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A biomechanical study

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This article uses biomechanical parameters to compare the microprocessor-controlled C-Brace orthosis with conventional KAFO orthoses while walking on level ground and descending slopes and stairs. The tests were conducted on 6 patients with varying underlying diseases (previous device: 4 SCOs, 2 locked KAFOs). The results show that knee flexion under weight bearing that was first made possible by the C-Brace was used with a high degree of confidence. This makes it possible to descend slopes and stairs step over step with a nearly physiological gait. The stance phase flexion detected in the majority of cases and the microprocessor-based control of the swing phase enable a more harmonious gait pattern while walking on level ground at variable speeds.

Key words:
microprocessor-controlled orthosis, orthotics, biomechanics, gait analysis

Introduction

In the past, a knee-ankle-foot orthosis (KAFO) with a complete knee lock was often used as an orthotic device for patients with paresis and paralysis of the lower limb. This "classical" principle of complete rigidity of the leg ensures the patients' safety while walking, but is associated with proven biomechanical and metabolic disadvantages. They include perceptible excessive strain on the musculoskeletal system [1] and abnormally high metabolic energy demand [2].

The stance-control orthoses (SCO) with the knee locked only in the stance phase and unlocked in the swing phase that have been available for around 10 years allow a more natural movement pattern in level walking and thus a measurable reduction of the disadvantages of conventional systems [3]. The most important functional limitation of these orthoses for the patient's daily life is that no dampened knee flexion under load is possible. This means that movement patterns that are important for everyday activities such as a nearly natural step-over-step descent of ramps and stairs or sitting down while loading the orthosis are not possible.

The newly developed C-Brace (Fig. 1) is the first orthotronic mobility system available that reduces the functional limitations of the SCO. The microprocessor-controlled hydraulic unit integrated in the C-Brace makes individually adapted movement resistance available in the knee joint for all routine motor activities. This allows, for example, step-over-step descent of ramps and stairs with specific damping of knee flexion, speed adjusted control of the swing phase and a reduced risk of falling.

Fig. 1 Patient with C-Brace.

The design details of the C-Brace and initial patient experiences have already been reported in an earlier study [4]. This article presents the results of biomechanical tests of movement patterns in daily life, which are used to compare the functions of conventional leg orthoses (complete knee lock and SCO) with those of the C-Brace.

The discussion of the results of the measurements focuses on the additional benefit to patients from the technical innovations of the C-Brace.

Patient number [#]	Gender	Age [years]	Height [cm]	Weight [kg]	Disorder	Side affected	Muscle status of the affected side 						Previous orthosis	Use of C-Brace [weeks]
1	M	61	176	89	Poliomyelitis	L	5	4-5	0	4-5	4	1	SCO (Neurotronic)	7
2	M	70	176	74	Disc herniation	R	3	3	0	0	0	0	SCO (E-MAG Active)	10
3	M	32	156	68	incomplete paraplegia	L	2	3	0	0	0	0	SCO (E-MAG Active)	30
4	F	56	168	66	Lesion of the femoral nerve after tumour removal	L	4	2	0	3	2-3	3	SCO (E-MAG Active)	7
5	F	59	160	72	Poliomyelitis	R	0	0	0	1-2	0	0	Locked KAFO	10
6	F	57	150	51	incomplete paraplegia	Both re:	1-2	0	1	1	1	0	Locked KAFO	7
						li:	1	0	1	1	1	0		
Mean:		56	164	70										12
SD:		13	11	12										9

***Tab. 1** Individual patient data.*

Methods

Patients and control group

Six patients with various underlying diseases and clinical symptoms who previously used a KAFO orthosis in their daily activities took part in the study. Four of the patients had used an SCO system (unilateral). Two patients could not be fitted with an SCO for reasons of safety and therefore used a KAFO orthosis with a completely locked knee joint (one unilateral and one bilateral). Details of the patients, including the status of the main muscle groups in the lower limb, are summarised in Table 1.

For the general assessment of the results, data were available from an earlier study of an orthopaedically and neurologically unremarkable control group using identical measuring methods [5].

