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Smart Passive Exoskeleton for Everyday Use with Lower Limb Paralysis: Design and First Results of Knee Joint Kinetics

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Abstract— **Exoskeletal systems become more important for the rehabilitation of people with lower limb paralysis. Today these systems are mainly used in clinical settings, but also devices to support activities of daily living are becoming reality. The uncontrolled environment of home use leads to new design challenges and loading situations that are not yet well known. In this paper a novel orthotic system that supports people with lower limb paralysis in their everyday life is introduced. To learn more about the mechanical stress on the device, the knee joint unit was equipped with various sensors to measure motion, forces and power in real-world situations. The influence of the user's residual function on these parameters was investigated. First results from a clinical trial with 3 paralyzed patients show that knee power is in the same range as for healthy humans, with peak values up to 5.9 W/kg. Peak torque on the knee joint can be as high as 1.8 Nm/kg. There are large differences between patients depending on their diagnosis. All systems were exposed to impacts with accelerations higher than 85 m/s² at exceptional events. These results show that patient pathology significantly influences system loads, and that mechanical robustness is important for the design of supportive systems.**

I. Introduction

Mechatronics has become an integral part of supportive technology for people with lower limb paralysis, and in the past few years numerous exoskeletons that restore walking ability for people with complete paralysis have been developed [1], [2]. Some of them, like the ReWalk Personal 6.0 (ReWalk Robotics, Yokneam, Israel) and the Indego Personal (Parker Hannifin, Cleveland, OH, USA) were the first powered devices cleared by the Food and Drug Administration (FDA) for personal use [3], [4]. These devices proved their effectiveness in clinical settings. Recently there has been research on the design of textile exosuits that provide active power support for people with muscle weakness [5]. The C-Brace (Ottobock, Duderstadt, Germany) is a knee ankle foot orthosis (KAFO) with a passive microprocessor controlled knee joint that provides high functionality for patients with lower limb paresis or paralysis [6]. In contrast to powered exoskeletons, which aim to support patients with severe paralysis, the C-Brace was developed for patients with partial lower limb paralysis, who still have residual functions. The system was designed as an everyday mobility device, which means that it has to support and endure all common activities of daily living (ADLs). These required functionalities lead to new loading situations [7], which resulted in design challenges. Additionally such a device has to be robust against shocks, water, and dirt. Ideally such a system is free of maintenance. The first generation of C-Brace fulfilled these requirements, but the system was large and the size of the product led to challenges for the patient when wearing normal clothing. To overcome these shortcomings, a smaller and lighter system was developed, which is described in this paper. It has similar functionality as the C-Brace. To optimize the joint mechanics, fundamental research on expected loads was necessary. Although there has been a lot of research in the field of exoskeletons, the loads on such systems that occur in everyday use by patients are not well known. Most of the available systems have specified limitations for weight and height. This leads to the implicit hypothesis that patient weight and height are the dominant factors for the loads on the supportive system. However, we assumed that besides these factors, the patient's pathology (muscular status) and anatomy (contractures) also have a significant impact on the loads acting on the system. One goal of this work was to investigate this potential correlation. As lab settings can only represent a part of real life, data was collected in the patient's everyday life environment. The research prototypes were equipped with sensors, which measure the load (knee torque) transmitted through the exoskeletal structure of the brace, as well as knee angle, leg orientation and accelerations. This information about loading situations in everyday life is important to optimize the design of supportive systems for ADLs.

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II. Materials

A. Leg brace system

The main components of the leg brace system, which is designed for a patient weight up to 125 kg, are shown in Figure 1.

