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A functional comparison of conventional knee–ankle–foot orthoses and a microprocessor-controlled leg orthosis system based on biomechanical parameters

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Abstract

Background: The microprocessor-controlled leg orthosis C-Brace enables patients with paretic or paralysed lower limb muscles to use dampened knee flexion under weight-bearing and speed-adapted control of the swing phase.
Objectives: The objective of the present study was to investigate the new technical functions of the C-Brace orthosis, based on biomechanical parameters.
Study design: The study enrolled six patients. The C-Brace orthosis is compared with conventional leg orthoses (four stance control orthoses, two locked knee–ankle–foot orthoses) using biomechanical parameters of level walking, descending ramps and descending stairs.
Methods: Ground reaction forces, joint moments and kinematic parameters were measured for level walking as well as ascending and descending ramps and stairs.
Results: With the C-Brace, a nearly natural stance phase knee flexion was measured during level walking (mean value 11° ± 5.6°). The maximum swing phase knee flexion angle of the C-Brace approached the normal value of 65° more closely than the stance control orthoses (66° ± 8.5° vs 74° ± 6.4°). No significant differences in the joint moments were found between the C-Brace and stance control orthosis conditions. In contrast to the conventional orthoses, all patients were able to ambulate ramps and stairs using a step-over-step technique with C-Brace (flexion angle 64.6° ± 8.2° and 70.5° ± 12.4°).
Conclusion: The results show that the functions of the C-Brace for situation-dependent knee flexion under weight bearing have been used by patients with a high level of confidence.

Clinical relevance

The functional benefits of the C-Brace in comparison with the conventional orthotic mechanisms could be demonstrated most clearly for descending ramps and stairs. The C-Brace orthosis is able to combine improved orthotic function with sustained orthotic safety.

Keywords

Biomechanics of prosthetic/orthotic devices, testing of prosthetic and orthotic components, rehabilitation of orthoses users, lower limb orthotics

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Background

Many patients suffering from lower limb paresis or paralysis can re-establish mobility only using a knee–ankle–foot orthosis (KAFO). In conventional orthoses, the knee joint is completely locked. This complete fixation of the leg ensures the patient's safety in the stance phase while walking, but is associated with proven biomechanical and metabolic disadvantages. They include perceptible excessive strain on the locomotor system[1]

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Table 1. Demographic patient data, previous orthoses used and duration of C-Brace use.

Patient number	Sex	Age (years)	Height (cm)	Mass (kg)	Affected side	Previous orthosis	Duration of C-Brace use (weeks)
1	M	61	176	89	Left	SCO	7
2	M	70	176	74	Right	SCO	10
3	F	32	156	68	Left	SCO	30
4	M	56	168	66	Left	SCO	7
5	F	59	160	72	Right	Locked	10
6	F	57	150	51	Spastic	Locked	7
Mean		56	164	70			12
SD		13	11	12			9

SCO: stance control orthosis.

and an increase in energy expenditure for walking of up to 23%.[2,3] These disadvantages of conventional orthoses have been partially reduced with the development of stance control orthoses (SCOs). In this type of orthosis, the knee joint is locked only in the stance phase, but is released to allow for a free swing phase. The movement pattern is thus more natural with an SCO and leads to a reduction of compensatory movements and an associated reduction of joint loads and energy expenditure during level walking (review article[4]). For safe control, however, these orthoses require a minimum level of residual motor function in the affected limb, so only a relatively small percentage of patients can be fitted with these systems for reasons of safety. In addition, the most important functional limitation of all of these orthoses is that no dampened knee flexion is possible in the weight-bearing condition. 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 recently introduced C-Brace orthosis (Duderstadt, Germany) has been developed to overcome the functional limitations of SCOs. The technology of the C-Brace involves the use of a microprocessor-controlled hydraulic unit that controls the movement resistance of the orthotic knee joint in all routine motor function situations, both with and without loading the orthosis. This mechanism is intended to support, for example, a step-over-step descent of ramps and stairs with specific dampening of knee flexion and also a reduction in the risk of falling. During level walking, the orthotic mechanism should allow for natural knee flexion in the stance phase and speed-adjusted control in the swing phase. Following a description of the technical details and initial patient reports with the C-Brace orthosis,[5] this study attempts to compare the functionalities of conventional KAFOs and the C-Brace by using established biomechanical tests.

These objective data will be used to verify the hypothesis that the new orthotic mechanism of action allows for more natural motion patterns with nearly physiologic joint loads.

Methods

Patients and control group

The study enrolled six patients who were fitted with a C-Brace for periods between 7 and 30 weeks and who had previously used other KAFOs. Four patients had used unilateral SCO systems and two patients, one unilateral and one bilateral, did not qualify for SCO fitting for safety reasons and had therefore used a KAFO with a locked knee joint (locked KAFO). Inclusion criteria for the patients in this study were ages between 18 and 70 years and dependency of the ability to walk on a KAFO, regardless of locked or posterior off-set KAFO or any type of SCO. Patients were excluded from participation if they were using additional walking aids to ambulate on level ground.