C-Brace orthotronic mobility system

The C-Brace orthotronic mobility system (see Fig. 1) is a custom fabricated KAFO with a microprocessor-controlled knee joint. By means of a knee angle sensor and a system of strain gauges attached to a carbon fibre composite spring spanning the ankle, three essential biomechanical parameters are continuously recorded: knee angle, knee angle velocity, and ankle moment. These data are used to identify the current phase of movement and control a linear hydraulic unit. With a working frequency of 50 Hz, the required movement resistances of the knee joint are adjusted depending on movement and speed. This means that knee flexion under loading and swing phase control can be individually optimised. A more comprehensive discussion of the technical principles is provided in the earlier study cited above [4].

Examinations conducted

All patients examined were fitted with the C-Brace during the controlled market launch of the system. In an initial examination in the laboratory, the biomechanical tests were first conducted with the previous orthosis. These tests consisted of a gait analysis of level walking at a self-selected speed. Since one patient (patient number 4 in Tab. 1) could vary walking speed perceptibly, the gait analysis was conducted at her self-selected speed and at slower and faster speeds. For patients who were able to negotiate ramps or stairs step over step, these movement patterns were also recorded.

After these tests, the patients were fitted with the C-Brace and were trained for several hours in the functions of the system by a physiotherapist. The patients then used this orthosis in their daily lives for several weeks. After this period, all tests were repeated in a second analysis in the laboratory using this orthosis. Due to organisational reasons, a uniform test time was not possible. The length of each test phase is indicated in Table 1.

Measuring technology and data processing

Ground reaction forces acting during level walking were measured using two force measurement plates (9287A Kistler, Kistler, Winterthur, Switzerland, scanning rate 1080 Hz). The kinematics of movement were measured by recording the trajectories of passive markers using an optoelectronic camera system (460 Vicon, Vicon, Oxford, UK; scanning rate 120 Hz). For this, 14 markers from a specially developed model were used [6, 7].

Ambulating stairs was measured on a five-step test setup. The middle step was connected to a measuring plate so that the ground reaction force could be measured on contact with the step. The test ramp (slope 10°) was 5 m long. An element located in the middle was connected with the force plate so the ground reaction force could be measured at this point as well. A detailed description of the test setup for stairs and ramps is provided in an earlier study [8].

Eight to ten gait cycles were measured for each of the movement patterns examined. The sagittal joint angle was calculated using the marker data. The external joint moments were determined using kinematic data and ground reaction forces. Specially developed programs (Vicon Body Language 3.5) were used for all calculations.

Individual mean values of a standardised gait cycle were formed for all biomechanical parameters. Local peak values over time were also extracted. Due to the different functional options of the previous orthoses and the relatively small number of patients, we dispensed with a comparison of the group mean values using a statistical analysis for the comparison of the biomechanical parameters of the previous orthosis and the C-Brace. The same applies to the comparison of the parameters between the patients and the control group due to the different velocities. A comparison based on a statistical analysis was conside-

