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Activities with a Microprocessor-Controlled Leg Brace for Patients with Lower Limb Paralysis: A Series of Case Studies

Roland Auberger, Barbara Pobatschnig, Michael Russold, Robert Riener, Hans Dietl

Abstract— **Lower limb paralysis often leads to depreciation in mobility of the affected individuals. Computer-controlled leg brace systems open up new possibilities for these patients, by improving the safety of mobility tasks in everyday life, especially when walking on uneven terrain, inclined surfaces, steps and stairs. This paper introduces such a system. To investigate the use of device functionalities in the patient's everyday environment, the knee joint of the brace was configured to store data of various sensors, measuring motion with a high temporal resolution over several weeks of home use. Results from a clinical trial including 8 patients with different pathologies show that the system was used by the patients for more than 10 hours per day on average, taking more than 2,100 steps per day. Maximum use time was more than 20.24 hours with 12,609 steps per day. An implemented yielding function to support walking down slopes or stairs was used by all patients. This function can also catch the user in case of stumbling, which on average happened 3 times per day. Seven out of eight patients reported improvements in quality and safety of many activities in daily life using the novel system, compared to their previous device.**

I. INTRODUCTION

IMPAIRMENTS in lower limb motor function can have various causes, and often they significantly reduce the quality of life of the affected person. One common and well investigated etiology is spinal cord injury (SCI). According to the National SCI Statistical Center (Birmingham, Alabama, US) [1] approx. 288,000 people in the United States suffered SCI and have to cope with consequences such as paralysis of the lower and upper extremities. Every year another 17,700 people are affected by SCI in the US. 20.4% of the SCI cases lead to incomplete paraplegia [1], where only the lower extremity is affected. In this patient group, there is still residual sensory or motor function present. Improvements in acute care, therapy [2] and neuroscience [3] have the potential to reduce the functional losses due to SCI, and, therefore, will increase the number of patients with residual muscle function. Other etiologies of lower limb paralysis, that result in (complete or incomplete) motor impairments, are Post-Polio Syndrome, Multiple Sclerosis (MS), Traumatic Brain Injury (TBI) or stroke. Residual voluntary muscle function is quite common in these cases. However, due to gait impairments, these patients are often confined to wheelchairs. This leads to secondary complications, such as neural and muscular atrophy, or comorbidities of cardiovascular or musculoskeletal system such as osteoporosis or decubitus [4]. To avoid these secondary complications, it is important to keep patients as active as possible. Walking is an excellent form of exercise that promotes musculoskeletal and mental health benefits, which can counteract the effects of long-term wheelchair use. It may also increase functional independence, community participation and re-integration back into normal life and work.

The goal of this project was to develop an assistive device that enables patients to use their residual muscle function for ambulation in their daily life. This should lead to higher levels of activity, with the added benefit that this activity can be considered additional training, integrated into the patients' activities of daily life (ADL).

There is evidence that acceptability and use of orthoses depends on a range of factors. Effectiveness, reliability, comfort and durability are the most important considerations for patients in deciding whether or not to use a specific device [5]. Additionally, it is important to note that superior functionality outperforms cosmetic limitations [6]. With this in mind, the C-Brace (Ottobock, Duderstadt, Germany) was developed as a stance and swing phase control Knee-Ankle-Foot Orthosis (KAFO) with a microprocessor controlled hydraulic damper. Critically, it uses the patient's residual muscle function to control the active propulsion of the system, while the hydraulic damper provides support at the knee joint when needed.

A key factor is safety. The patient has to be stabilized during stance phase. Traditional KAFOs lock the knee in an extended position. This leads to compensatory motion such as hip

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hiking or circumduction during walking. With microprocessor control, the C-Brace can stabilize during stance phase (STP) and allow for motion during swing phase (SWP). It can be configured in various brace design options with different ankle joint systems. Therefore, this system provides essential functionality to integrate legged mobility in patients' ADLs.

For more than two decades, similar systems with microprocessor controlled dampers have been used successfully in prosthetic knee joints [7]. In 2012 microprocessor controlled hydraulics were also implemented in commercial orthotic products [8]–[12]. Pröbsting et al., evaluated the safety and walking ability of KAFO users with a previous version of the C-Brace [13]. They indicated that ADLs became easier and safer with the C-Brace compared to previously used orthoses. They also found improvements in quality of life and perceived orthotic function. However, this study relied on survey information, and did not collect data over an extended period of time. The biomechanical study of Schmalz et al. [14] showed that the overall gait pattern, especially while descending stairs and ramps, was performed more naturally with the C-Brace. Auberger et al. showed that patients using the system developed individual strategies to negotiate typical locomotion tasks [15].

In order to assess the relevance of the functions provided by the system to patients' daily activities, this report examines the intensity of use of these functions during the patients' daily lives. The patient group observed is the same as in [15], including one additional patient. The pathologies of the observed patients were diverse, including compression damage to the spinal cord (e.g. due to slipped discs), damage of the nerve roots exiting the spinal cord (peripheral nerve lesions), and neurological diseases (polio and neurofibromatosis).