During the fitting process, the functional status of the muscles of the lower limb was determined for each patient with manual muscle testing (MMT) using the Janda[6] scale from 0 to 5. In contrast to the common pronounced weaknesses of the extensors of the knee joint, considerable individual variations of weakness of the other muscles of the affected lower limb were found resulting from different underlying clinical conditions. The general patient data are summarised in Table 1, and information on the clinical conditions and results of the manual muscle test are presented in Table 2.

For the general appraisal of the results, data were available from an earlier study using identical measurement methods in a sound control group without any orthopaedic and neurological conditions[7] (n = 15; 7 female and 8 male; mean age 27 (standard deviation 3)years; mean height 177 (9) cm; mean mass 72 (14) kg).

All the patients were aware of the possible risks, and informed consent was obtained from each subject. This study was conducted in agreement with the guidelines of the Georg-August-University of Göttingen Ethics Committee.

Table 2. Underlying clinical condition and results of manual muscle testing (MMT) of the main muscle groups (affected limb).

No.	Underlying condition	Hip joint extension	Hip joint flexion	Knee joint extension	Knee joint flexion	Ankle joint plantarflexion	Ankle joint dorsiflexion
1	Polio	5	4–5	0	4–5	4	1
2	Disc herniation	3	3	0	0	0	0
3	Incomplete spinal cord injury	2	3	0	0	0	0
4	Incomplete femoral nerve lesion after resection of a soft tissue sarcoma	4	2	0	3	2–3	3
5	Polio	0	0	0	1–2	0	0
6 Right	Incomplete spinal cord injury	1–2	0	1	1	1	0
Left		1	0	1	1	1	0

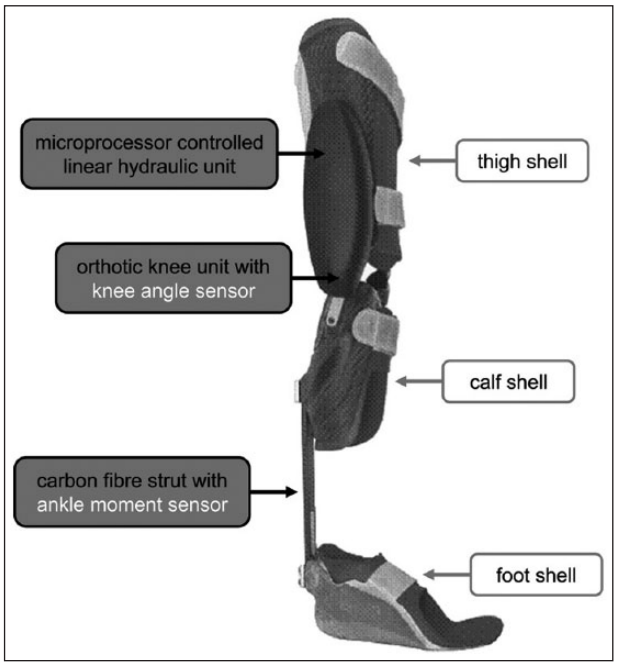

Figure 1. C-Brace orthosis with its components.

Functional description of the C-Brace orthosis

The C-Brace orthosis (Figure 1) represents a microprocessor-controlled leg orthosis system that is the first one designed to allow for controlled dampened knee flexion in the weight-bearing condition. A sensor system records important biomechanical data (knee angle, knee angle velocity, and ankle moment) in the orthotic limb. Using this information, the integrated software identifies the patient's current movement status and, with a working frequency of 50 Hz, uses linear hydraulics to control the required movement resistances of the orthotic knee joint for stance and swing phases.

This basic mechanism has been designed to support difficult movement patterns in everyday life such as the step-over-step descent of ramps and stairs in a nearly natural manner. Also, for the first time, an orthosis has the technological basis to allow for physiological stance phase flexion for level walking.

By managing the swing knee flexion angle, the microprocessor-controlled swing phase enables a more natural gait pattern, even at varying walking speeds. This is a specific limitation in functionality of the established SCO systems, as they only allow for an undampened pendulum movement during swing. Such undampened calf movement, however, represents an insufficient compensation of the function of the paretic leg muscles.

A detailed technical description of the C-Brace orthosis has been given in a previous article.[5]

Examination procedure

All patients examined were fitted with the C-Brace orthosis during the controlled market launch of the system. Immediately before being fitted, biomechanical tests were conducted with the patients using their previous orthoses in the gait laboratory. Level walking was tested first. For those patients who were able to descend ramps or stairs, respectively, step over step, this movement pattern was also analysed. After having been fitted with the C-Brace orthosis, the patients used it in their everyday routine for at least 7 weeks. After this, all tests were repeated in the gait laboratory at a follow-up session using the C-Brace.