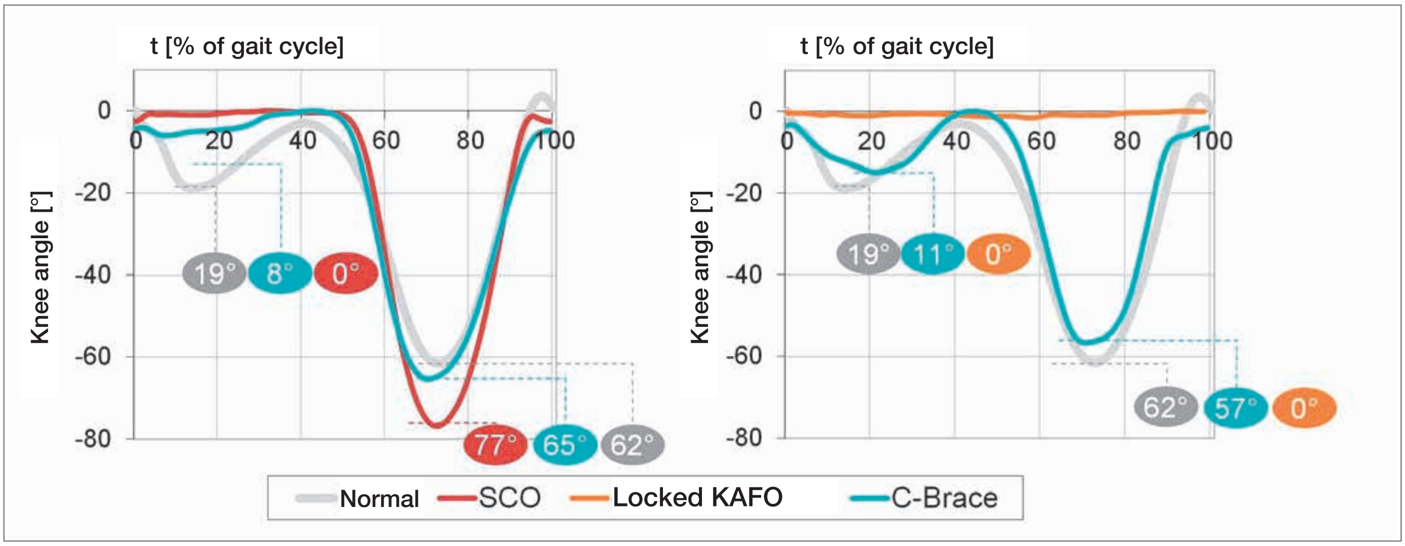

Fig. 2 Examples of knee angle comparisons between the C-Brace and the previous orthosis indicating the maximum flexion angle in the stance and swing phase (left: patient previously fitted with an SCO orthosis [E-MAG Active], right: patient previously fitted with a locked KAFO orthosis).

red to be useful only for the time-distance parameters and was conducted using the Wilcoxon test.

Results

Level walking

On average, the patients used an almost identical walking speed with both orthoses – previous orthosis 1.12 (mean) ± 0.10 (standard deviation) m/s; C-Brace 1.11 ± 0.10 m/s – significantly slower than the control group (1.45 ± 0.11 m/s, $p < 0.01$). The stride length asymmetry (difference in stride lengths between the affected and the non-affected side) was also significantly increased by a similar magnitude in both situations (previous orthosis 0.06 ± 0.04 m; C-Brace 0.05 ± 0.04 m; $p < 0.01$) in comparison with the control group (natural right-left difference 0.02 ± 0.01 m).

The knee angles measured on the orthosis side show that the knee flexion under loading made possible by the C-Brace was utilised by 5 of 7 limbs fitted with the orthosis (4 of 6 patients) with a mean of 11.0 ± 5.6°. The mean swing phase flexion angle for all C-Brace orthotronic mobility system was 66.6 ± 8.5°. A mean flexion angle of 74.0 ± 6.4° was measured for the 4 SCO systems. Two different examples of knee angle comparisons between the C-Brace and the previous orthosis are presented in Figure 2.

There were sustained high hip moments in the stance phase on the orthosis side for all patients regardless of the fitting. With respect to the mean maximum value of the flexion moment acting in the early stance phase, slightly higher values were measured with the microprocessor-controlled orthosis compared with the SCO (0.72 ± 0.12 vs. 0.62 ± 0.05 Nm/kg), lower values compared with the locked orthosis (0.55 ± 0.15 vs. 0.68 ± 0.02 Nm/kg). The measurable extension moment immediately before initiation of the swing phase was uniformly reduced with the C-Brace in comparison with the previous orthosis (-0.21 ± 0.31 vs. -0.36 ± 0.30 Nm/kg [SCO] and -0.41 ± 0.24 vs. -0.53 ± 0.25 Nm/kg [locked KAFO]).

With respect to the joint moments of the major joints of the sound side – indicators of load in the musculoskeletal system [1] – only slight differences were measured uniformly in the 5 unilateral patients when comparing the C-Brace with the SCO system. Pronounced changes, especially in the hip joint, were found in the patient previously fitted unilaterally with a locked orthosis. The maximum value of the flexion moment acting after the early stance phase was reduced from an extremely high level of 1.24 Nm/kg (complete lock) to 0.60 Nm/kg (C-Brace), that of the extension moment before the start of the swing phase from 0.49 Nm/kg to 0.06 Nm/kg.