A microprocessor controlled knee joint (1) is mounted on the lateral side of the brace. The shape of the joint unit can be adjusted in the frontal plane to fit the user's anatomy as closely as possible (cf. Figure 1B). The orientation of the joint unit in the frontal plane is fixed with the medial follower joint (2), which consequently has to bear significant loads and was therefore custom designed for this application. Depending on the patient's needs, two design variations of the lower leg component have been developed. The first version is shown in Figure 1A and B and comprises a standard ankle joint (3) (17LA3=T-16, Ottobock, Duderstadt, Germany) with adjustable range of motion. The second version is shown in Figure 1C. It has a custom made composite spring (6) in the shank section, which is used to store energy during roll over in stance phase (STP) and release it in terminal stance to support swing phase (SWP) initiation. As significant loads are transmitted between the brace and the user's leg, a good anatomic fit of the interface parts is necessary. Therefore, the interface parts (4) are custom made out of carbon fiber composites, based on cast models of the patient's anatomy. The leg is fixed in this structure with Velcro straps (5).

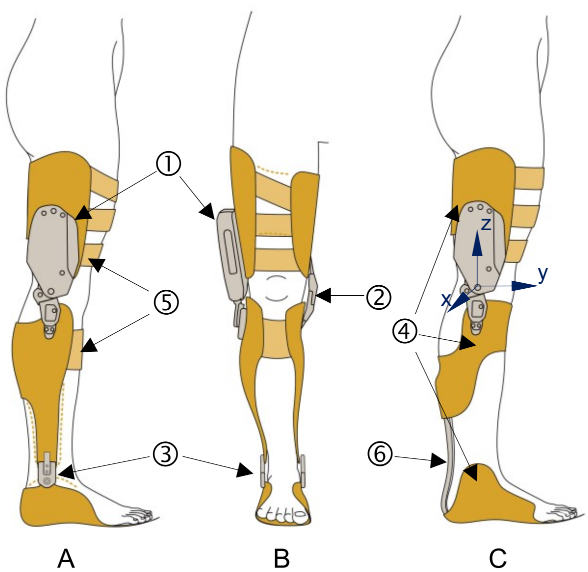

Figure 1. Overview of the brace system: A , B version with ankle joint, C version with dorsal spring. (1) microprocessor controlled knee joint, (2) medial follower joint, (3) ankle joint, (4) interface parts, (5) fixation straps, (6) composite spring. Definition of coordinate system for joint accelerations: The coordinate system is local with respect to the thigh section. The x-axis is parallel to the knee joint, the z-axis points towards the proximal end of the thigh.

B. *Knee joint design*

The motion of the supported leg is controlled by a computer controlled knee joint, which is a fully autonomous functional unit, with integrated microprocessor controlled hydraulics, sensors, battery and control circuity. A linear hydraulic cylinder is used to control the knee joint by means of a lever mechanism as shown in Figure 2. The mechanism transforms the linear motion of the hydraulics to the rotational motion of the knee joint. Hydraulic force is controlled by the microprocessor via integrated servo valves. There are two separate valves for the two directions of motion. This enables the hydraulic to provide a high resistance in one direction (e.g. knee flexion) and at the same time a low resistance in the other direction (e.g. knee extension) without adjusting valves, which is an important safety feature.