Measuring technology and procedure

Ground reaction forces acting during level walking were measured using two force plates (Kistler 9287A, Winterthur, Switzerland; scanning rate of 1080 Hz). The kinematics of movements were measured by recording the trajectories of passive markers using an optoelectronic camera system (six MCam series cameras, Vicon 460; ViconPeak, Oxford, UK; scanning rate of 120 Hz). To do this, 14 markers were used based on an established model[8] (metatarsophalangeal joint V, lateral malleolus, knee centre defined by Nietert[9] (pivot axis of the orthotic knee joint), trochanter, acromion, lateral humeral epicondyle, ulnar styloid process).

The stairs used for the test consisted of five steps; the middle step was attached to a force plate. To measure descending a ramp, a 5-m-long ramp with an incline of 10°

Table 3. Mean velocity V and lenghts SL for level walking.

	KAFO (previous)	C-Brace	Healthy individuals
V (m/s)	1.12 (0.10); n = 6	1.11 (0.13); n = 6 (ns)	1.45 (0.11); n = 15**
SL (m)			
Orthotic side	0.65 (0.02); n = 7	0.63 (0.06); n = 7 (ns)	
Non-affected side	0.63 (0.07); n = 5	0.65 (0.05); n = 5 (ns)	0.79 (0.11); n = 15**
Asymmetry	0.06 (0.04); n = 5	0.05 (0.04); n = 5 (ns)	0.02 (0.01); n = 15**

SL: step length; KAFO: knee–ankle–foot orthosis; ns: no significant difference between the mean values of the two orthotic conditions.
**Significant difference between the values for the control group and the two orthotic conditions, $p \leqslant 0.01$.

was used. In the middle of the ramp, a 40-cm-long element was integrated with a direct connection to a force plate. On foot contact with this element, the ground reaction forces could thus be recorded for this movement as well. A detailed description of the test setup for stairs and ramps has been provided in an earlier study.[10] For each of the movement patterns examined, 8 to 10 gait cycles were measured.

Data processing

From the coordinates of the markers, the sagittal joint angles were calculated using software self-developed for this purpose (Vicon BodyLanguage, V3.5; ViconPeak). The external moments acting on the large joints of the lower limbs were calculated based on the ground reaction forces and kinematic data using standard inverse dynamics computations[11] also using Vicon BodyLanguage. A detailed description of these algorithms has been published in a previous article.[8] For all biomechanical parameters, mean values standardised for the gait cycle were determined from the step cycle data and maximum values were extracted.

Statistics

For the comparison of the biomechanical parameters of the previous orthosis and the C-Brace, we refrained from a comparison of group mean values using a statistical analysis due to the diversity of functional options of the previous orthoses and the relatively small number of patients. Because of the different walking velocities, the same applied to the comparison of the parameters between the patient and the control group.

A comparison based on a statistical analysis was considered useful only for the time–distance parameters, and this was conducted using the Wilcoxon signed-rank test or the Mann–Whitney U test.

Evaluation parameters

To present the results as clearly as possible, only parameters with the potential to demonstrate functional differences between the C-Brace and the previous orthoses were selected from the complete set of parameters as described above for presentation.

During level walking, the knee angle on the orthotic side was considered to be of primary importance.[12–14] The sagittal hip moment on the orthotic side was used to evaluate whether altered motor control patterns are required to utilise the different functional properties of the orthoses studied. A change of loads to the locomotor system that may result from different orthotic properties can be evaluated using the maximum values of the external joint moments of the unaffected lower limb.[1]

The knee angles and hip moments measured on the orthotic side were used to evaluate the orthotic function when walking on ramps and stairs. The load on the locomotor system was quantified using the maximum values of the external joint moments of the unaffected limb and the vertical component of the ground reaction force, also measured on the sound side. In previous studies, this parameter had been shown to be sensitive for measuring the effect of prosthetic device interventions on the loads acting on the locomotor system when descending ramps and stairs.[10,15]

Results

Level walking

The group means of the time–distance parameters velocity and stride length presented in Table 3 do not show any significant differences between the previous KAFO and the C-Brace. The step length asymmetries (difference between the step length on the orthotic side and the sound side) measured for all five patients with a unilateral orthosis result from individually varying conditions. In three cases, a longer step was measured on the orthotic side with the previous device. With the C-Brace in these subjects, there was no difference in step length in one case and a longer step on the orthotic side in another case. Compared with healthy individuals, velocity and step length are considerably reduced with clearly greater step asymmetry. These effects are significant and independent of the type of orthosis (Table 3).

