figure 3: Descending slopes: mean sagittal knee angle (1), mean sagittal angular velocity of the knee (2), mean thigh segment angle (3), mean sagittal knee moment (4), all prosthetic side. Ascending slopes: mean sagittal knee angle (5) and mean sagittal angular velocity of the knee (6), both prosthetic side.

Kinetics

Prosthetic side

From approximately 30% of the gait cycle, the knee flexion moment of the C-Leg was greater compared to the Rheo Knee XC (C-Leg 0.85 ± 0.11 Nm/kg; Rheo Knee XC 0.77 ± 0.07 Nm/kg; $p = 0.046$) (Figure 3).

Contralateral side

On the contralateral side, the maximum vertical ground reaction force was comparable (117.2 ± 4.1% BW for the Rheo Knee XC; 122.1 ± 5.4% BW for the C-Leg; $p = 0.345$).

Ascending

Time-distance parameters

The walking speeds were comparable for both joints (C-Leg 0.56 ± 0.04 m/s; Rheo Knee XC 0.52 ± 0.04 m/s; $p = 0.075$). For the Rheo Knee XC, the stance phase duration on the prosthetic side was 1.7% longer than with the C-Leg (62.4 ± 3.0% vs. 60.7 ± 2.6%; $p = 0.116$).

Kinematics

Prosthetic side

The Rheo Knee XC achieved a significantly smaller maximum knee flexion angle than the C-Leg (54.7 ± 5.7° vs. 61.7 ± 8.4°; $p = 0.028$). In the terminal swing phase, the extension was slower for the Rheo Knee XC. At 100% of the motion cycle, the joint was still in extension motion (Figure 3). The maximum angular knee flexion velocity differed significantly (C-Leg 406.5 ± 63.9°/s; Rheo Knee XC 367.1 ± 50.8°/s; $p = 0.028$) as well as the angular knee extension velocity (C-Leg 377.9 ± 91.1°/s; Rheo Knee XC 314.6 ± 69.5°/s; $p = 0.028$) (Figure 3).

Walking backwards

With the Rheo Knee XC, an undesirable knee flexion sometimes occurred during the swing phase when stepping backwards with the prosthesis resulting in a preflexed position at ground contact and followed by an uncontrolled knee flexion. It was irrelevant whether the first step was performed with the prosthetic or the contralateral side. With the C-Leg, the prosthesis allowed reliable load bearing for all backwards steps.

Two individual trials of subject #5 were considered as examples (Figure 4). The Rheo Knee XC flexed during the step with the prosthesis backwards (Figure 4, top: phases 1–3). At ground contact the knee flexion angle was approximately 32° (phase 4) followed by an uncontrolled flexion up to a maximum knee flexion angle of approximately 100° (phases 5–6). A maximum knee angular velocity of approximately 272°/s occurred and the subject was saved from falling by the safety harness. The C-Leg flexed minimally during the backwards step with the prosthesis (Figure 4, bottom: phases 1–3) and achieved a knee flexion angle of approximately 1° at ground contact (phase 4). It remained extended during single limb stance on the prosthetic side (phases 5–6).

Toe tripping during the swing phase

Table 3 shows all single trials with manually induced perturbation of the swing phase extension. According to the sagittal knee angle of the prosthesis during prosthetic side ground contact, the trials were arranged into two angular areas:

Knee angles below 40° at ground contact: For both knee joints, compensatory movements at knee angles greater than 25° were found. The number of trials with compensation was smaller for the C-Leg. For knee angles up to 40°, an extension was evident in approximately all trials for the C-Leg. For the Rheo Knee XC, extension was observed for fewer trials.

Knee angles above 40° at ground contact: With the C-Leg, only one trial for a knee angle greater than 50° led to a fall. In almost half of the trials (seven out of 15), the C-Leg could still be extended. With the Rheo Knee XC, an extension could not be performed for a knee angle greater than 40°. Most of the trials (11 out of 15) led to a fall.

Discussion

The results of this study suggest that safety-relevant differences can partly be explained by the fundamentally different technological concepts of these two microprocessor-controlled prosthetic knee joints. Nevertheless, functional improvements as compared to previous technological standards of these knee joints can be found for both products in certain situations.

