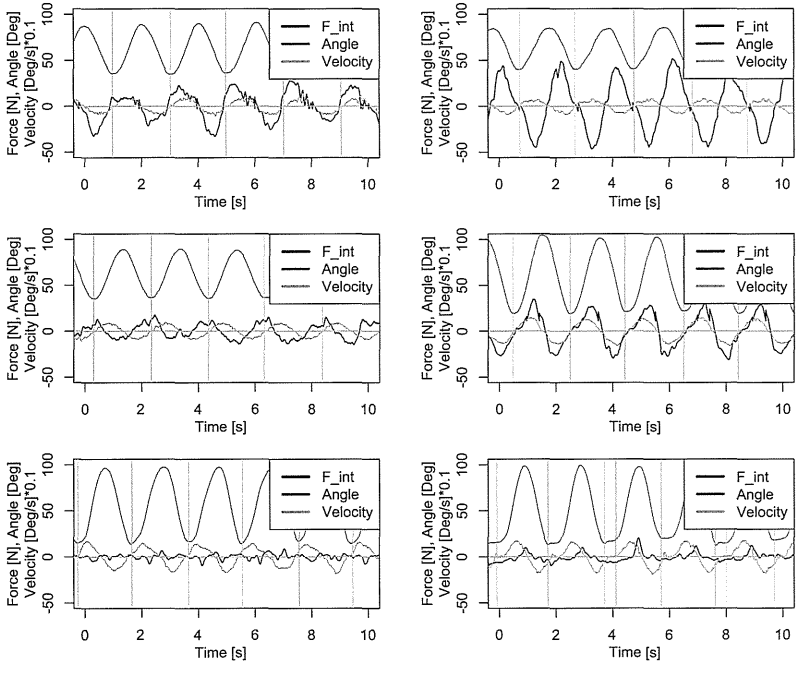

Fig. 9 Knee joint angle, its velocity and the interaction force at the shank cuff. Larger joint angle indicates flexion and positive force indicates pushing (ex. HAL pushes human leg into extension). Top Left: Autonomous control. Wearer tries to swing earlier than HAL as if to increase pace. Top Right: Autonomous control. Wearer tries to swing later than HAL as if to decrease pace. Middle Left: Autonomous control. Wearer tries to swing in accordance with HAL. Middle Right: No actuation. Wearer swings according to the metronome. Bottom Left: Viscosity compensation control. Wearer swings according to the metronome. Bottom Right: CVC mode. Wearer swings according to the metronome.

the force is almost anti-phase with the velocity, since the wearer is trying to decelerate HAL. In the case of no actuation (Middle Right), the force is almost in-phase with the velocity, since the wearer has to exert against mechanical viscosity. In the other three cases, interaction force was comparatively small, reflecting the nature of the motions. It is interesting to see that with a healthy subject viscosity compensation control and CVC do not make much differences in amplitude, since his bio-electric signal and motion is almost synchronized.

Compared to the joint angle and velocity trajectories which seem to be resembling to each other among the various control conditions, which is natural after the task was to swing the lower limb at the same frequency and amplitude, the interactive force varies a lot. It implicates the importance of measuring the interaction force directly. For example, inverse dynamics method which computes the interactive force based on kinematic movement is not appropriate to uncover such variation, since the interactive force may not appear in joint motion by being balanced with joint torques of human skeleton and HAL. Simply put, it is possible that the human leg and HAL pushing or pulling strongly each other, but still keeping a static situation. Also, as shown in the results, HAL may be assisting or preventing the motion of the human leg, which is very important in evaluating the role of motion assistive robots.

In this experiment, a simple task of single joint motion was conducted to evaluate the plausibility of the method. It was adopted as a test motion because it allows intuitive interpretation of the estimated forces. At the same time, this motion has clinically significant implication. In the treatment course of rehabilitation after damage caused by stroke or other neural or biomechanical injuries, patients

first go through training of single joint motions lying on a bed or seated on a chair, before going into the stage of walking training. Since the robot assisted rehabilitation is expected to be applicable to the single joint training as well as walking training, data obtained in this section has possibility to provide reference for evaluation of clinical single joint training in a future perspective.