The main objective is to evaluate and describe the acceptance, intensity and frequency of use of the C-Brace, based on different parameters related to activities of daily life. Observed parameters were associated with patient activities (steps taken per day, daily usage time, sitting mode activations) and safety (stumbles). Data were observed over a period of multiple days.

II. Materials

A. Leg brace system

The microprocessor stance and swing control orthosis (mpSSCO) used in this study (see Figure 1) was a prototype version of the C-Brace system (Ottobock, Duderstadt, Germany). This system provides assistance for everyday life mobility tasks such as walking, standing, sitting down and negotiating ramps and stairs. The main functionalities are identical with the commercially available product [17]. It was designed for a patient weight of up to 125 kg. The key component of the system is a microprocessor controlled knee joint, which is mounted on the lateral side of the brace. The joint incorporates a microprocessor controlled hydraulic damper that can adjust the flexion and extension resistance of the knee joint in real-time [16], [17], to support the intended motion of the user [15]. The alignment of the knee joint unit can be adjusted in the frontal plane to fit the user's anatomy as closely as possible (see Figure 1B).

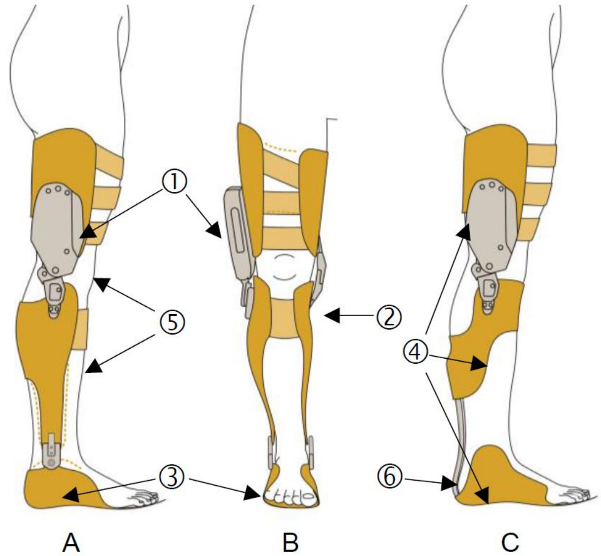

Figure 1. Overview of the brace system: A, B version with ankle joint, C version with elastic beam. (1) microprocessor controlled knee joint, (2) medial follower joint, (3) ankle joint, (4) interface parts, (5) fixation straps, (6) elastic composite beam. Figure adapted from [16].

Significant loads are transferred between the brace and the user's leg. Therefore, a good anatomical fit is required. To achieve this, the interface parts were custom fabricated out of carbon fiber composites, based on cast models of the patient's limb. The leg is secured in this structure with Velcro straps. Depending on the patient's needs, the brace design was adapted in close collaboration with an orthopedic technician and physical therapist. For example, one option is to employ a standard orthotic ankle joint with adjustable range of motion. These joints can be equipped with a dorsiflexion stop and a spring for drop foot lift. Another possibility is to build a custom composite spring (elastic beam) with energy storing capabilities. With this option energy can be stored in the roll-over phase and returned to assist swing phase initiation during walking. The elastic beam has the disadvantage in that the neutral position of the ankle joint is fixed and cannot be adjusted (e.g. for different heel heights).

B. Brace functionality (Working Principle)

To provide stability during level ground walking STP knee flexion resistance is set according to the patients' needs. To enable knee flexion during the SWP of level walking, knee flexion resistance is typically set to a low value. Typical torque levels during each gait phase as well as a control schematic are provided in [15]. Figure 2 illustrates characteristic data for a specific patient (P2). The knee joint dynamically controls the maximum knee angle during SWP to achieve a physiologically appropriate target angle of approximately 60° [18]. This value can be adjusted depending on user preferences. This helps to achieve symmetric gait, even at different walking speeds, because it limits excessive knee flexion due to the dynamics at high walking speeds. During swing phase extension knee flexion resistance is already set high, to provide immediate stability in case of stumbling. The adjustable resistance against knee flexion facilitates controlled yielding, which enables the patient to walk down ramps and stairs step-over-step. The brace supports standing with a specific standing mode, where the knee joint is blocked at a slightly flexed angle. Most of the patients activate this mode intuitively. Additionally, there is a sitting mode where knee joint resistance is reduced to a minimum while seated. This allows for easy repositioning of the leg and increases comfort, especially while sitting in chairs or cars [17]. When patients were provided this functionality, they developed individual strategies to navigate locomotion tasks in daily life, as was investigated in [15].

C. Sensors and Data acquisition

The knee joint comprises sensors to measure knee joint angle and hydraulic force. With this information the knee moment can be calculated, using a kinematic model of the knee joint mechanism [16]. Additionally, the knee joint contains an inertial measurement unit (IMU) with a 3-axis accelerometer and 3-axis gyroscope, a real time clock (RTC), a dual mode Bluetooth module for data exchange and a Li-Ion battery that provides more than 18 hours of power autonomy when fully charged. Details on how these sensor signals are used to control the device can be found in section III.C, as well as in [15], [16].