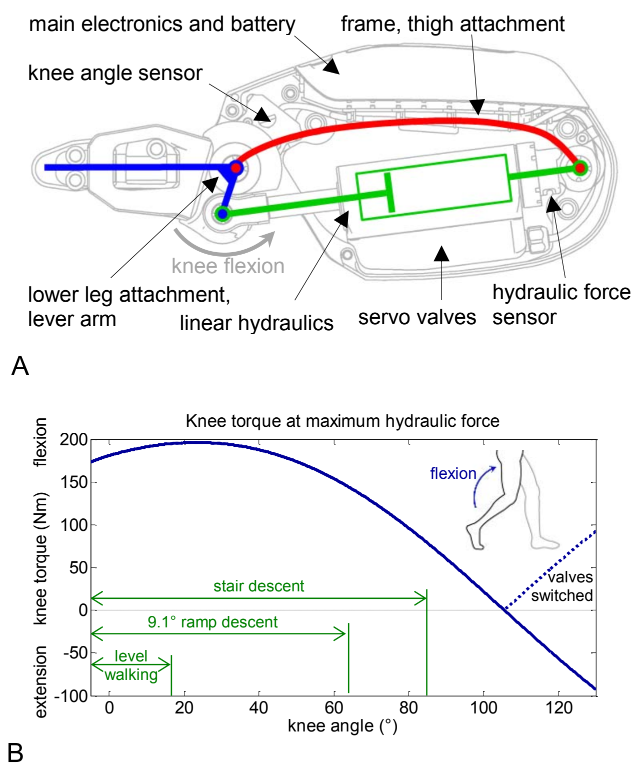

Figure 2. A Functional components of the knee joint unit (cover part removed) with schematic of lever arm mechanism. B Diagram of maximum achievable knee torque at maximum hydraulic force (9,000 N). The green arrows depict the relevant range of motion where the knee is flexed under load for typical activities.

The lever arm geometry of the knee joint was chosen to provide an angle dependent maximum torque as shown in Figure 2B. The torque values in the diagram are based on a maximum hydraulic force of 9,000 N, which is the maximum force of the hydraulic unit. Hydraulic force is limited to this value by a relief valve to protect the structural parts. 0° represents the fully stretched position of the knee; negative values represent hyperextension, positive values knee flexion. As the extension stop is elastic, the knee joint unit allows up to 1° of hyperextension. With constant hydraulic force, the torque support of the knee joint is progressive up to 21° knee flexion. This behavior is beneficial in level walking to support stance phase flexion during the load response phase. Maximum knee flexion in this phase is typically 20° [8]. Maximum possible knee torque is above 160 Nm over a range of motion of more than 55°. This is enough to support safe descending of stairs, as the peak torque in this activity is expected to be between 35° and 40° of knee flexion [7]. The cylinder motion reverses at 105° knee flexion. Theoretically, the effect of the hydraulic on the joint torque cylinder can be reversed in this situation by switching the valves, as indicated with the dashed lines in Figure 2B. In practice, this range is irrelevant for walking. It is more important for sitting, where the user desires free motion of the leg without any resistance. Consequently, the hydraulic valves should be opened in this situation.

C. *Electronics and sensors*

The knee joint contains sensors to measure joint angle and hydraulic force, an inertial measurement unit (IMU) with 3-axis accelerometer and 3-axis gyroscope, a slot for a SD Card for data logging, a real time clock (RTC), a dual mode Bluetooth module for data exchange and a 3.3V Li-Ion battery. As can be seen in Figure 2A, most of the components are packed into the housing at the front of the joint unit. A fully charged battery provides more than 18 hours of power autonomy. The Bluetooth link to an external PC is used only for data acquisition and to set patient specific control parameters.

D. *Control*

The joint is controlled by a state machine on the local microcontroller, which runs at an update rate of 100 Hz during regular walking. As human force control bandwidth is in the order of 20 to 30 Hz [9], the control cycle frequency of 100 Hz is assumed to be perceived as real time control. Sensor information is processed in each cycle to control extension and flexion dampening of the hydraulic knee joint unit. For walking activities, a proven control paradigm from prosthetics [10], [11] was adopted. It is based on the "default stance" principle which means that most of the time the system is in a safe stance phase (STP) mode, providing a high resistance against knee flexion to stabilize the patient. Only if the sensor information implies that the patient wants to perform a swing phase (SWP) during walking, is knee flexion resistance reduced to initiate SWP.

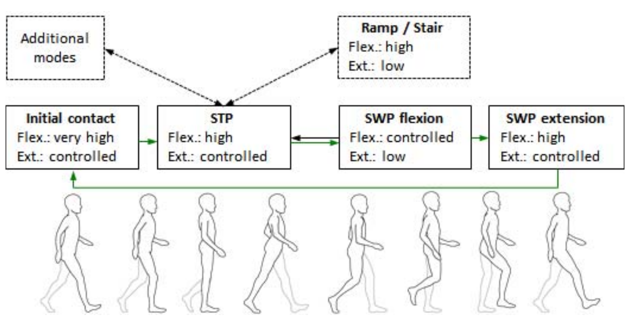

Figure 3. Schematic of the control states for level walking. For each state the damping mode of the hydraulic unit for knee flexion (Flex.) and knee extension (Ext.) is shown in the respective state box, where "controlled" means that resistance is generally low but might be increased to achieve a desired knee angle. Green arrows depict state transitions for level walking, black arrows symbolize the state transitions if a movement is interrupted (default stance).