Prosthetic alignment next to functioning of the prosthetic knee joint has a significant influence on the biomechanical performance of a prosthesis [33, 34]. In order to attribute functional differences of the knee joints exclusively to their properties, an identical prosthetic alignment

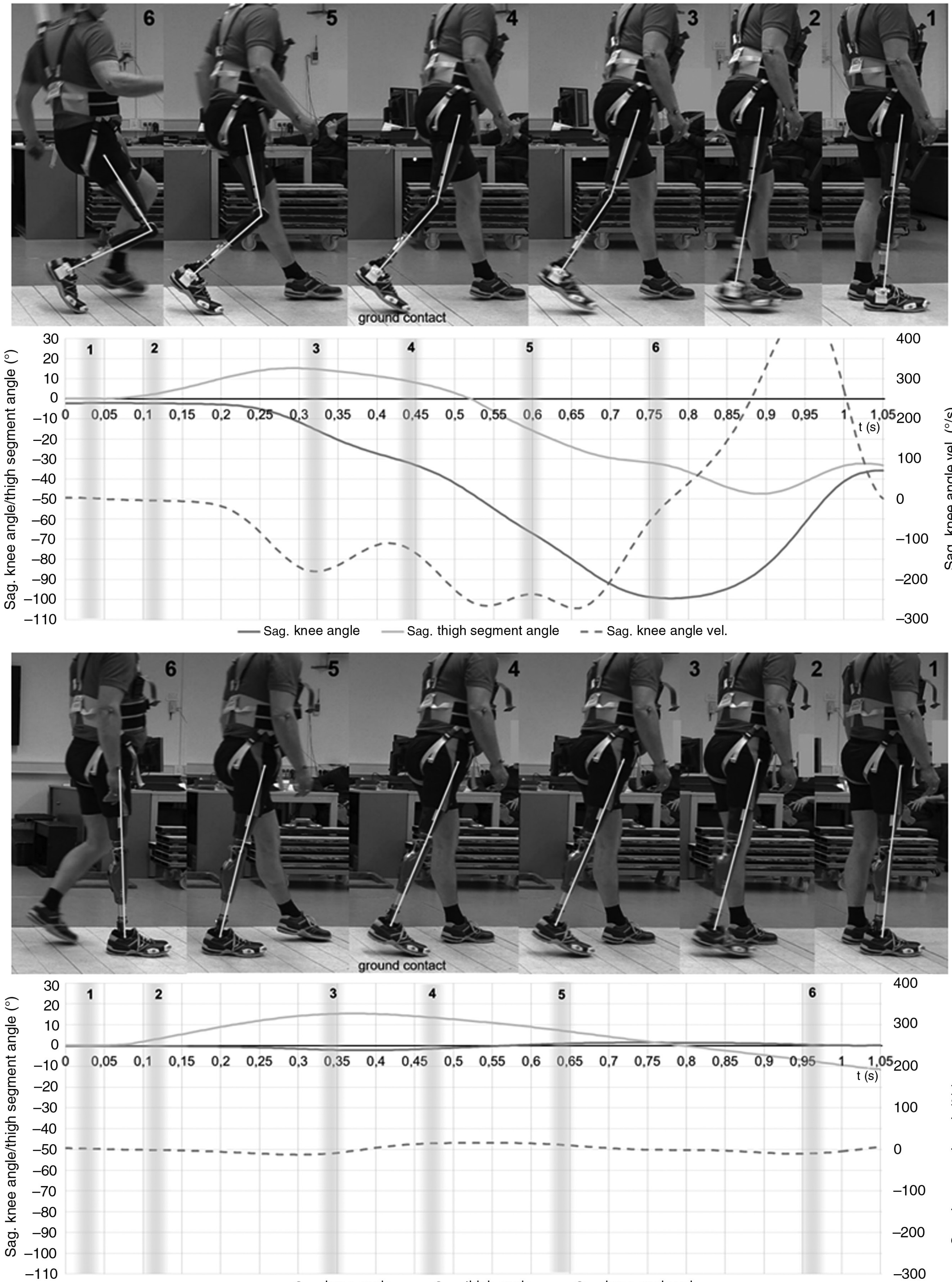

Figure 4: Phase images of a single trial (subject #5) when reversing with Rheo Knee XC (top) and C-Leg (bottom) with specification of the sagittal knee angles, thigh segment angles and the angular velocity of the knee; the individual phases are marked with the corresponding numbers in the diagrams.