For this study the knee joint units were equipped with SD-cards with 32 GB storage capacity, where relevant sensor data was stored in 10ms cycles when the system was in use.

III. Methods

To investigate the use of the device functionality in the patient's everyday environment, a clinical pilot study was conducted over a period of 19 months.

A. Patient experiments

Recruitment and experiments took place at two sites. Subjects suffering from either lower limb paresis or flaccid paralysis, older than 18 years without flexion contracture above 20° and varus / valgus above 18° and body weight between 45 and 100 kg were enrolled in the trial. They were willing to use the provided orthosis and agreed to comply with the study procedure. Subjects with unstable medical conditions (osteoporosis, spasticity, balance problems not related to paresis) were not considered for the study. All subjects provided written informed consent before being enrolled in the study, which was approved by the local ethic committees from Universitätsmedizin Göttingen (21/1/17) and the ethics commission of the city of Vienna (16-271-0017). In total eight subjects were enrolled in this pilot study (details can be found in TABLE I).

To investigate differences in the use of the brace a heterogeneous patient group, in terms of pathology and residual function, was chosen. All patients had the possibility to familiarize themselves with the brace system in several gait training sessions in the lab. Training included exercises recommended in the "C-Brace Phsysiotherapy Guideline" [19] and was supervised by an experienced physical therapist. Once the patients were able to safely use the device, they were allowed to take the brace home for everyday use. According to the study protocol, follow-up appointments were planned every eight weeks. On these occasions the SD card was exchanged and the patients were asked to answer a self-implemented "Activity of Daily Live – Quality" (ADL-Q) questionnaire covering satisfaction with the device, including ratings of quality and safety in daily activities. A similar ADL-Q has previously been used in a prosthetic study [20] to rate the difficulty of activities of daily living. A modified version for orthotic applications was already published with results comparing C-Brace to locked KAFOs and SCOs [13], [14]. Patients rated overall satisfaction with the device in daily life using a numeric scale from 1 to 5, where 1 indicates "most satisfied" and 5 "most unsatisfied". Subjects were also asked to evaluate ADLs in three categories (personal hygiene and dressing, mobility and public transport, and family and social life activities). They rated quality and safety using the C-Brace in comparison to their previously used orthosis, with the following scale: -2 "much better with old orthosis", -1 "better with old", 0 "neutral", 1 "better with C-Brace", 2 "much better with C-Brace". Each category consists of a number of items for rating: personal hygiene and dressing (4), mobility and public transport (19), and family and social life activities (11). The score per category is the average rating of all items in the category, as a percentage of the maximum achievable score. The total score was calculated by averaging the categories. The median was taken to prevent outlier bias.

B. Data acquisition

The control software of the knee joint was configured to store all sensor information of the system from each control cycle (every 10ms, when the patient is active) to the SD card. Data captured includes hydraulic force, knee angle, knee angle velocity, 3D IMU data (thigh acceleration, thigh rotation and orientation), positions of hydraulic valves and a RTC time stamp.

C. Data processing

The data from the SD-Cards was clustered in files that represent one day each. Data analysis was performed with Matlab R2019b, using the statistics toolbox. The C-Brace is designed as a mobility assistance device for all-day use. As the main interest was to investigate usage over extended periods of time, only data from days where the brace was used for more than 60 minutes were considered for further analysis. Knee torque was calculated from the hydraulic force and knee angle, based on joint kinematics. To determine usage characteristics, stored sensor data, as well as the internal states of the controller that are typical for certain activities (e.g. level walking), were analyzed. Daily usage time was calculated by summing up the time elapsed between state changes, but only if this time was shorter than 60 minutes. For periods longer than 60 minutes in the same state, the brace was considered inactive (i.e. not worn by the patient).

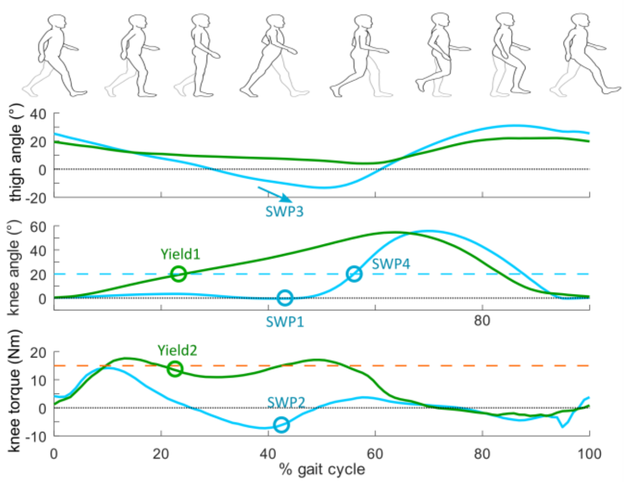

Figure 2. Thigh orientation angle, knee angle, and knee torque from a representative patient (P2) for level walking (blue) and yielding steps recorded during ramp descent (green). The dashed orange line represents the 15 Nm knee torque threshold for stumbling count, the dashed blue line shows the knee angle threshold for step analysis. Circles and arrows symbolize the criteria for level walking and yielding count.