5. CONCLUSION

We proposed a method to measure the intraction force between human and wearable robot based on strain gauges installed on cuff frame. By this method, total force of interaction at cuff can be measured at a good accuracy, without affecting the interaction, whose plausibility was shown in a single joint motion experiment with HAL and a human wearer. Future work includes application to locomotion support and analysis of effectiveness of assist and safety.

ACKNOWLEDGMENTS

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Exoskeletal Neuro-Rehabilitation in Chronic Paraplegic Patients – Initial Results

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Abstract. Treadmill training after traumatic spinal cord injury is established as a therapy to improve walking capabilities in incomplete injured patients. In this study we investigate walking capabilities after a three month period of HAL® exoskeleton supported treadmill training in patients with chronic (>6 month) complete/incomplete (ASIA A – ASIA C) spinal cord injury. We monitored walking distance, walking speed and walking time with additional analysis of functional improvement by using the 10-m-walk test, the timed-up-and-go test and the WISCI II score in combination with the ASIA classification.

1 Introduction

Previous studies have confirmed that regular treadmill training can improve walking capabilities in incomplete spinal cord injury patients [1-4]. Over the last ten years,

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Previous studies have confirmed that regular treadmill training can improve walking capabilities in incomplete spinal cord injury patients [1-4]. Over the last ten years,

driven gait orthoses have been applied for such treadmill training in order to move the patient's legs continuously and physiologically [5-7]. However, such training requires extensive resources, is locally limited to the treadmill, does not allow supported walking abilities outside the driven gait orthoses attached to the treadmill, and is limited only to passive motion of the legs. More recently, various exoskeleton systems for paraplegic patients became available, which allow patient mobilization outside the treadmill, though, mainly on a basis of passive range of motion (ROM).

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The HAL® Robot Suit (Cyberdyne Inc. Japan) however, additionally allows voluntary machine supported active ROM (CVC mode) of incomplete paraplegic patients by using minimal bioelectric signals recovered from hip and knee flexors and extensors [8-10]. The goal of this study is to evaluate initial functional results in chronically complete/incomplete paraplegic patients after using the supported active ROM mode of the HAL® Robot Suit Exoskeleton.

2 Material and Methods

2.1 *Subjects*

We have investigated four patients (35 years to 62 years of age; 3 males and 1 female) with chronic (time since injury > 6 months) paraplegic spinal cord injury participated in the HAL® Robot Suit training for a three months period. One patient suffered from incomplete thoracic spinal cord injury (ASIA C), two patients from an incomplete lesion of the conus medullaris / cauda equine (ASIA B/C), and one complete paraplegic patient below Th 12 with zones of partial preservation in L1-L3 (ASIA A).

2.2 *Treadmill Associated Measurements*

Walking distance, walking speed and walking time when wearing the robot suit were measured on the treadmill at the beginning of the training, as well as after 6 and 12 weeks. Also the body weight support was measured.

2.3 *Functional Measurements*

To describe the functional improvement we did the 10-m-walk test before and after each training. The timed-up-and-go test was done once a week. By using the WISCI II score the needed support was documented.

2.4 *Others*

Additionally we measured individual spasticity of one patient with the modified Ashworth scale. The muscle strength according to the Frankel scale was recorded although as the ASIA score.

3 Results

During the training period, initial body weight support when wearing the HAL® robot suit could be reduced from 30% body weight to 15% (3 patients) and 0% (1 patient) of body weight. The walking distance when wearing the robot suit with voluntary machine supported active motion (CVC mode) increased significantly from 62 m – 216 m to 260 m – 1153 m after three months of training (as shown in Fig.1).

Ashworth scale. The muscle strength according to the Frankel scale was recorded

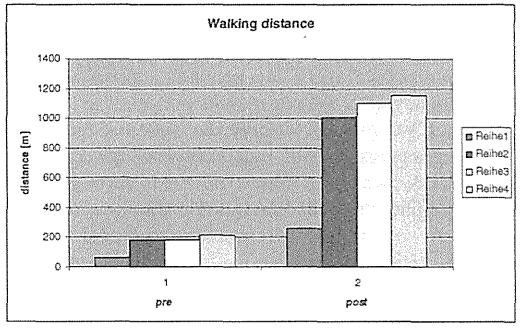


Fig. 1 Walking distance in pre and post evaluation

The walking speed increased from 0.7 km/h up to 2.2 – 2.8 km/h. Only one patient with spasticity had no improvement.