Figure 3 depicts the main states for walking. The positions of the state boxes for level walking (lower row) correspond to the posture of the avatar at the bottom. Additional modes (e.g. sitting, standing, negotiating ramps or stairs, user definable modes) are symbolized by dashed lines, they are not shown in the diagram. The resistance against knee flexion in the "STP" state is high but the knee is not locked, so the patient can sit down in this state. For shock absorption in the loading response phase, a knee flexion of approx. 20° followed by an extension is performed in the physiologic gait pattern [8]. This is supported in "STP" state, because the joint kinematics provides progressive damping behavior up to 21°. To avoid hard impact at the extension stop the extension behavior is controlled in this gait phase. For a smooth and reliable transition between "STP" and "SWP flexion" in level walking, the orthosis uses knee angle, IMU and hydraulic force information. To initiate swing phase the following criteria have to be fulfilled: Brace is stretched with an extending knee torque, leg is rotating forward. Once the knee identifies that "SWP flexion" should be initiated, the flexion dampening is reduced to a minimum level to allow the leg to swing. Later in this phase, the maximum knee joint flexion angle is controlled by the hydraulics using the flexion valve, to limit the maximum knee flexion angle to an adjustable physiological value. This should improve gait symmetry for the user at different walking speeds. As soon as the sensors detect that knee motion reverses, the state "SWP extension" is activated. Flexion resistance is increased to a high value, to provide safe support against knee buckling for the case that swing phase extension is interrupted (e.g. during stumbling). This safety feature is possible because knee flexion and extension can be controlled individually. Towards the end of SWP extension the extension valve controls the deceleration of the leg in order to reduce the impact at the extension stop to an adjustable value.

Due to anatomical restrictions (e.g. contractures in the hip or knee joint), some patients need additional support at initial heel contact and in the load response phase during walking. To address this problem the flexion resistance can be set to a value that is higher than the regular stance phase resistance in the "Initial contact" state.

If the patient walks down a ramp or stair, the knee joint unit is set to a high resistance, and the "Ramp / Stair" state is activated instead of a swing phase initiation. Knee extension is always possible in that mode.

The system also provides additional functions like an optional standing and sitting function or a freely configurable personal mode (e.g. for biking). The standing function locks the knee flexion in a slightly flexed position during standing, providing additional support, especially when standing on uneven ground. It is automatically deactivated as soon as the user starts walking again. The knee joint control is configured to fit the individual's specific requirements via an adjustment app. Additionally the patient can use a smartphone application to instantly change certain settings to adapt the system to fatigue or to switch into predefined modes for unique activities such as riding a bike.

III. METHODS

A. *Patient experiments*

Recruitment and study conduct took place at two sites. Inclusion criteria were as follows: Subjects fulfills indications (unilateral or bilateral lower limb paresis or flaccid paralysis, flexion contraction in the knee below 20°, varus or valgus below 18° beyond anatomic neutral, body weight between 45 and 100 kg), subject is older than 18 years and willing to use the provided orthosis. Exclusion criteria were as follows: subjects with unstable medical conditions, unstable bones or unstable spasticity, subjects with balance problems not related to paresis. All subjects provided written informed consent before being included 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 8 subjects were enrolled in the study. For this article preliminary data from the first three subjects is used. All patients had the possibility to familiarize themselves with the brace system in several gait training sessions in the lab under supervision of a physical therapist. Once they were able to safely use the device, the patients were allowed to take the braces home for everyday use.