For all patients, the stance knee flexion angle on the orthotic side clearly approaches a more physiological

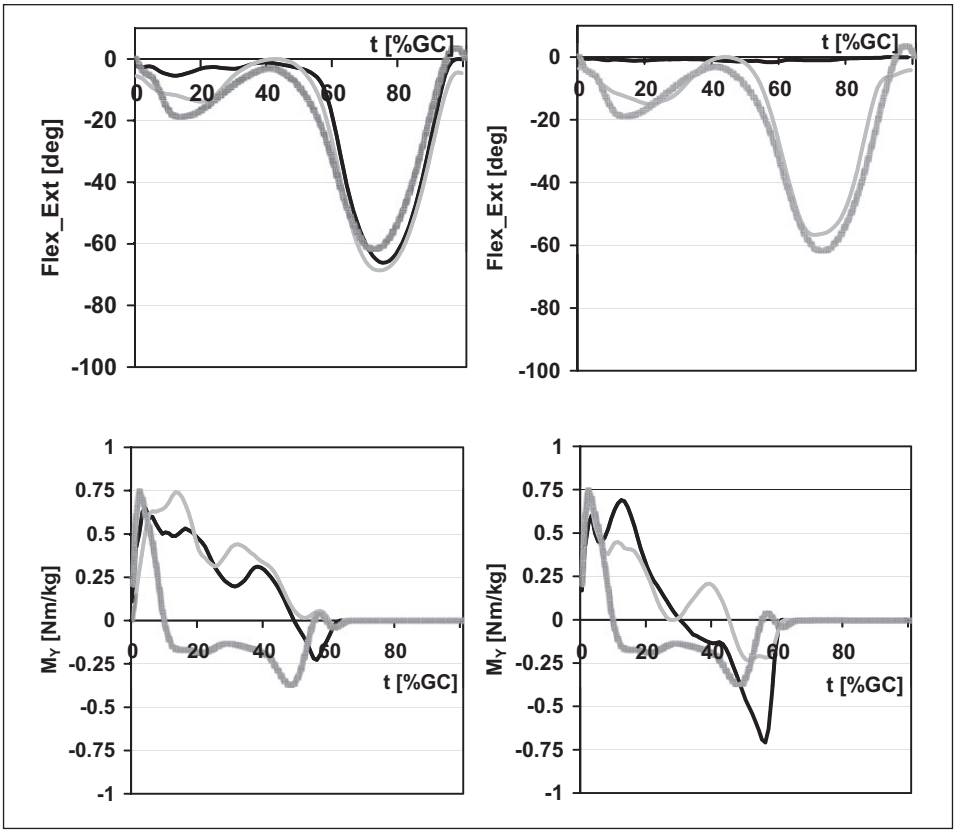

Figure 2. Examples of the comparison between the previous orthosis and C-Brace. Knee angles measured on the orthotic side (top) and hip moment measured on the orthotic side (bottom) for level walking (left: patient with a previous SCO, right: patient with a previous locked KAFO; grey: C-Brace, black: previous orthosis, hatched: normal).
SCO: stance control orthosis; KAFO: knee–ankle–foot orthosis.

Table 4. Kinematic parameters of the knee angle on the orthotic side during level walking (n = 7).

Parameter	KAFO (previous)	C-Brace
Stance phase flexion		
Number of orthotic limbs	0/7	5/7
Mean value (°)	0	11.0 (5.6)
Swing phase flexion		
Number of patients using	4/7	7/7
Mean value (°)	74.0 (6.4)	66.6 (8.5)

KAFO: knee–ankle–foot orthosis.

pattern with the C-Brace compared to the previous orthoses. In Figure 2 (top), this comparison is presented using one example each of a patient previously wearing an SCO (left) and a locked orthosis (right). In both cases, there is evidence of pronounced stance phase flexion with the C-Brace. The orthotic function of allowing for knee flexion during weight bearing in stance is confirmed in four of six patients (five of seven orthotic limbs) when using a C-Brace; a mean flexion angle of 11.0° (5.6°) is measured. In the swing phase, a mean maximum flexion angle of 74.0° (6.4°) was measured with the SCO system in contrast to 66.6° (8.5°) with the C-Brace (summary of the kinematic parameters in Table 4).

There were sustained high hip moments in the stance phase on the orthotic side for all patients regardless of the orthosis used. Two examples are presented in Figure 2 (bottom), one each for a patient previously using an SCO or a locked orthosis, respectively. With respect to the mean maximum value of the hip flexion moment acting in the early stance phase, higher values were measured with the C-Brace compared to the SCO (0.72 (0.12) vs 0.62 (0.05) Nm/kg) and lower values compared to the locked orthosis (0.55 (0.15) vs 0.68 (0.02) Nm/kg). The hip extension moment measured immediately before swing initiation is uniformly reduced with the C-Brace compared to the previous orthoses (−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 in the sound limb, only relatively small differences were found at the knee joint with the C-Brace in comparison to the previous SCO. The mean knee flexion moment acting in the first half of the stance phase was reduced (−0.51 (0.08) vs −0.44 (0.15) Nm/kg); the knee extension moment measured in the second half of the stance phase was increased