The walking time increased also from 12.09 – 18.14 min. to 18.01 – 30.03 min.

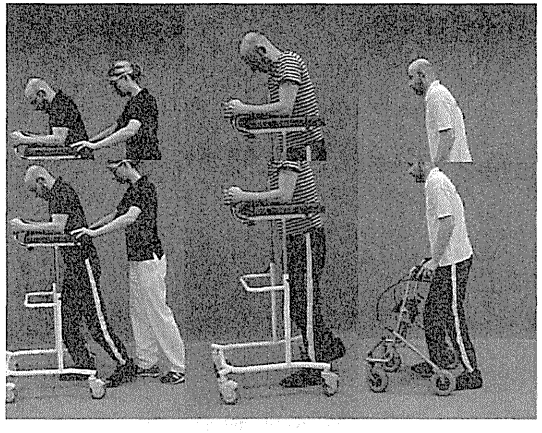
The needed time for the 10-m-walk test was significantly reduced in three patients from 56.82 – 72.02 sec. to 16.50 – 27.44 sec.

All patients showed reduction of the needed time for the timed-up-and-go test (31.22 – 82.03 sec. to 34.22 sec. – 74.06 sec.)

After the HAL® exoskeleton training the spasticity in one patient was reduced from Ashworth IV to Ashworth II.

Two patients were able to reduce the support in the 10-m-walk test, measured with the WISCI II score. The score increased from 6 to 9 points after 12 weeks (as shown in Fig. 2).

One patient (date of injury 25.05.2011) switched from ASIA B (24.02.2012) to ASIA C (05.06.2012). In the other patients we found no significant increase in muscle strength.



4 Discussion

Our preliminary results present in all patients significant increases in their functional abilities already after a three months period of active training using the HAL® robot suit in a CVC mode. Not only the treadmill associated walking and the on ground walking increased. Although an improvement in the WISCI II score and a switch in the ASIA classification were shown in some patients. These results have to be evaluated against the background that all patients were chronic spinal cord injured and were already on a constant functional level after intensive standard neuro-rehabilitation training.

5 Conclusion

Treadmill training using the HAL® exoskeleton might be a useful innovative training in chronic SCI-patients. However, these promising preliminary results are only descriptive and must be confirmed in a larger group of patients, allowing detailed statistical analysis before further conclusions can be drawn.

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Neurorehabilitation in Chronic Paraplegic Patients with the HAL® Exoskeleton – Preliminary Electrophysiological and fMRI Data of a Pilot Study

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Abstract. Training leads to increased neuronal excitability, decreased inhibition and different types of neuronal plasticity. Most studies focus on cortical plastic changes after cerebral lesions or in healthy humans. In this study, we investigate cortical excitability and plastic changes after a three month period of HAL® exoskeleton supported treadmill training in patients with chronic incomplete spinal cord injury by means of electrophysiological measurements and functional magnetic resonance imaging. Here we report preliminary results of four patients.

1 Introduction

Recent studies have confirmed that regular treadmill training can improve walking capabilities in patients with incomplete spinal cord injury (SCI). In the last ten years, driven gait orthotics have been used in treadmill training to move the legs of patients in a physiological way. Now exoskeletons for paraplegic patients are available. In a pilot study, the exoskeleton HAL® (Cyberdyne, Japan) was used in treadmill training with bodyweight support. The HAL® system records voluntary electromyographic activity with surface electrodes from the extensor und flexor

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muscles of hip and knee, and then actively supports the voluntarily initiated movements.