The changes in knee angles in tests at various walking speeds conducted on one patient are documented in Figure 3. The patient walked with the C-Brace at speeds between 0.74 and 1.44 m/s; the maximum flexion angle in the swing phase varied between 59 and 70°. With the SCO system (E-MAG Active), the patient could not trigger the swing phase function at her selected low speed of 0.73 m/s. The medium and high speeds were 0.96 and 1.35 m/s. In this range, the swing phase flexion angle varied between 58 and 70°.

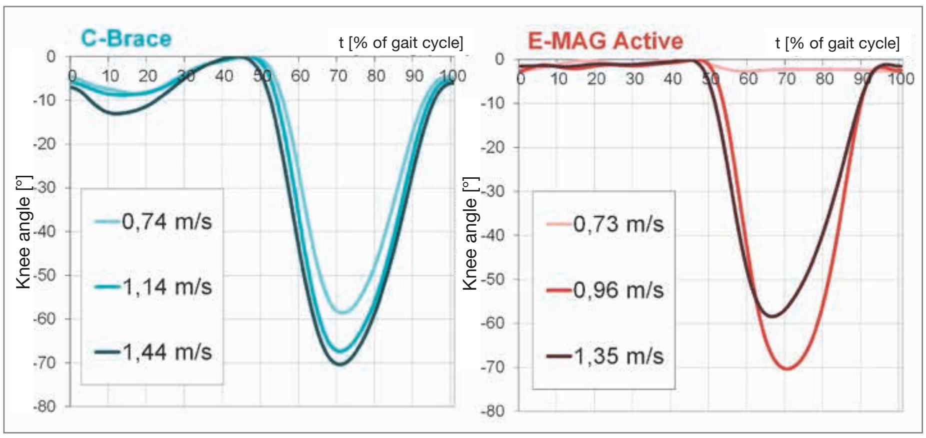

Fig. 3 Changes in knee angles during level walking at different walking speeds.