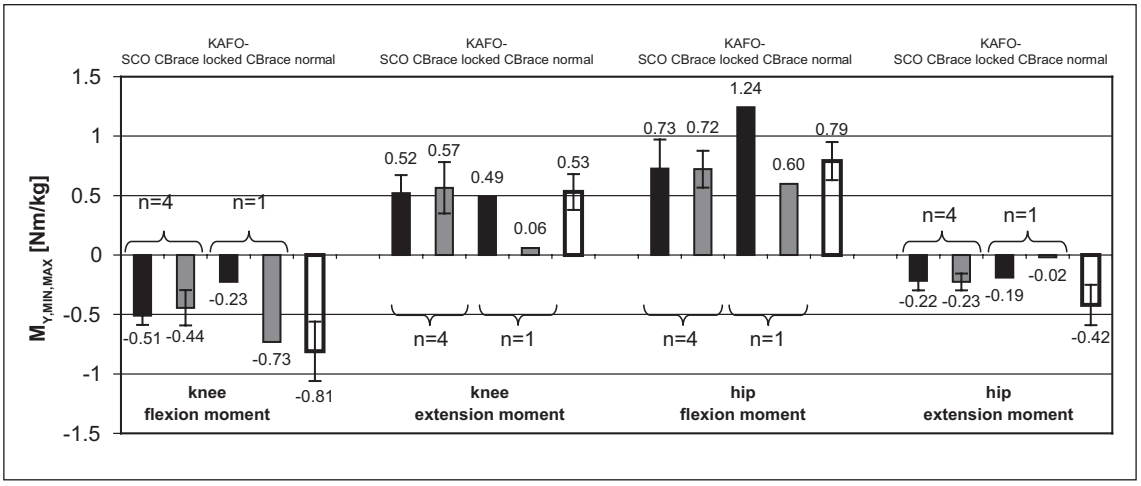

Figure 3. Mean local maximum values of external joint moments of the knee and hip joint of the sound limb (level walking): comparison between the previous orthoses and the C-Brace.
SCO: stance control orthosis; KAFO: knee–ankle–foot orthosis.

(0.52 (0.15) vs 0.57 (0.21) Nm/kg, Figure 3). The differences were much greater for the patient who had previously used a unilateral locked KAFO. The knee flexion moment increased from a very low level (−0.23 vs −0.73 Nm/kg); the extension moment decreased to an extremely low level (0.49 vs 0.06 Nm/kg; Figure 3). Similar relations depending on the previous orthosis were measured for the hip joint. There were only slight differences between the orthoses for patients who had previously used an SCO. This applies both to the mean hip flexion moment measured in the early stance phase (0.73 (0.24) vs 0.72 (0.16) Nm/kg) and to the hip extension moment acting before swing initiation (−0.22 (0.08) vs −0.23 (0.07) Nm/s; Figure 3). An extremely high flexion moment of 1.24 Nm/kg was measured for the patient who had previously used a locked orthosis; with the C-Brace, this was reduced to 0.60 Nm/kg and was thus much closer to the normal physiological mean (Figure 3). The hip extension moment was also reduced considerably (−0.19 vs −0.02 Nm/kg; Figure 3).

Ramp

Two patients each were able to descend a ramp step over step using a handrail with their previous SCO or locked KAFO, respectively (Table 5). However, individually varying considerable compensatory patterns were required to do this. The other two patients employed a step-to technique and made use of the handrail and a walking aid in this situation. With the C-Brace, all patients were able to descend a ramp using the natural step-over-step technique; only one patient needed the handrail. Since the C-Brace is the first orthosis designed to enable a movement pattern that closely approaches the natural pattern, the biomechanical data measured with this orthosis are compared with those in sound subjects.

The patients walked on the ramp at a significantly reduced mean speed in comparison with healthy individuals (0.89 (0.15) m/s vs 1.40 (0.15) m/s, $p \leqslant 0.01$); there was also a significantly greater mean asymmetry of step lengths (0.13 (0.09) m vs 0.02 (0.01) m, $p \leqslant 0.01$). With respect to the asymmetry of step lengths, no uniform trend was found: three patients used longer steps on the orthotic side and three used longer steps on the sound side to descend the ramp.

The pattern of the knee angle measured on the orthotic side during stance phase qualitatively resembles that of healthy individuals. In all patients, continuous knee flexion was seen in early stance phase, regardless of the previous orthosis. An example of the stance knee angle pattern for one patient is shown in Figure 4 (bottom). The maximum stance flexion in patients was reduced by an average of about 10° compared with healthy subjects (64.6° (8.2°) vs 75.8° (4.8°)). The maximum of the hip moment on the orthotic side in the early stance phase was reduced in the patient group to a mean of 0.64 (0.27) Nm/kg vs 0.73 (0.20) Nm/kg in the control subjects. However, there was clear evidence in all cases of sustained high moments acting on the hip joint on the orthotic side later in the stance phase, in deviation from the movement pattern of healthy individuals. This is again illustrated using an example (Figure 4, bottom). The maximum values of the biomechanical parameters of the sound limb summarised in Figure 6 are lower for all patients compared with the mean values of healthy individuals.