Table 3: Single trials of test scenario “perturbations during swing phase”; contact angle and ground contact indicate the knee flexion angle at the event of prosthetic side ground contact after the perturbation of the swing phase extension (in degrees), knee extension describes whether full extension was achieved, compensation/fall indicates the final result of the individual trial.

Rheo Knee XC				C-Leg			
Subject	**Ground contact (°)**	**Knee extension**	**Compensation/fall**	**Subject**	**Ground contact (°)**	**Knee extension**	**Compensation/fall**
Contact angle <40°							
4	13.4	x		6	4.5	x	
6	20.2	x		6	7.0	x	
1	21.4			4	8.8	x	
5	22.4	x		4	18.0	x	
2	24.2	x		1	24.5	x	
3	25.7	x		3	26.3	x	
6	27.8	x	Compensation	4	26.7	x	
1	29.4			4	27.1	x	Compensation
1	31.6		Compensation	6	27.3	x	
5	33.1	x	Compensation	2	28.4	x	
2	33.3	x		4	30.2	x	Compensation
6	34.4		Compensation	3	30.8	x	Compensation
5	34.6	x	Compensation	6	32.0	x	
2	34.7	x	Compensation	5	32.7	x	
3	34.9	x	Compensation	6	32.9	x	Compensation
4	35.1	x	Compensation	6	33.0	x	Compensation
1	36.3		Compensation	4	33.6	x	Compensation
3	36.4		Compensation	5	34.3	x	
2	37.1		Compensation	4	34.7	x	Compensation
4	37.2	x	Compensation	6	37.0	x	
1	37.3		Compensation	6	37.0		Compensation
2	37.4		Compensation	3	37.7	x	
6	37.9	x		1	37.9		Compensation
5	39.8	x	Compensation	4	39.6	x	Compensation
Contact angle >40°							
2	40.4		Compensation	5	40.1	x	
6	41.9		Fall	6	40.2		Compensation
5	42.4		Compensation	2	40.4		Compensation
4	42.5		Fall	3	42.5	x	Compensation
3	42.9		Fall	5	42.7	x	
6	43.0		Fall	3	42.8		Compensation
3	43.8		Compensation	2	44.0	x	
1	44.4		Fall	5	44.7	x	
2	44.5		Compensation	5	44.9	x	
4	44.6		Fall	3	45.8	x	Compensation
2	45.1		Fall	2	47.7		Compensation
5	46.1		Fall	1	48.3		Compensation
3	47.2		Fall	1	51.1		Fall
5	51.6		Fall	1	52.4		Compensation
1	51.9		Fall	5	53.1		Compensation

is mandatory for comparative biomechanical studies. The results of the alignment analysis of this study show that this basic requirement was met across all subjects and joints. Also, the acclimation time of a few hours seems to be sufficient for the transition between microprocessor-controlled knee joints which do not need specific motor control strategies of the patient to use functions like, e.g. walking down stairs and ramps alternatingly. This is confirmed by published biomechanical data [29]. Longer acclimation times of up to 3 months might be expected for the transition from a mechanical knee joint to a microprocessor-controlled knee joint [8] if entirely new motion or walking patterns are required to get used to different knee joint functions.