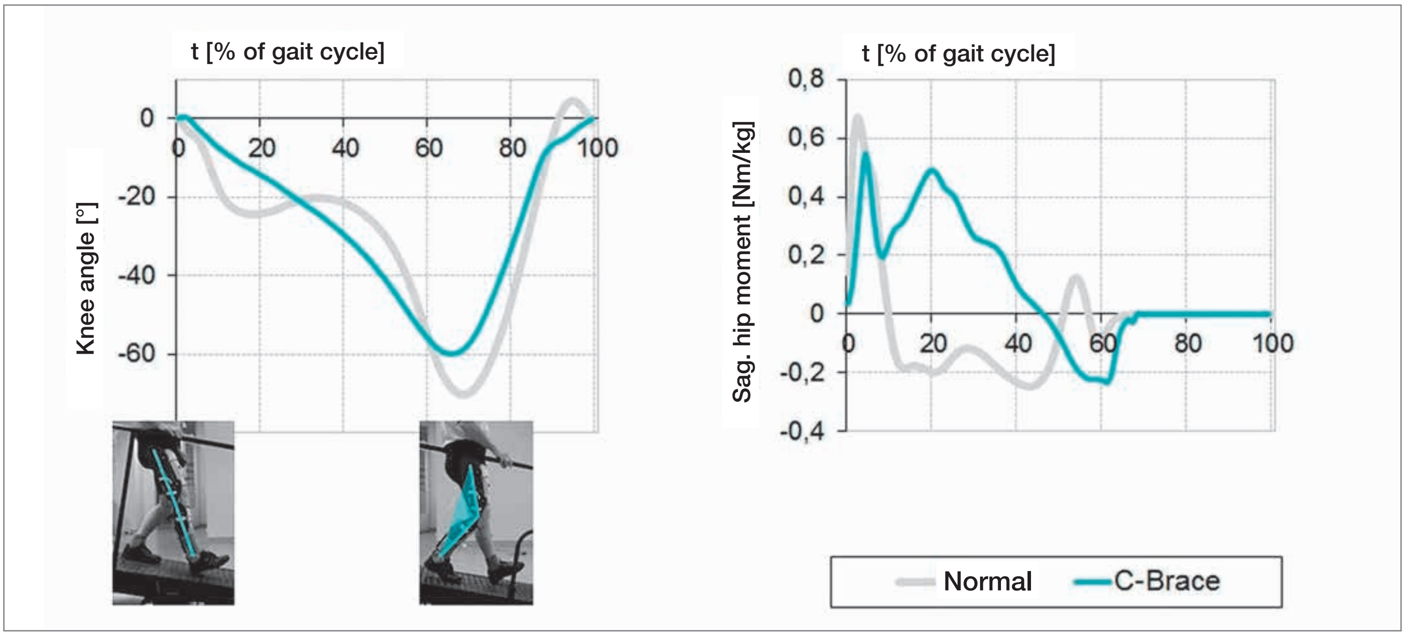

Fig. 4 Example of the knee angles (left) and hip moment on the orthosis side when descending a ramp with a 10° slope (patient's previous orthosis: SCO).

Ramp
Two patients who were fitted with an SCO and both patients with a locked KAFO were able to descend a ramp step over step. However, due to sustained knee extension in the stance phase, they needed drastic compensation movements; the use of a handrail was necessary. With a microprocessor-controlled orthosis, all patients were able to perform this movement nearly normally; one patient used a handrail. Since the C-Brace is the only orthosis designed to enable a movement pattern that closely approaches the natural pattern, only biomechanical data measured with this orthosis are compared with normal measurements.

The patients walked on the ramp at a significantly reduced mean speed in comparison with the control group (0.89 ± 0.15 m/s vs. 1.40 ± 0.15 m/s; $p < 0.01$); there was also a significant increase in the mean asymmetry of stride lengths (0.13 ± 0.09 m vs. 0.02 ± 0.01 m, $p < 0.01$).

The knee angles measured on the orthosis side showed that the patients utilised the possibility of knee flexion under loading with this orthosis. In all cases, continous knee flexion was measured in early stance phase as in the individual example in Figure 4 (left). In comparison with the control group, the mean maximum flexion angle was reduced by approx. 10° (64.6 ± 8.2° vs. 75.8 ± 4.8°). With respect to the hip moment on the orthosis side, an effect similar to that of level walking was measured. Unlike the moments measured in healthy individuals, a continuously high moment in the stance phase was found for all patients, see Fig. 4 (right). The maximum values of the vertical ground reaction force measured on the healthy side and the external joint moments, which according to earlier studies are reliable indicators of the load of the musculoskeletal system from prostheses when using ramps and slopes [9], were all lower than in healthy individuals (Tab. 2).

Stairs
No patient was able to use stairs in a step-over-step technique with the previous orthosis. When using the C-Brace, every patient was able to do so with the aid of a handrail. The biomechanical evaluation of the parameters measured with this orthosis is therefore again made based on the comparison with the control group.

The knee joint angles measured on the orthosis side with the C-Brace are qualitatively similar to normal values regardless of the previous orthosis. Continuous flexion under load begins in the early stance phase until the maximum flexion angle is reached. This is again illustrated using a patient ex-

			Descending a ramp		Descending stairs	
			C-Brace	Normal	C-Brace	Normal
	Max. hip moment in flexion	[Nm/kg]	0.56 (0.13)	0.73 (0.2)	0.68 (0.16)	0.76 (0.27)
	Max. knee moment in flexion	[Nm/kg]	0.71 (0.35)	1.01 (0.26)	1.08 (0.4)	0.88 (0.25)
	Max. ankle moment in dorsiflexion	[Nm/kg]	1.14 (0.24)	1.44 (0.16)	1.10 (0.11)	1.29 (0.24)
	Max. vertical ground reaction force	[% BW]	121 (10)	128 (8)	130 (4)	131 (5)

***Tab. 2** Mean maximum values (standard deviation) of the external joint moments and vertical ground reaction force of the contralateral limb when descending a ramp (slope 10°) and stairs.*

ample, (Fig. 5, left). The mean maximum knee flexion angle was reduced by nearly 15° (70.5 ± 12.4° vs. 85.4 ± 6.2°). The analysis of the hip moment acting on the orthosis side showed an effect similar to that of ambulating ramps. The maximum value occurring in the early stance phase was reduced (0.68 ± 0.22 Nm/kg vs. 0.76 ± 0.27 Nm/kg), however, unlike the movement pattern of healthy individuals, relatively high moments acted later, especially between 15 and 40% of the gait cycle. This is also illustrated using a patient example (Fig. 5, right). The maximum values of the biomechanical parameters of the sound limb were reduced in comparison with the reference values of healthy individuals; the sole exception was the maximum knee flexion moment (-1.08 vs. 0.88 Nm/kg, Tab. 2).