Stairs

No patient was able to descend stairs in a natural step-over-step technique with the previous orthoses. Without exception, this situation was handled only with difficulty using the step-to technique. When using the C-Brace, however, all patients were able to descend stairs using the

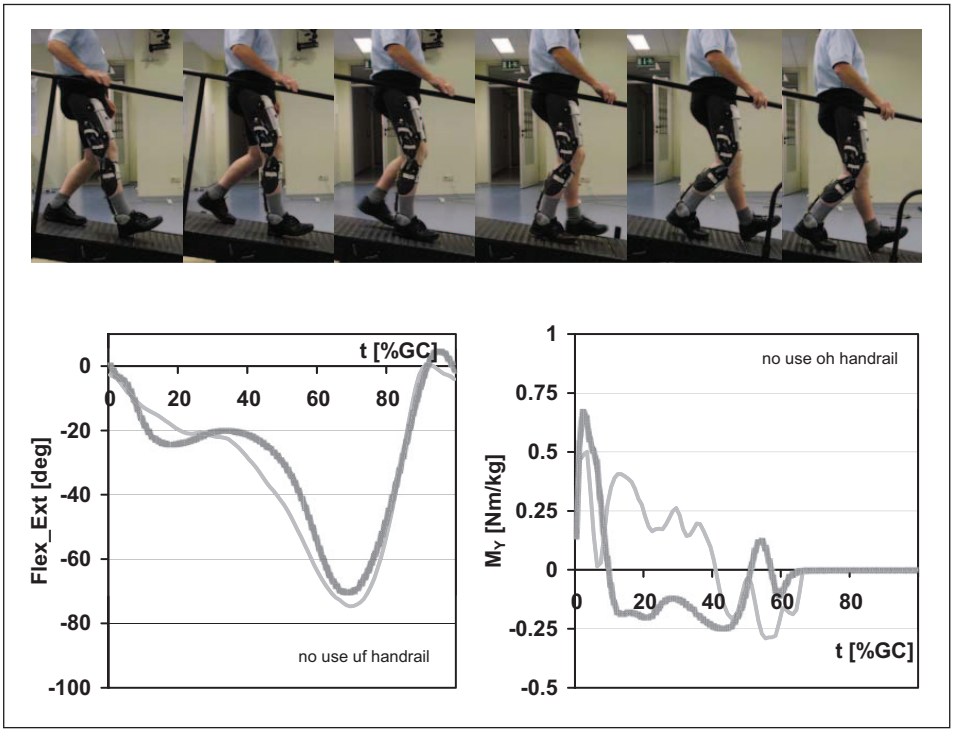

Figure 4. Descending a ramp with the C-Brace. Top (photograph series): step-over-step pattern with knee flexion under weight bearing; bottom left: patient example of the knee angle curve on the orthotic side and bottom right: the hip moment acting on the orthotic side (grey: C-Brace, hatched: normal; previous orthosis: SCO).
SCO: stance control orthosis.

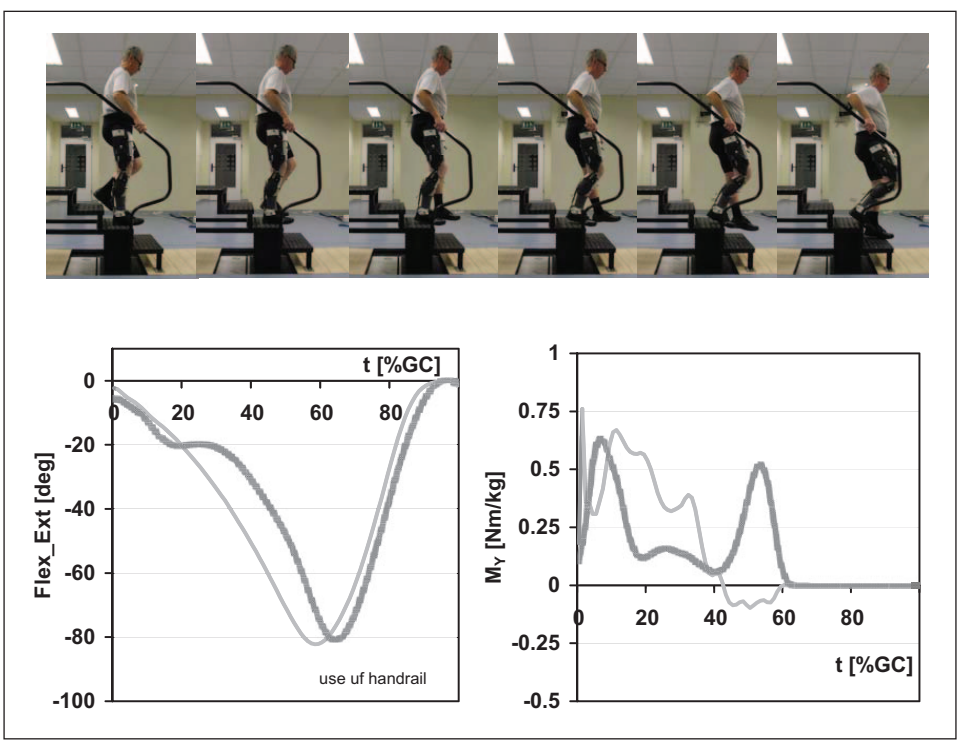

Figure 5. Descending stairs with the C-Brace. Top (photograph series): step-over-step pattern with knee flexion under weight bearing; bottom left: patient example of the knee angle curves on the orthotic side and bottom right: hip moment acting on the orthotic side (previous orthosis: SCO, grey: C-Brace, hatched: normal).
SCO: stance control orthosis.