Level walking steps were identified by looking at the characteristic state for SWP initiation. To initiate SWP during level walking, the following criteria must be fulfilled: Brace is stretched (SWP1 in Figure 2) with an extension knee torque (SWP2 in Figure 2), IMU detects forward rotation of the leg (SWP3 in Figure 2). Only steps with a maximum knee angle higher than 20° during SWP (SWP4 in Figure 2) were counted. Yielding steps, where the brace is flexed (knee angle > 20°, Yield1 in Figure 2) under load (positive knee moment, Yield2 in Figure 2) against the hydraulic resistance, were identified by the internal state of the controller and counted accordingly. Such steps typically occur during stair descent and sloped walking [15].

Stumbles were identified by the activation of the stumbling mode, which is activated if the sensor signals during level walking SWP deviate from a predefined pattern, especially if there are changes in monotony [25]. During SWP flexion, when flexion resistance is low, the leg pendulum is in a "ballistic phase" because the leg is swinging. Expected sensor signals can be calculated. As soon as there are any sudden changes in knee torque, angle or accelerations, or larger deviations from the expected sensor signal pattern, stumbling mode is activated. In this case the knee flexion resistance is increased for high damping that provides safety in the stance phase. For safety reasons the tolerances for stumbling mode activation are tight. Consequently, this mode is activated quite often, even during normal use. As the interest was in "real" stumbling events, only stumbling events where the brace was loaded with more than 15 Nm flexion load after activation of stumbling mode were counted. This value is significantly higher than the knee moment that usually occurs during SWP, as can be seen in Figure 2.

During sitting, sitting mode of the C-Brace is activated. In this mode the knee joint resistance is minimized, to allow for comfortable repositioning of the leg. As this mode gets deactivated as soon as the patient gets up, the number of sitting mode activations is representative of the number of stand-to-sit and sit-to-stand transitions for a patient. For each day the following characteristics were evaluated:

- Device usage time
- Number of regular steps (>20° max. SWP angle)
- Number of yielding steps
- Number of stumbling events
- Maximum supportive torque of stumbling events
- Number of sitting mode activations

TABLE I
PATIENT CHARACTERISTICS AND FITTING TYPE

Patient ID	P1	P2	P3	P4	P5	P6	P7	P8
Age (years)	24	51	65	62	40	74	67	52
Height (cm)	180	163	161	149	161	170	176	188
Weight (kg)	82	74	85	45	60	80	78	55
Pathology	Peripheral nerve lesion	Peripheral nerve lesion	Polio	Neurofibromatosis Recklinghausen	Polio	Slipped disc L3/4	Polio	Slipped disc Th7/8
Previous fitting	E-Mag active	UTX Swing	C-Brace 1st generation	C-Brace 1st generation	E-Mag active	KAFO with gas spring	C-Brace 1st generation	locked KAFO
Muscular status (Janda Scale [21])	0…no function	5…normal function						
Hip abd / add	L 0/3 R 5/5	L 5/5 R 0/0	L 1/3 R 5/5	L 0/0 R 0/0	L 1/4 R 4/5	L 4/5 R 5/5	L 5/5 R 4/4	L 5/5 R 3/3
Hip ext / flex	L 1/0 R 5/5	L 5/5 R 2/1	L 1/3 R 5/5	L 0/0 R 0/0	L 0/4 R 5/5	L 5/5 R 5/5	L 5/5 R 3/3	L 5/5 R 3/4
Knee flex / ext	L 0/1 R 5/5	L5/5 R 2/2	L 0/0 R 5/5	L 0/0 R 0/0	L 0/0 R 5/5	L 5/4 R 5/5	L 4/5 R 3/0	L 5/5 R 2/5
Foot plant / dors	L 0/0 R 5/5	L 5/5 R 3/1	L 0/0 R 5/5	L 0/0 R 0/0	L 2/1 R 5/5	L 5/4 R 5/5	L 5/4 R 3/2	L 5/5 R 4/3
C-Brace fitted side	left	right	left	both	left	left	right	right
Plantarflex control	drop foot lift	drop foot lift	drop foot lift	elastic beam	drop foot lift	drop foot lift	drop foot lift	drop foot lift
Dorsiflex control	dorsal stop	dorsal stop	dorsal stop	elastic beam	dorsal stop	free	dorsal stop	dorsal stop

E-Mag active [21], [22] and UTX swing [23] are stance control orthoses. C-Brace 1st generation is the predecessor of the system used in this study [10], [24], which provides similar functionality but with bigger size and weight. The other Knee Ankle Foot Orthosed (KAFO) are built with standard components.