Discussion

In this study, the benefits for patients derived from the technology of the C-Brace compared with previous KAFO orthoses are presented on the basis of the results of biomechanical tests. The new functions, resulting mainly from microprocessor-controlled knee joint resistance, must be discussed in relation to movement.

The stance phase flexion for level walking made possible by this new orthosis principle is utilised by the majority of patients and with a mean value of 11°; it largely corresponds with the physiological value, taking into consideration the lower walking speed in comparison with healthy individuals [10]. The two patients who did not use this function of the orthosis were the only subjects in the group with a high muscle strength level of the hip extensors (patients 1 and 4, Tab. 1). This muscle strength was possibly used with the previous orthoses to execute the necessary compensatory movement patterns, which were still not corrected even after several weeks of the adaptation phase with the C-Brace and thus "block" the initiation of stance phase flexion. This aspect makes it clear that due to the innovative orthosis functions, all newly-fitted patients should have accompanying physiotherapeutic support.

The hip moments on the orthosis side, which are at consistently high levels during the stance phase compared with the gait patterns of healthy individuals, indicate that changes in motor function are necessary regardless of the type of orthosis. As a consequence, control of the respective orthosis is achieved mainly by increased compensatory activity in the hip or trunk, which can be demonstrated most clearly by determining the kinetics of sagittal hip moment.

With respect to the clearly identifiable peak values, only the external extension moment that acts immediately at the end of the stance phase is substantially elevated in a completely locked KAFO. This is explained by the unavoidable increased effort needed to move the completely rigid limb to the swing phase. This effect is considerably reduced in this case using the C-Brace. Earlier studies show a similar effect for the comparison between an SCO and a completely locked KAFO [1].

The load on the sound side lower limb joints can be measured for all orthoses is drastically increased over normal values only for the hip joint with a completely locked orthosis and in this case indicates critically increased load on the musculoskeletal system. No such increased load was determined for previous fittings with an SCO or for the new orthosis. Initially, this applies strictly only to the walking speed measured. However, from the correlation of measured joint moments with walking speed determined in earlier studies [11], it can be concluded that there is no perceptible additional load to the musculoskeletal system in patients with an SCO or a microprocessor-controlled orthosis, even at a speed increased by approx. 0.3 m/s, which would then be equivalent to the speed of the normal group. Similar values are measured for joint stress in the direct comparison between the SCO and the C-Brace. This can be interpreted to be an indication that the use of the C-Brace, which weighs approx. 1 kg more than the SCO systems, did not have an unfavourable effect on the musculoskeletal system.

The individual tests at varied speeds showed the inherent potential of microprocessor-controlled swing phase control. The relatively slight change of 11° in the maximum flexion angle leads to a harmonious gait pattern in the speed range studied that is only slightly dependent on gait dynamics. This single example documents the fundamental limitations of the SCO system in this respect, among other things because the patient was not able to trigger the free swing phase at the low speed.