In the somatosensory and motor cortex of patients with SCI, large-scale somatotopic reorganization was demonstrated in a large number of studies [1-6]. For example, Henderson et al. investigated 20 subjects with complete thoracic SCI [7]. SCI resulted in significant primary somatosensory cortex (S1) reorganization, with the little finger representation moving medially towards the lower body representation. Furthermore, although SCI was associated with gray matter volume loss in the lower body representation, this loss was minimized as reorganization increased. As analyzed by diffusion tensor imaging, the authors postulated that S1 reorganization resulted from the growth of new lateral connections, and not simply from the unmasking of already existing lateral connections.

Considering these results, we hypothesized that treadmill training with the exoskeleton HAL® would lead to plastic changes in the primary somatosensory cortex of patients with incomplete chronic SCI as assessed by functional magnetic resonance imaging (fMRI). Moreover, plastic changes were expected to be a result of increased inhibition as assessed by somatosensory evoked potentials after paired-pulse stimulation of the median nerves.

Here we report preliminary results of the first four patients with chronic SCI, who participated in the HAL® training for a three-months-period.

2 Material and Methods

2.1 Subjects

We investigated four patients with chronic incomplete SCI with a time since injury of more than 6 months. One patient suffered from incomplete thoracic SCI, three patients from an incomplete lesion of the conus medullaris / cauda equina.

2.2 Electrophysiological Measurements

All patients underwent standard electrophysiological measurements with motor evoked potentials, somatosensory evoked potentials and nerve conduction studies before and after three months of training.

To assess changes of excitability of somatosensory cortex, we applied a paired-pulse electrical stimulation protocol to the median nerves while recording SEPs from the right and left S1, respectively. The stimulation protocol consisted of a single pulse (pulse duration 0.2 ms) followed by a paired pulse (pulse duration 0.2 ms, ISI 30 ms) delivered transcutaneously via a block stimulator located above the median nerve at the wrist at a frequency of 3 Hz. Stimulation intensity was 2.5 times of each patient's individual sensory threshold and was accompanied in all patients by a small muscular twitch in the thenar muscles.

SEPs were recorded using an electrode over the left and right S1, located 2 cm posterior to C3 and C4 (CP3 and CP4) according to the International 10–20 system. A reference electrode was placed over midfront (Fz) position. SEPs were recorded in epochs from 20 ms before to 200 ms after stimulus onset with a 32-channel amplifier (bandpass filter, 100–2000 Hz; Brain AMP MR; Brain Products) and stored for off-line analysis. For each single- and paired-pulse stimulation, 800 stimulus-related epochs were recorded. Peak-to-peak amplitudes of the cortical N20–P25 SEP components were analyzed. Paired-pulse suppression was expressed as a ratio (A2s/A1) of the amplitudes of the subtracted second (A2s) and the first (A1) N20–P25 peaks. Amplitude ratios < 1 indicate paired-pulse-suppression while ratios > 1 represent paired-pulse facilitation.

2.3 *Functional MRI Scan*

fMRI studies were conducted in a 3 Tesla scanner using a 32-channel head coil (Achieva 3.0T X, Philips Healthcare). Blood-oxygen level-dependent (BOLD) images were obtained with a SpinEcho EPI sequence (TR 3200 ms, TE 35 ms, 224 mm "field of view", 3 mm slice thickness, voxel 2 x 2 x 3 mm). During the scan, tactile stimuli were delivered simultaneously to the three phalanges of the second digit of both hands using an airpuff device. A total of 480 stimuli were applied to each side at a frequency of 1.25 Hz. Preprocessing and analysis of the event-related fMRI data were performed using SPM8 (Wellcome Trust Center for Neuroimaging, University College London, UK). Functional imaging data were corrected for slice-timing and head motion.

2.4 *Treadmill Training with HAL®*

All patients performed daily treadmill training with the exoskeleton HAL® (Cyberdyne, Japan) and body weight support for a three month period. Training was supervised by a physiotherapist and a medical doctor.

3 Results

After three months of training, which led to a significant functional improvement in all patients (results are presented separately at this conference), we found an increased paired-pulse inhibition of somatosensory evoked potentials in both hemispheres following median nerve stimulation at the wrist (as shown in Fig. 1). This increased inhibition was accompanied by a reduced S1 activation of the activated area in both hemispheres after tactile stimulation of the index finger (as shown in Fig. 2). Standard electrophysiological measurements did not differ between pre- and post-conditions (not shown).