When walking with small steps or slower walking speed, insufficient ground clearance during the prosthetic side swing phase is a safety risk for transfemoral amputees. This is mainly affected by an incorrectly triggered swing phase flexion resistance and a knee flexion angle of less than 40°. The maximum knee flexion angle on the prosthetic side tends to be lower compared to average walking speeds over 1 m/s. Minor differences in the flexion angle significantly affect ground clearance [35]. A prosthetic knee joint, which achieves a greater knee flexion angle even at slow walking speeds or when walking with small steps, indirectly provides more safety for the amputee. Almost the same knee flexion angle was achieved for both knee joints during the swing phase. One of the switching criteria of the C-Leg for stance phase release is the forward tilt angle. The necessary amount of forward tilt might not be reached consistently while walking with small steps. One reason might be an incomplete stump extension at the end of mid-stance, which correlates with a reduced forward tilt of the entire prosthesis. In about 90% of the steps, the C-Leg switches into the swing phase. Nevertheless, compared with formerly published results, the control strategy of the current C-Leg provides an improvement [16]. The Rheo Knee XC switches reliably into the swing phase for all small steps. Consequently, the “default swing” principle appears to offer advantages in terms of stance phase release in this specific gait situation.

While descending stairs or slopes, yielding knee joints must meet the following safety-relevant criteria [14–17, 31]:

1. For an exact positioning of the prosthetic foot on the stair (middle of the foot on the edge of the stair), the prosthetic knee joint must extend reproducibly at the end of the swing phase.
2. A consistent internal flexion resistance must be generated to ensure a high load-bearing capacity of the prosthesis during the prosthetic single support stance phase. Thus, during the subsequent stair contact the unaffected side is loaded less.
3. The flexion resistance must be activated before prosthetic side ground contact.

In this context, these two technological concepts differ significantly. The C-Leg meets all mentioned criteria. In the Rheo Knee XC, the underlying default swing principle does not switch to a higher flexion resistance before a defined axial load is applied at ground contact. Furthermore, the extension stop is not reached reliably. Due to the unpredictable extension position of the Rheo Knee XC at the end of the swing phase, the subjects might not be able to position the prosthetic foot exactly on the stair as required. This may lead to an inconsistent flexion behavior and insecurity during stair/slope negotiation. Consequently, three of the six test subjects decided to use the handrail of the stairs to increase the perceived safety during the measurements. There are two potential reasons for the inadequate extension motion. Either the installed extension spring is too weak or the swing phase extension resistance is too high. The latter can be adjusted in the Rheo Knee XC software and has been set to the minimum for all participants. Essentially, to achieve full extension, a consciously executed compensatory extension movement of the residual limb before heel strike was performed. Due to the inertia of the shank segment, it was possible to partially reach the final extension position.

The characteristics of the stance phase flexion resistance are different. The Rheo Knee XC generates a higher resistance at initial contact, but a lower resistance at the end of the stance phase. However, the linear hydraulics implemented in the C-Leg creates a progressively increasing resistance at the end of the yielding phase. These different flexion characteristics had an impact on the contralateral side. Due to the lower resistance level of the Rheo Knee XC at the end of the stance phase, the load-bearing capacity of the prosthesis was reduced, inducing higher loads of the unaffected side. As a result, knee flexion angle, knee flexion moment and vertical ground reaction force for the contralateral side during the first half of the stance phase were increased while descending stairs. Compared to previously published data, higher maximum external knee flexion moments at the end of the stance phase were found for both knee joints [15]. This correlates with higher flexion resistance values and thus higher load-bearing capacities. Consequently, the characteristics of the resistance in combination with a reproducible and reliable extension position provide a higher safety potential for the C-Leg technology while descending stairs.

Like walking on stairs, the Rheo Knee XC produced less flexion resistance than the C-Leg at the end of the stance phase when walking down a slope. An initially high resistance, which decreases noticeably during flexion, was measured and perceived when walking with the Rheo Knee XC. The low angular knee extension velocity of the Rheo Knee XC during swing was detected in this gait situation as well. This confirms a restricted extension movement the amputees had to actively compensate. In terminal swing, subjects performed a compensatory extension of the thigh segment in order to reach the required extension stop. The load on the unaffected side tends to be slightly higher when walking down the slope with the C-leg. This can be explained by the higher walking speed chosen by the subjects, which has a direct influence on the prosthetic and contralateral side kinetics.

The technological differences also influence the biomechanical outcome when walking up the slope. Although walking speed was comparable with the data recorded for the C-Leg, the Rheo Knee XC flexed slower in the swing phase and reached a significantly lower mean maximum knee flexion angle which may lead to a reduced ground clearance. Thus, the risk of stumbling may be increased. Again, the Rheo Knee XC extended slower in the terminal swing phase and reached the extension position just before heel strike.