IV. RESULTS

All eight patients finished the study with a C-Brace usage duration of at least six months. Some patients asked to extend their participation in the study, because they wanted to continue using the system. According to the feedback given in the questionnaires, seven out of eight patients used the brace for most (more than half) of the days. P2 stated that she used her old brace quite often because she had difficulty driving her car with the C-Brace, an activity that was easier with her previous brace.

In total 332 GB of data was recorded. Depending on available data, 95 to 303 days per patient were analyzed. Due to technical issues with the SD recording software, recordings were not available for every day of the observation period. Consequently, only days where data was available were used for further analysis. Figure 3 gives an overview of the days with available data. It can be seen that duration and the start of the observation period varied between patients. For some patients, data recording was disabled for several days, which is represented by the gaps in the plot. The observation period, the number of days analyzed for the respective patients, as well as the number of analyzed days where the brace was used, are summed up in Table II. Only days represented by a dot in Figure 3 were considered for further analysis. As this number of days is high (≥ 95), and the timing of gaps is random, it is assumed data from these days represent typical daily activities by the patients.

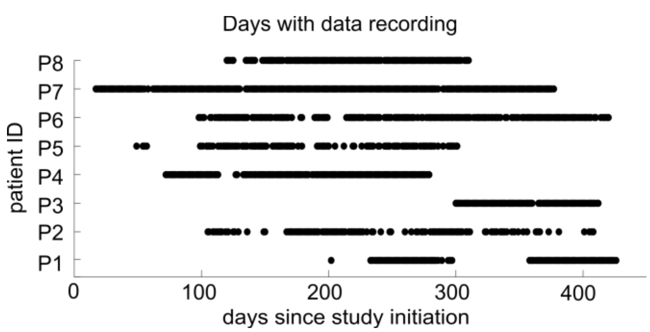

Figure 3. Overview of data recordings: points denote days where data was recorded, starting from the day of study initiation.

Characteristic parameters about brace usage and activities are visualized in Figure 4, using box plots. The width of the boxes corresponds to the number of analyzed days per patient. The red lines indicate the median and the dashed black lines the mean of the data per patient. The edges of the boxes represent the 25th and 75th percentiles. Whiskers are drawn from the ends of the interquartile ranges to the furthest observations within the whisker length, also called adjacent values. [26]. Observations beyond the whisker length are outliers and are marked with dots. An Outlier is defined as more than 1.5 times the interquartile range (IQR) away from the top or bottom of the box.

A. Usage frequency and duration

Based on the number of days analyzed, the device was used by all the patients for most of the days (see Figure 4A). The patients typically used their brace during a large part of their assumed daily activity period. Mean daily use time was highest for P7 (12.94 h), and lowest for P5 (6.64 h). Maximum daily use time was 20.24 h (P7). The overall average use time for all patients was 10.07 (SD 4.08) hours per day.

B. Level walking

In this study 2,482,513 walking steps with more than 20° SWP angle were identified during 1,179 observation days. This corresponds to 2,106 (SD 1,888) steps per brace, per day on average. The number of counted steps varied between patients. Six out of eight patients took more than 1,000 steps, and four out of eight patients more than 2,000 steps on most days. The most active patient (P4) took more than 5440 steps on most days, with an extreme value of 12,609 steps on the most active day.

C. Yielding steps

Figure 4C indicates the number of yielding steps, which was below 50 on most days for the majority of patients. However, almost all patients have outliers with several hundred yielding steps on certain days. One patient (P3) used the function intensively, with a maximum of 3,865 yielding steps on one day, and 671 (SD 636) yielding steps per day on average.

D. Stumbling steps

The daily occurrence of stumbling events, where the brace stabilized the patients by providing more than 15 Nm of assistive torque, is visualized in Figure 4D. For all patients the number of these events was below five for most days. In three out of eight patients this function was activated at least three times on most days. Again there are outliers for most of the patients, with a maximum of 67 events on a single day for P2. During the whole observation period for all patients (1,179 days) 3,535 stumbling steps where observed. This means that on average every day approximately three stumbling steps occurred per patient. Looking at the maximum flexion torque that occurred during stumble recovery (see Figure 4E), a big variation between patients can be observed. Please note that all stumbling mode activations (also those with less than 15 Nm supportive torque) are considered in Figure 4E. Most of the stumble recoveries required less than 60 Nm of supportive torque, but several patients had outliers that required higher torques. P1, P5 and P6 required 90 Nm or higher, with a maximum value of 92 Nm (P6).

E. Sitting mode activation

Most of the patients performed between 18 and 40 sitting mode activations per day (see Figure 4F). P4 had more than 76 transitions to sitting on most days. Comparing Figure 4A and Figure 4F, it can be seen that patients with longer daily use duration had more sitting mode activations.