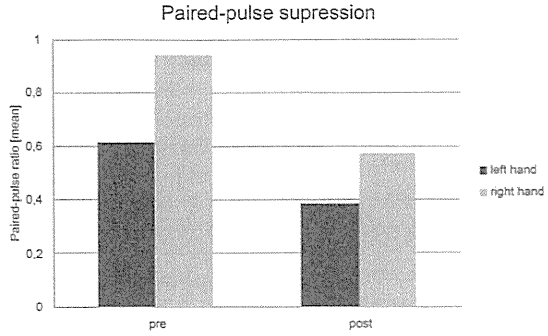

Fig. 1 Mean paired-pulse ratios are plotted for both hemispheres contralateral to the stimulated hand. After exoskeleton training period (post), the patients show decreased amplitude ratios compared with the baseline (pre).

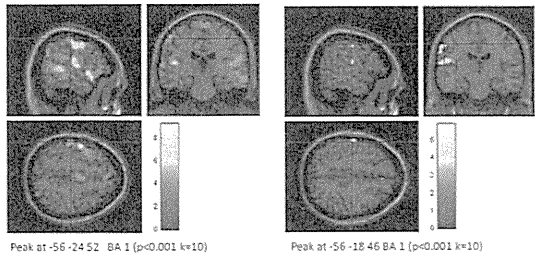

Fig. 2 Functional magnetic imaging data of one patient show a decreased activation in the somatosensory cortex during tactile stimulation after exoskeleton HAL® training.

4 Discussion

These preliminary results show plastic changes in the brain, which accompany the functional improvement in these four patients. Since standard electrophysiological parameters (MEP, SEP, nerve conduction studies) did not change after three months of training, the results suggest that cortical plastic changes due to improved use of the remaining intact spinal connections, rather than regeneration of the lesioned spinal connections might be responsible for the functional improvement in these patients.

5 Conclusion

Treadmill training using the exoskeleton HAL® seems to be a useful innovative training method for chronic paraplegic SCI patients. However, so far these

preliminary results are only descriptive, and must be confirmed in a larger group of patients allowing detailed statistical analyses before further conclusions can be drawn.

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Clinical Study

Voluntary driven exoskeleton as a new tool for rehabilitation in chronic spinal cord injury: a pilot study

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Abstract

BACKGROUND CONTEXT: Treadmill training after traumatic spinal cord injury (SCI) has become an established therapy to improve walking capabilities. The hybrid assistive limb (HAL) exoskeleton has been developed to support motor function and is tailored to the patients' voluntary drive.

PURPOSE: To determine whether locomotor training with the exoskeleton HAL is safe and can increase functional mobility in chronic paraplegic patients after SCI.

DESIGN: A single case experimental A-B (pre-post) design study by repeated assessments of the same patients. The subjects performed 90 days (five times per week) of HAL exoskeleton body weight supported treadmill training with variable gait speed and body weight support.

PATIENT SAMPLE: Eight patients with chronic SCI classified by the American Spinal Injury Association (ASIA) Impairment Scale (AIS) consisting of ASIA A (zones of partial preservation [ZPP] L3–S1), n=4; ASIA B (with motor ZPP L3–S1), n=1; and ASIA C/D, n=3, who received full rehabilitation in the acute and subacute phases of SCI.

OUTCOME MEASURES: Functional measures included treadmill-associated walking distance, speed, and time, with additional analysis of functional improvements using the 10-m walk test (10MWT), timed-up and go test (TUG test), 6-minute walk test (6MWT), and the walking index for SCI II (WISCI II) score. Secondary physiologic measures including the AIS with the lower extremity motor score (LEMS), the spinal spasticity (Ashworth scale), and the lower extremity circumferences.

METHODS: Subjects performed standardized functional testing before and after the 90 days of intervention.