B. Data acquisition

For the study the knee joint units were equipped with SD-cards with 32 GB storage capacity. The control software was configured to store the whole sensor information of the system at each control cycle (every 10ms, if the patient is active). Captured data contains 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. Dependent on the patient data was recorded for between 37 and 48 days, resulting in 6 to 10 GB of recorded data per patient.

C. Data processing

The data from the SD-Cards was clustered to files that represent one day each. Data analysis was performed with Matlab R2015b and GNU Octave V4.2.1. Only data from days where the brace was actively worn were considered for further analysis. Knee torque was calculated from hydraulic force and knee angle, based on joint kinematics. The joint load and power data were normalized for patient weight. Daily extreme values for knee torque, knee power, maximum knee angle, and acceleration of the thigh section were evaluated for each patient. 2000 data points of these signals around these extreme values, representing approx. 10 seconds before and 10 seconds after the extreme event were extracted for more detailed analysis of the related activities.

IV. Results

All three test patients were suffering from neuromuscular deficits of different severity, resulting in limited ability to walk safely without a brace. None of the patients had major contractures in the hip or knee joint, or major foot deformations. Patient characteristic details are provided in TABLE I. P1 wore the braces on 35 out of 37 days, P2 wore it daily. P3 only wore it on 35 out of 44 days due to (not device related) medical conditions.

TABLE I. PATIENT CHARACTERISTICS

	Patient ID		
	P1	***P2***	***P3***
Age (years)	62	67	74
Height (cm)	149	176	170
Weight (kg)	45	78	80
Affected side	bilateral	right	left
Pathology	NF1 Reckling-hausen	Post-Polio	Slipped disc L3/L4 Hip TEP R Knee TEP L
Muscular status (Janda Scale [12]) 0…no function 5…normal			
Hip abd / add	L0/0 R0/0	L4/4 R3/3	L4/5 R5/5
Hip flex / ext	L0/0 R0/0	L5/5 R3/3	L5/5 R5/5
Knee flex / ext	L0/0 R0/0	L4/5 R3/0	L5/4- R5/5
Foot plant / dors	L0/0 R0/0	L5/4 R2/3	L5/4 R5/5

TABLE II. sums up the main results of the gathered data. The main activities where the peak values of load and power occurred are listed for each patient. For the bilateral patient P1 the peak values for each leg side are listed separately.

TABLE II. RESULTS FROM GATHERED DATA

	Patient ID		
	P1	***P2***	***P3***
Days recorded	37	48	44
Days analyzed	35	48	35
Peak flexion torque (Nm/kg)	1.8 (L) 1.7 (R)	1.2	1.0
related activities	descent[a] stumble	descent[a] sit down	descent[a] stand sit down
Peak knee power (W/kg)	4.4 (L) 5.9 (R)	3.8	2.5
related activities	descent[a] stumble	descent[a] sit down	descent[a] sit down

a. descent of ramps or stairs

For all patients ramp or stair descent and sitting down were the main activities where the highest loads on the system were reached. For P3 also high flexion loads were produced when standing in a flexed position, using the standing function of the system.

The Figures 4, 5 and 6 visualize the daily maximum values of the respective parameters using box plots. The red line indicates the median of the data; the edges of the boxes represent the 25th and 75th percentiles. The whiskers extend to the most extreme data points not considered outliers [13]. Outliers are plotted individually, using the '+' symbol for values that lie between 1.5 and 3 times interquartile range (IQR) and the "o" symbol for values outside 3 times IQR.