F. Personal perception reports

Seven out of eight patients reported “most satisfied - (1)” with the C-Brace at the end of the study. After the study, one of them (P8) reported that she was “unsatisfied - (5)”, due to the weight of the C-Brace. She went back to her previously used orthosis at the end of the study. At the six month follow up visits, patients reported improvements in safety and quality in all categories of ADLs according to the ADL-Q questionnaire (see Figure 5). As this study focuses on mobility items, the mobility and public transport category is highlighted in these results. Items of this category are listed in TABLE III, separating tasks into quality and safety. The majority of tasks were rated “better with the C-Brace”, except for the item “get up off the floor”.

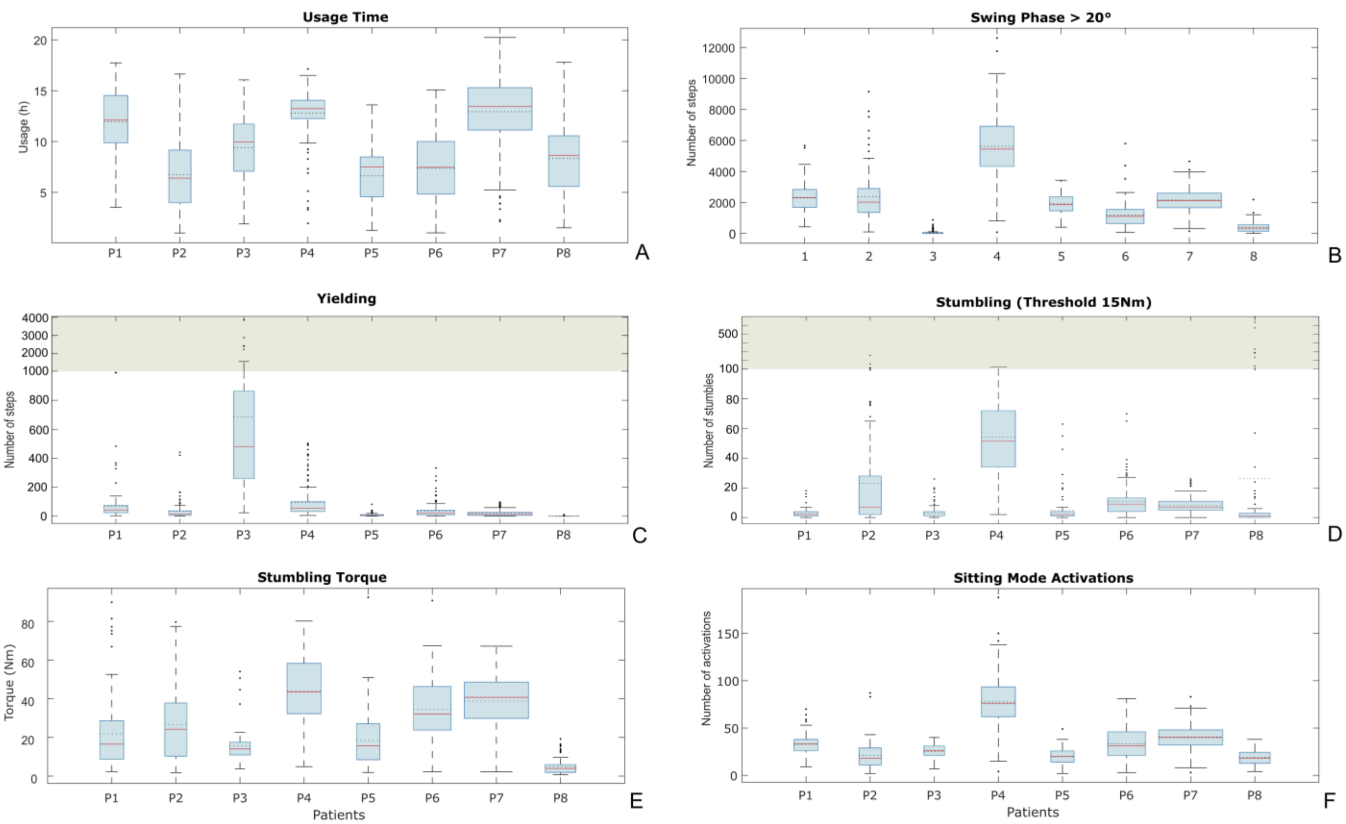

Figure 4. Boxplots for typical daily use parameters of the brace for the respective patients. (A) usage time per day , (B) level walking steps with more than 20° swing phase angle per day, (C) yielding steps per day, (D) number of stumbling events with more than 15Nm supportive torque per day, (E) maximum supportive torque during stumbling (all stumbling mode activations are considered), (F) number of sitting mode activations per day.