RESULTS: Highly significant improvements of HAL-associated walking time, distance, and speed were noticed. Furthermore, significant improvements have been especially shown in the functional abilities without the exoskeleton for over-ground walking obtained in the 6MWT, TUG test, and the 10MWT, including an increase in the WISCI II score of three patients. Muscle strength (LEMS) increased in all patients accompanied by a gain of the lower limb circumferences. A conversion in the AIS was ascertained in one patient (ASIA B to ASIA C). One patient reported a decrease of spinal spasticity.

CONCLUSIONS: Hybrid assistive limb exoskeleton training results in improved over-ground walking and leads to the assumption of a beneficial effect on ambulatory mobility. However, evaluation in larger clinical trials is required.

Keywords: Exoskeleton; Treadmill training; Rehabilitation; Paraplegia; Hybrid assistive limb; Spinal cord injury

FDA device/drug status: Not applicable.

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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Authors' contributions: MA and OC carried out the experiments and data analysis as well as drafting of the manuscript. RCM, PS and MT helped with the experimental set up. MS-K and OH contributed to the data analysis. TAS participated in study design and coordination of the study.

All authors read and approved the final manuscript.

YS is a founder, shareholder, and the CEO of Cyberdyne, Inc., which produces the HAL.

YS and Cyberdyne were neither involved in study funding, design, data collection, and analysis, nor in writing or submitting this article, therefore concluding in no specific influence on the trial. We certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on us or on any organization with which we are associated.

YS and Cyberdyne as the manufacturer of the device provided exclusively technical and advisory support.

YS as the CEO of Cyberdyne has been involved exclusively in terms of an advisory capacity, regarding technical support and the limitations of the exoskeleton. Therefore, the inclusion and exclusion criteria have been modified (eg, body weight and contractures).

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Introduction

About 1,200 people suffer a traumatic spinal cord injury (SCI) each year in Germany. Recent statistics indicate that more than 50% of these injured patients have a motor incomplete lesion [1]. In patients with initial motor incomplete SCI, at least 75% regain some kind of ambulatory function. Better functional outcome is associated with age, level of lesion, and the classification in the American Spinal Injury Association (ASIA) Impairment Scale [2]. In the first 2 months after initial SCI, approximately half of the recovery occurs. Within the following 4 months, a decreasing rate of recovery has been observed. One year after injury, neurologic recovery is assumed to be nearly complete [3]. Although conventional rehabilitation programs enhance the performance of functional tasks, the loss of strength and coordination substantially limit one's capacity for over-ground ambulation training [4]. In the past two decades, body weight supported treadmill training (BWSTT) has been proposed as a useful adjunct to enhance locomotor function after motor incomplete SCI [5]. In patients with incomplete or complete SCI, a bilateral leg muscle activation combined with coordinated stepping movements can be induced in partially unloaded patients, standing on a moving treadmill. Body weight supported treadmill training enables early initiation of gait training and integration of weight-bearing activities, stepping and balance, by the use of a task-specific approach and a systematic gait pattern [6]. To facilitate the delivery of BWSTT in SCI patients, the locomotor training evolved over the last 12 years and a motorized robotic driven gait orthosis (DGO) has been developed [7]. The advantages over conventional BWSTT methods are considered to be less effort for attending physiotherapists [8], longer duration, more physiologic and reproducible gait patterns, and the possibility to measure a patients' performance. Several studies pointed out that DGO training improves over-ground walking [9–13]. However, there was no reported difference in the outcome of DGO training compared with conventional training. A significant switch in the ASIA classification has not been found [10,14].

Over the last 5 years, exoskeletal systems became available for SCI patients. These systems offer different possibilities. Three exoskeletons (Ekso [EksoBionics, Richmond, CA, USA], Rex [Rex Bionics, Aukland, New Zealand] and Re-Walk [ARGO Medical Technolgies, Israel]) allow SCI patients to stand up, walk with a defined pattern, and even climbing stairs mainly on a basis of passive range of motion (ROM). The exoskeleton hybrid assistive limb (HAL; Cyberdyne, Inc., Japan) offers the possibility of getting connected with the SCI patient through electromyography electrodes on the skin at the extensor/flexor muscle region of the lower extremities. This allows voluntary machine supported ROM of incomplete SCI patients by using minimal bioelectrical signals, recorded and amplified from hip and knee flexors and extensors [15–17]. More recently, these various exoskeletal systems allow the patients mobilization outside the treadmill. A former study by Kawamoto et al. [18] concerning locomotion improvement using HAL in chronic stroke patients, emphasized the feasibility for rehabilitation of these particular patients.