In all daily-life situations, also when walking backwards, precisely designed criteria for switching between stance and swing phase resistance are an essential safety feature for transfemoral amputees. Mostly, the amputee cannot compensate for a lack of high stance phase flexion resistance, resulting in a joint collapse and thus in a fall [32]. Walking backwards showed a marked safety-relevant disadvantage of the basic "default swing" mode used in the Rheo Knee XC concept. Once the axial load of the prosthesis decreases below the threshold, the knee joint switches into low swing phase resistance. If the amputee moves the prosthesis backwards during the swing phase, the shank segment may flex before ground contact due to inertia. With a flexed knee joint, the ground reaction force vector is located more posteriorly at ground contact and thus a knee flexion moment may occur. The axial load threshold was not always exceeded, and the knee joint did not provide a sufficient flexion resistance in this phase. As a result the prosthesis collapsed. This effect was further enhanced by the residual limb flexion to accelerate the body's center of gravity posterior shortly after ground contact (Figure 4) as it is required for walking backwards step over step. For the C-Leg, at least two switching criteria like forward movement and rotation were not met when walking backwards. Therefore, the joint remains in the stance phase mode with high flexion resistance and thus the prosthesis offers a reliable load-bearing.

After a perturbed swing phase extension movement such as tripping, the risk of falling depends on several factors. These are primarily:

1. Knee angle during subsequent ground contact of the prosthetic side
2. Responsiveness of the amputee
3. Performance capacity of the residual limb including muscle strength and limb length
4. Features of the prosthetic knee joint

A greater knee flexion angle at ground contact after perturbation of the swing phase extension requires a stronger counteraction by compensatory movements of the amputee in order to prevent a fall. However, the extent of compensation depends on the amputee's responsiveness and physical condition. Typically, the amputee tries to fully extend the knee joint with a strong and quick extension of the residual limb immediately after the perturbation in order to safely load the prosthesis. Amputees with a long residual limb and good muscular conditions have advantages. To extend the knee as quickly as possible, the knee joint must provide a low extension resistance. However, if the amputee's responsiveness and stump conditions are weak and the knee joint cannot be extended actively by stump extension, a high flexion resistance should provide sufficient load-bearing capacity to prevent uncontrolled knee flexion [15]. Shortly after ground contact of the flexed prosthesis, both knee joints reliably provide a high flexion resistance although the load-bearing capacity differs. In this situation, the C-Leg has a pre-defined higher flexion resistance compared to the adjusted stance phase flexion resistance [24]. As a result, knee flexion appears comparatively slower, leaving more time to prevent a fall by compensating with the contralateral side. Furthermore, the linear hydraulic system used in the C-Leg simultaneously provides a low resistance in the direction of extension. Thus, an extension of the knee joint is immediately possible. Therefore, a reliable knee joint extension can be performed up to a flexion angle of approximately 46° at ground contact if the amputee is physically capable. Only for a knee angle above 50° the prosthesis did not perform reliably to prevent a fall. On the other hand, the magnetorheological principle of the Rheo Knee XC generates a high resistance in both the direction of flexion and extension simultaneously. As a result, the knee joint extension appears to be more difficult compared to the C-Leg. The Rheo Knee XC can be extended up to approximately 35°. Knee angles at ground contact above 40° seem to be safety-critical for this knee joint concept. However, in comparison to previous studies with former versions of these knee joints, compensation of greater knee angles at ground contact was achieved [15, 17].

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 load-bearing 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.

Author Statements

Ethical conduct of research: We confirm that this study was conducted in compliance with the World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Ethics approval was granted by the ethics committee of the Medical University of Göttingen (no. 7/10/16). **CE-conformity:** All tested knee joints and other prosthetic components used in this study are CE-certified. **Conflict of interest:** Malte Bellmann, Thomas Maximilian Köhler and Thomas Schmalz work in the Clinical Research & Services department, division of Biomechanics Research at Ottobock SE & Co. KGaA, Germany.

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