TABLE II
RESULTS ON USAGE INTENSITY

Patient ID	P1	P2	P3	P4	P5	P6	P7	P8
Observation period (days)	224	303	112	207	252	321	360	190
Days analyzed	111	141	95	162	124	204	299	151
Days with brace use >1 hour	110	102	95	156	107	173	295	141

TABLE III
COMPARISON WITH PREVIOUS FITTING REGARDING QUALITY AND SAFETY FOR SELECTED MOBILITY TASKS

Mobility items	Quality rated by % of patients					Safety rated by % of patients					No answer
	-2	-1	0	+1	+2	-2	-1	0	+1	+2	
Get up off the floor	13	0	13	25	38	13	0	25	25	25	13
Step over a curb	0	13	13	0	75	0	0	13	13	75	0
Climb over smaller obstacles like (stones or branches)	0	13	0	13	75	0	0	13	13	75	0
Stepping or standing on obstacles (stones)	0	13	0	13	75	0	0	13	13	75	0
Walk in different shoes	25	0	38	13	13	0	0	38	25	25	13
Ascend stairs	13	13	13	13	50	0	0	25	0	75	0
Descend stairs	0	13	0	13	63	0	0	13	0	75	13
Ascend ramps / slopes	0	13	13	25	50	0	0	13	13	75	0
Descend ramps / slopes	0	0	13	25	63	0	0	0	0	100	0
Walk on uneven / unknown terrain	0	13	0	13	75	0	0	13	13	75	0
Walk at different speeds	0	13	0	13	75	0	0	13	13	75	0
Go backwards	0	13	0	13	75	0	0	13	13	75	0
Carry heavy objects	0	13	0	13	75	0	0	13	13	75	0
Walk outside in bad weather (rain or snow)	0	13	13	13	63	0	0	25	0	75	0

Legend for comparative ratings (rounded values):
-2 "much better with previous fitting", - 1 "better with previous fitting", 0 "no difference", +1 "better with C-Brace", +2 "much better with C-Brace"

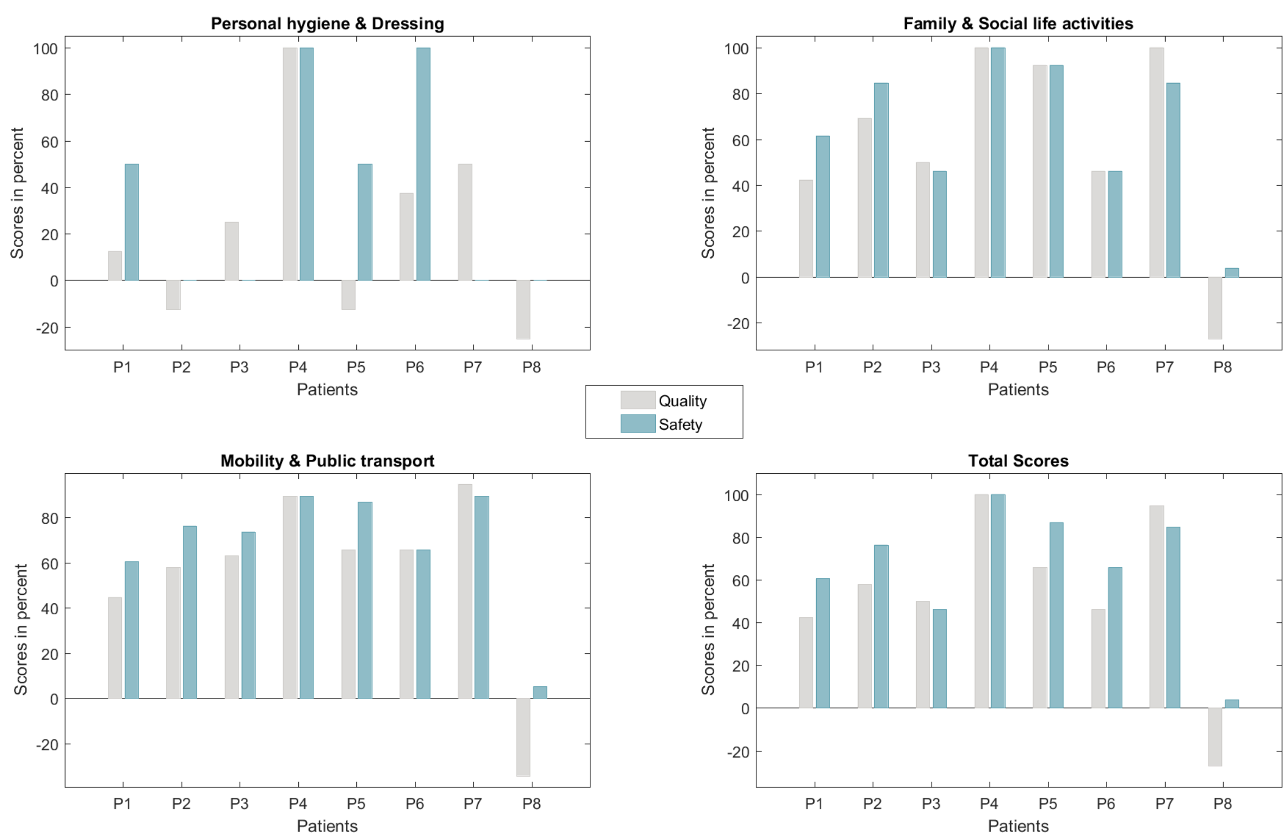

Figure 5. Quality and safety ratings of the C-Brace compared to the previous fittings for categories of everyday life activities. The bars represent the percentage of the maximum achievable score. Positive ratings indicate that the C-Brace was perceived better than the previous fitting.