A. Knee angle

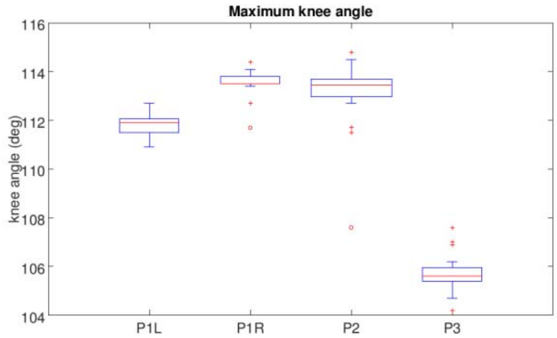

Figure 4. Box plot of maximum knee angle for the patients. 0° represents full extension, positive values represent knee flexion

As can be seem in Figure 4, the variation of maximum knee angles between the days is small for all patients, except for some outliers. For all patients maximum knee flexion was reached when sitting. The range of motion is similar for P1 and P2. For P3 it is smaller due to anatomical restrictions (knee TEP).

B. Knee torque

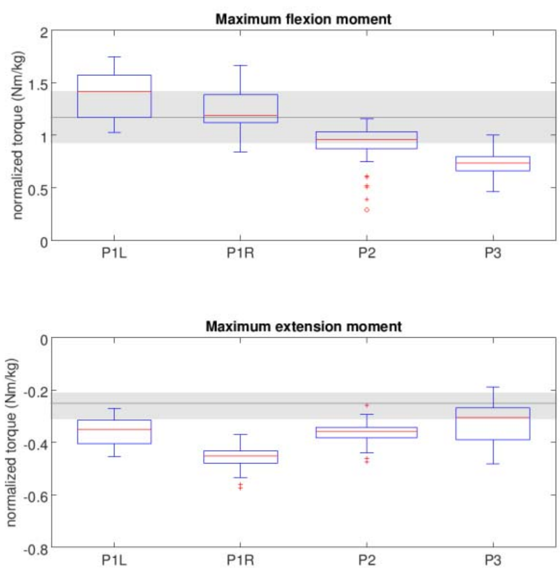

Figure 5. Box plot of maximum knee moment for the patients in flexion (positive torque values) and extension (negative torque values) direction. The shaded area represents reference data from healthy subjects walking down stairs (flexion) and walking on level ground at high walking speed (extension) [14]: The line shows the average value, the shaded area represents the standard deviations.

Although the data is normalized for patient weight, there were large differences in knee torque values between patients. P1 had the highest values in flexion with both legs, and the highest values in extension with the right leg. The values of the two legs of P1 are similar, with a tendency of more flexion on the left leg. The loads on the brace for P1 and P2 in flexion are similar to the torque generated by healthy subjects when walking down stairs [14]. The extension load is higher for all patients than reference data obtained in level ground walking with high speed [14]. P3 had the lowest values in both directions. Knee angle at maximum knee flexion torque was typically between 50° and 60° for all patients.

C. Knee power

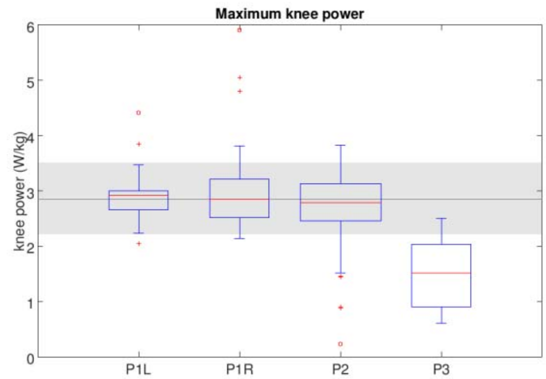

Figure 6. Box plot of maximum power dissipated by the knee joint unit. The shaded area represents reference data from healthy subjects walking down stairs [14]: The line shows the average value, the shaded area represents the standard deviations.

Looking at normalized power dissipated by the knee joint, the values for P1 (both legs) and P2 are similar, for P3 they are lower. Usual situations where peak power values occurred were walking down ramps or stairs and sitting down. During these activities the power dissipated by the brace is similar to the power dissipated in the muscles of healthy subjects descending stairs [14]. P1 had some outliers with a peak value of 5.9 W/kg on the right leg, which occurred during stumbling. In this situation velocity of movement and load on the device are high.