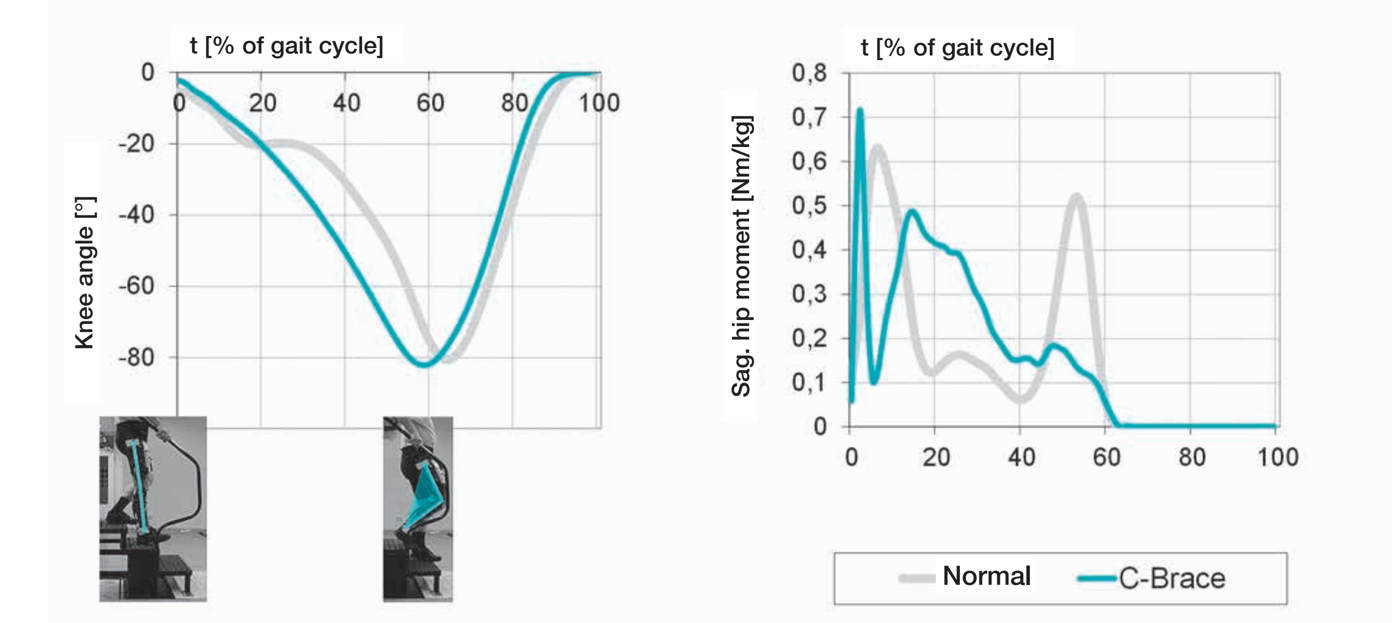

Fig. 5 Example of the knee angles (left) and hip moment on the orthosis side when descending stairs (patient's previous orthosis: SCO).

As was expected, the functional benefits of the new orthosis in comparison with the possibilities of previously known orthosis concepts were demonstrated most clearly for descending ramps and stairs. The step-over-step technique on the ramp observed in 4 patients with the previous orthosis requires an extremely unnatural movement pattern due to the absence of knee flexion under load, which leads to excessive load to the musculoskeletal system, especially in the ankle and knee joint [4]. The dampened knee flexion under loading with the C-Brace allows a nearly natural lowering of the body's centre of gravity. The peak values of the joint moments measured on the contralateral side are considered to be a reliable indication that the musculoskeletal system is subjected to nearly physiological stress when ambulating ramps with the C-Brace. The relatively high hip moments on the orthosis side measured both for level walking and when ambulating ramps and stairs indicate that the neuromuscular control of the innovative orthosis function must be achieved using compensatory muscle activity in the hip and trunk.

For ambulating stairs step over step, the design requires a specific movement technique to utilise knee flexion under loading. The edge of the step must be contacted by the midsection of the foot; the foot then "rolls" over the edge of the step. It is possible that this necessary movement technique sometimes results in higher contralateral joint moments that were detected to a small extent at the knee joint and correspond with a known effect in leg prostheses [9]. Despite this unavoidable compensation mechanism, in the movement patterns tested in this study, the most pronounced functional benefit for patients in comparison with all previously known orthosis concepts was found in step-over-step descent of stairs.

One noteworthy aspect was the high degree of confidence with which patients used the innovative orthosis function of knee flexion under load. This is demonstrated by the fact that the handrail was not generally used for ambulating on ramps, indicating a perceptible increase in safety potential when using the C-Brace orthotronic mobility system in comparison with all previously known KAFO concepts. This increased safety potential exists not only when descending stairs and ramps, but in other everyday situations as well, as flexion resistance is generally available. This thus reduces the danger of falls, for example due to stumbling or uneven ground.

Due to the increased safety of the new orthosis, it is anticipated that in the future, patients will be able to be fitted with it who were not able to use an SCO system. This applies, for example, to the two patients in this study who previously used a locked KAFO orthosis. The safety aspect is of great importance for patients with paralysis or muscular weakness of the lower limb and must always be taken into consideration when discussing the functionality of a KAFO orthosis.

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