Table 5. Use of the step-over-step technique to descend ramps and stairs.

	Ramp		Stair	
	Step-over-step (number)	**Use of handrail**	**Step-over-step (number)**	**Use of handrail**
KAFO (previous)	4/6	4	0/6	
C-Brace	6/6	1	6/6	5

KAFO: knee–ankle–foot orthosis.

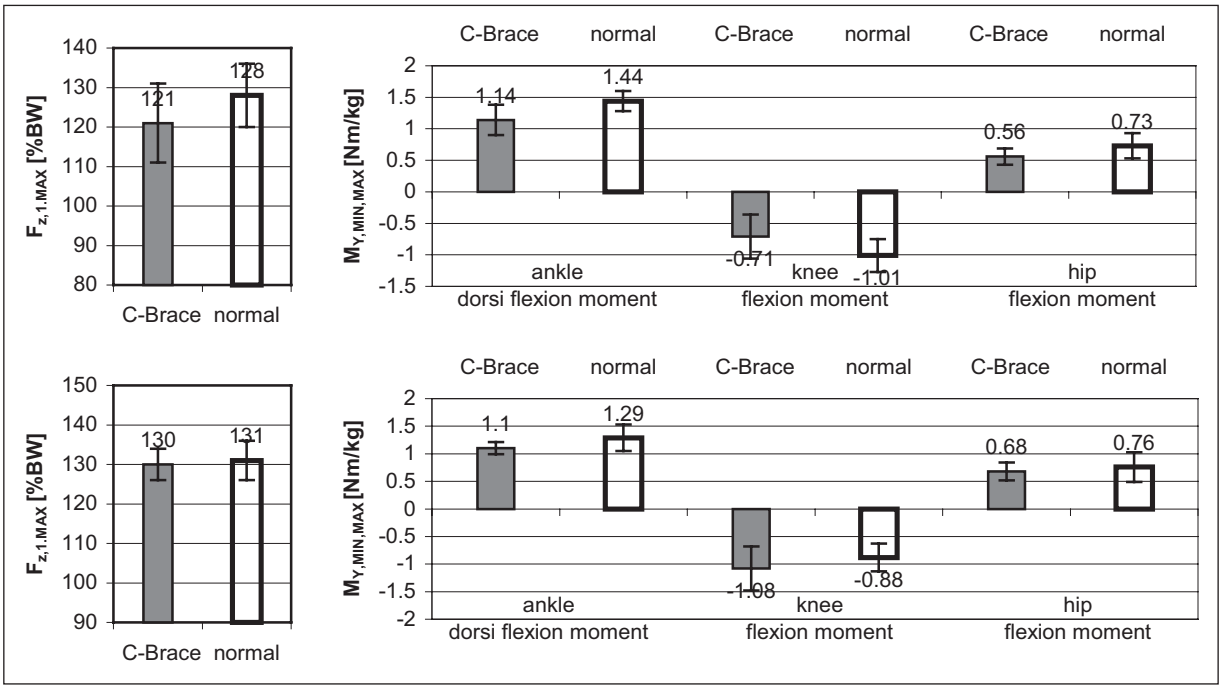

Figure 6. Mean peak values of biomechanical parameters of the unaffected limb compared with the values of healthy individuals when descending ramps (top) and stairs (bottom). $F_{z,1.MAX}$: maximum value of the vertical ground reaction force; $M_{Y,ankle,MAX}$: maximum value of the external sagittal moment acting on the ankle joint; $M_{Y,knee,MIN}$: maximum value of the external flexion moment acting on the knee joint in the early stance phase; $M_{Y,hip,MAX}$: maximum value of the external flexion moment acting on the hip joint in the early stance phase.

step-over-step technique with the use of the handrail (Figure 5, top). A biomechanical evaluation of the parameters measured with the C-Brace is made based on the comparison with healthy individuals.

The knee angles on the orthotic side are qualitatively similar to normal angles, regardless of whether the patients were previously using an SCO or a locked KAFO. Continuous flexion during weight bearing begins in the early stance phase until the maximum knee flexion angle is reached. This is again illustrated using a patient example (Figure 5, top). The mean maximum knee flexion angle was reduced by nearly 15° (70.5° (12.4°) vs 85.4° (6.2°)) as compared with healthy individuals. The analysis of the hip moment acting on the orthotic 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 in up to approximately 40% of the gait cycle. This is also illustrated using a patient example (Figure 5, bottom). The maximum values of the biomechanical parameters of the unaffected limb were reduced compared with the peak values of healthy individuals; the sole exception was the maximum knee flexion moment (−1.08 (0.44) Nm/kg vs 0.88 (0.25) Nm/kg).