D. Thigh acceleration

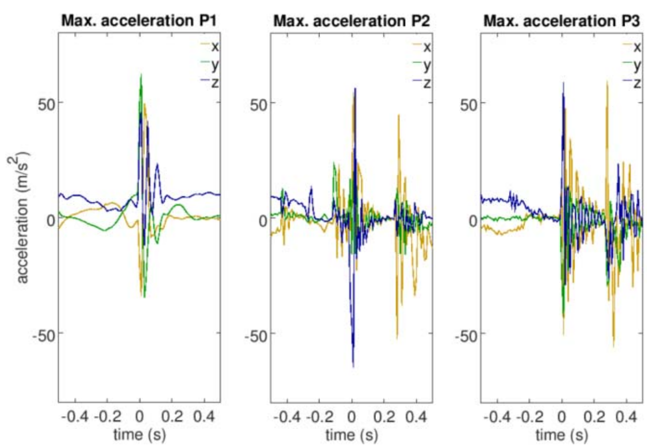

Figure 7. Maximum tigh accelerations for the individual patients. For P1 only the right leg (which had the higher acceleration peaks) was considered. Maximum absolute acceleration occurred at t=0 in the plots. Accelerations refer to a local coordinate system as defined in Figure 1.

Maximum absolute accelerations reached values of 85 m/s² for P1, 87 m/s² for P2 and 89 m/s² for P3. For all patients these extreme values were outliers. The median values of the maximum absolute accelerations of individual days were 71 m/s² for P1, 70 m/s² for P2 and 61 m/s² for P3. Figure 7 shows the component values for acceleration around the absolute maximum of the measurement period for each patient. High accelerations occur in different directions, which indicates, that these events are probably caused by impacts or collisions. For P2 and P3 there were two acceleration peaks within a short time period. The direction of the acceleration was very different at the peaks. Additionally, the brace was extended while not loaded, which indicates that the brace was falling down and bounced back while not being worn.

V. Discussion

Assuming that body weight is a dominant factor for the magnitude of maximum system loads, the normalized values should be similar for each patient. As the presented results show significant differences between patients, this might not be the case. The deviation also cannot be explained taking patient height into consideration, because for P1, the shortest and lightest patient the highest normalized values were produced. One might be able to explain the differences taking the residual muscular functions into account. In this study purposely patients with different residual functions were chosen, because it was hypothesized that residual functions might play a significant role on joint loads. The first results support this hypothesis: P1, who produced the highest normalized load, was the most severely affected patient and therefore had the lowest residual muscular function. Although the patients in the study were without major contractures, many patients with lower limb paralysis have contractures, resulting in geometric deviations from the normal anatomy. These deviations, as well as the age of the user, might also have an influence. Consequently further research with younger patients and patients with contractures is necessary.

At least for the activities with high energy exchange considered in this paper, peak load and power data obtained from healthy subjects seem to be good references to estimate the loads on an exoskeleton created by severely paralyzed patients. As the main interest was on extreme loads, the most common activity of daily living, level walking, was only considered with regard to the maximum knee extension moment. The measurements for this load were higher for all patients than for healthy subjects. Individual compensation mechanisms of the patients, who often try to gain stance stability by extending the leg, likely play a role. One other reason might be the control of the knee joint unit, which requires an extended knee before initiating swing phase.

Maximum knee torque and power in everyday life can be very high in certain situations (e.g. during stumbling). Consequently it makes sense to provide compliant systems with overload protection, which can at least passively handle these loads. The braces were exposed to peak accelerations of almost 90 m/s² in different directions. These maximum values seem to be related to collision events. These events and the corresponding impacts on the system have to be taken into consideration when designing a supportive system for everyday use.

VI. Conclusion

For patients with partial paralysis, patient weight and height are insufficient criteria to estimate expected loads on a supportive exoskeletal systems. The patient's muscular status seems to play an important role. Peak loads that occur at exceptional events (e.g. stumbling) have to be considered for the system design. As realistic reproduction of these events is not possible in a lab, further field research is necessary.

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