V. Discussion

All the patients used the brace on the observed days over a period of several hours. There were variations in usage intensity between patients. Interestingly, the most severely paralyzed patient (P4) had the highest usage counts throughout all observed activities (Figure 4). The number of steps with regular SWP initiation was comparatively low for P3 and P8. The reason for the low number of steps with knee flexion >20° in SWP for P8 might be spasticity in the knee extensor musculature, which inhibited knee flexion during SWP.

P3 had troubles with initiating SWP because of flexion contractures in the hip and knee. This resulted in a high number of yielding steps compared to the other patients. Although the yielding functionality of the C-Brace is intended to support patients when descending ramps and stairs, it also gets activated during level walking, if a regular SWP cannot be initiated (e.g. on uneven terrain or if the patient cannot initiate SWP). In this situation the patients can rely on the brace and bend the knee joint against the resistance of the hydraulics. It was assumed that P3 was not able to initiate the SWP functionality of the brace for many steps. Consequently, the yielding functionality was also used during level walking.

Although the typical number of daily yielding steps is rather low for most patients, there are outlier days indicating that the yielding functionality is more relevant on certain days. Generally patients tend to avoid situations where they need the yielding function, e.g. by use of elevator instead of stairs if an elevator is available. The outlier days show that this functionality is important and contributes to quality of life, by providing the freedom to use it when necessary. An example for such an outlier day could be an icy day in winter, where patients walk more carefully and use the yielding function instead of SWP initiation.

The stumbling support functionality was used several times throughout the study by all patients. As stumbling is an inherently uncontrolled event, the variation of torque provided to support the patient was high. Half the patients activated the stumble recovery mode at least once a day. The high variation of activation numbers between days can be explained with different personal daily conditions. Seven out of eight patients had a supportive torque of more than 50 Nm at least once during stumbling recovery. Therefore, it is assumed that several falls have been avoided with this important safety feature. This is also reflected in the user satisfaction score related to safety, which is positive for all patients for mobility related activities. Future work will investigate automated detection and classification of falling events in the data.

On average, each system endured 2,106 steps per day, which corresponds to 768,690 steps per year, assuming daily use of the system. However, there are outliers such as P4 who typically took more than 5,400 steps per day (almost 2 million steps per year). These numbers are in a similar range observed with transfemoral amputees [27]. This high number of expected cycles should be taken into account when designing supportive systems. The ISO 10328 standard for the structural design of prosthetic components, which often also is applied to orthotics, requires 3 million cycles for fatigue testing [28]. Assuming a product life span of 6 years this would correspond to only 500,000 steps per year, a significantly lower number than what was observed with active patients in this study.

Compared to healthy individuals, which perform approximately 60 transitions between standing and sitting [29], and taking into account that some patients do not wear the brace the whole day, the number of sitting mode activations (see Figure 4F) is in a similar range.

The personal feedback of the patients was mainly positive. Seven out of eight patients saw an improvement in their quality of life and wished to continue to use the C-Brace after terminating the study. This was despite the increased size and weight, which is approximately 900 g higher than a standard brace.

Improvements to quality and safety were reported for social activities and mobility tasks. Similar results were observed in studies with a previous version of the device [13], [14]. The only category, where ratings were not consistently better with the C-Brace was “personal hygiene and dressing”. The reason for this might be the increased size of the C-Brace compared to classic braces. The knee joint unit adds volume to the thigh section of the brace, which makes dressing more difficult. Only P8 did not continue to use the system, although she reported improvements in safety (TABLE III). She probably could not take advantage of the benefits because she sometimes had trouble flexing her knee in SWP, which is the most important feature of the system. Not being able to efficiently use this functionality, the disadvantages of the system (increased size and weight) outweighed the benefits for her. This shows that patients have to be selected carefully to achieve a successful fitting. Additionally, psychological factors (e.g. the demand for safety) and the motivation of the patient play an important role. Therefore, it appears beneficial to do a trial fitting, in order to find out if a patient can benefit from the system. Ideally, patients should have the possibility to try out such a system over an extended time period in their everyday life environment.

Limitations of the study were that only eight patients were observed, and data was not available for the whole study period. As only days with data available (in total 1,179 for all eight patients) were analyzed, the results regarding usage intensity might be biased. Based on the number of analyzed days (1,179, with at least 95 days analyzed per patient), it is assumed that the results are representative for the whole study period. Future studies will include more patients, to gain more information about differences in system use related to different pathologies.

VI. Conclusion

The C-Brace system provides functionalities that improve the safety and quality of motion for patients when performing locomotion activities of daily life. This applies to a wide range of pathologies. Most of the patients intensively used the functionality of the system. Consequently, the expected use cycles can be as high as 2 million steps per year for some patients. The stumbling support functionality is an important safety feature of the system. It was activated several times a day on average, and therefore contributes significantly to the safety of the system.

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