Discussion

This study used objective biomechanical tests to investigate functional differences between conventional orthotic mechanisms and the C-Brace orthosis that will be separately discussed in the context of each activity tested.

Stance phase flexion for level walking made possible by this new orthotic mechanism of the C-Brace orthosis

has been utilised by four of six of patients and, with a mean value of 11°, largely corresponds with the physiological value, taking into consideration the lower gait velocity compared with healthy individuals.[16] 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, Table 2). Possibly this muscle strength was used with the previous orthoses to execute the necessary compensatory movement patterns, which had still not been corrected even after several weeks of adaptation to the C-Brace and thus 'blocked' the initiation of stance phase flexion. This aspect suggests that patients newly fitted with the C-Brace should receive proper physical therapy and device training.

The analysis of the swing phase shows the high quality of the C-Brace's microprocessor control, which achieves a maximum knee flexion angle close to the normal physiological level of approximately 65°.[16] Due to the greatly limited muscular control, the free swing phase of the SCOs often results in a flexion angle that is clearly too high, which can lead to a perceptible impairment of gait harmony. The hip moments on the orthotic side, which are at consistently high levels during the stance phase compared with the gait pattern of healthy individuals, are an indication of necessary alterations in the movement pattern that are nearly independent 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 using the sagittal hip moment that can be determined reliably. With respect to the clearly identifiable peak values, only the external extension moment that acts immediately at the end of the stance phase demonstrates an abnormally elevated value in the locked KAFO condition. This can be interpreted as a perceptibly increased effort needed to move the completely stiff limb into the swing phase. This effect is known from previous studies[1] and is clearly reduced by using the C-Brace. The load on the unaffected joints that can be measured for all orthoses compared with normal values is drastically increased only for the hip joint with a locked KAFO. This indicates a critically increased load on the locomotor system. No such increased load was determined for SCOs or for the C-Brace. Initially, this applies strictly only to the walking speed measured. However, from the extent of the joint moments' dependence on walking speed determined in earlier studies,[17] it can be concluded that no perceptible additional load to the locomotor system occurs in the patients with an SCO or C-Brace even at a speed increased by approximately 0.3 m/s, which would then be equivalent to that of the normal group. Similar values are measured for joint loads in the direct comparison between the SCO and the C-Brace conditions. This can be interpreted as an indication that the use of the C-Brace, which weighs approximately 1 kg more than an SCO, did not have an unfavourable effect on the locomotor system.

The functional benefits of the C-Brace compared to the options of conventional orthotic mechanisms could be demonstrated most clearly for descending ramps and stairs. The step-over-step technique on the ramp observed in four patients with the previous orthosis requires an extremely unnatural movement pattern due to the absence of knee flexion in the weight-bearing condition, which leads to excessive loads to the locomotor system, especially in the ankle and knee joint.[5] The dampened knee flexion during weight bearing with the C-Brace allows for a nearly natural downward movement of the body's centre of gravity.

The peak values of the joint moments measured on the unaffected side are considered a reliable indication that the locomotor system is subjected to nearly physiological loads when ambulating ramps with the C-Brace.

Compared with the movement patterns of healthy persons, altered hip moments were measured during single leg stance on the orthotic side, which indicates that the neuromuscular control of the orthotic function must be achieved using compensatory activities in proximal elements such as the pelvis and trunk. However, the peak values of the altered hip moments also do not exceed those of healthy persons.

For ambulating stairs step over step, the C-Brace mechanism requires a specific movement technique to utilise knee flexion during weight bearing. The midsection of the foot must be placed on the edge of the step to allow the foot for 'rolling over' the edge of the step. It is possible that this necessary movement technique sometimes results in higher joint moments on the unaffected limb that were detected to a small extent at the knee joint and that corresponds with a known effect in leg prosthesis.[18] Despite this unavoidable compensatory mechanism, among the activities tested in this study, the clearest functional benefit for patients compared to all conventional orthotic concepts was found in the step-over-step descent of stairs.

Overall, the tests showed that the new orthotic functions of the C-Brace for situation-dependent knee flexion in the weight-bearing condition have been used by patients with a high level of confidence. This is demonstrated by the fact that the handrail was not generally used for ambulating on ramps which indicates a clear increase in perceived safety compared to all previously used KAFO mechanisms. Due to the high safety potential, patients will be able to use the C-Brace even if they are not able to use an SCO. In general, patient safety is of utmost importance and should not be compromised by increased orthotic functionality. In this study, two patients who were previously using a locked KAFO and did not qualify for SCO fitting for reasons of safety were able to safely use and benefit from the C-Brace. This illustrates that the C-Brace is able to combine improved orthotic function with sustained orthotic safety.

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Author contribution

All authors contributed equally in the preparation of this manuscript.

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