The aim of this pilot study was to evaluate the possibilities of exoskeletal locomotor training (HAL; Cyberdyne, Inc.) under voluntary control and identify beneficial effects on functional mobility of the patients. The hypothesis was that exoskeleton treadmill training is feasible and safe in application and capable of improving ambulatory mobility in chronic SCI patients.

Materials and methods

Patients

We enrolled eight patients (two women, six men). The mean±standard deviation age at the time of enrollment was 48±9.43 years. All patients were in the chronic stage of traumatic SCI according to the time since injury of 1 to 19 years (97.2±88.4 months). Inclusion criteria were traumatic SCI with chronic incomplete (ASIA B/C/D) or complete paraplegia (ASIA A) after lesions of the conus medullaris/cauda equine with zones of partial preservation. Independent of ASIA classification, the enrolled patients

must present motor functions of hip and knee extensor and flexor muscle groups to be able to trigger the exoskeleton. Exclusion criteria were as follows: nontraumatic SCI, pressure sores, severe limitation of ROM regarding hip and knee joints, cognitive impairment, body weight more than 100 Kg, nonconsolidated fractures, and mild or severe heart insufficiency. Two patients suffered from an incomplete thoracic SCI (ASIA C/D) from 3 to 13 years. Two patients suffered from an incomplete lumbar SCI (ASIA B/C) from 12 to 13 months and four patients had a complete SCI with zones of partial preservation in L3–S1 after lesions of the conus medullaris. The classification according to the ASIA was carried out before the treadmill training was initiated. The study was approved by Ethical Board Committee of Bergmannsheil Hospital and the University of Bochum and followed strictly the declaration of Helsinki.

All patients provided written informed consent. The study design was a single case experimental A-B (pre-post) design by repeated assessments of the same patients (Table 1).

Intervention

During this study, the patients underwent a BWSTT five times per week using the HAL exoskeleton (Cyberdyne, Inc., Japan). The study was performed between June 2013 and September 2013 in the BG University Hospital Bergmannsheil, Bochum.

Neither adverse nor severe adverse events occurred during the intervention.

The exoskeleton

The HAL robot suit (Cyberdyne, Inc., Japan) is an exoskeleton with a frame and robotic actuators that attach to the patients' legs. The joint movement is supported by electric motors. Voluntary initiated minimal bioelectrical signals recovered from extensor and flexor muscles of hip and knee are detected via electromyography electrodes (Fig. 1).

Through a cable connection between the exoskeleton and patient, this system allows voluntary robotic supported ROM (cybernic voluntary control mode). Also a passive, nonvoluntary ROM (cybernic autonomous control mode) is possible (Fig. 2).

The treadmill

The treadmill system (Woodway USA, Inc., Waukesha, WI, USA) includes a body weight support system with a harness. The speed can be adjusted from 0 Km/h to approximately 4.5 Km/h. During treatments, the velocity of the treadmill was set individually between comfortable and maximum speed tolerated by the patients. Approximately 50% of each patient's body weight needed to be supported by the harness system, individually reduced during the following sessions as tolerated without substantial knee buckling or toe drag.

EVIDENCE & METHODS

Context
The authors present a series of patients treated with an assistive exoskeleton developed to facilitate treadmill exercise in patients with spinal cord injury (SCI).

Contribution
In a series of eight patients with SCI graded ASIA A to C/D, improvements in walking time, distance and speed were noted after treatment with assistive exoskeleton.

Implications
This study is a case series of eight patients with heterogeneous clinical characteristics, including the severity of their spinal cord injury. The findings are limited to clinical contexts specific to these patients and clearly cannot be translated to the care of other individuals. This is simply a report that may show proof of concept. It should be noted that one of the authors reports a substantive conflict of interest (founder and shareholder of the company that produces the exoskeleton device).

—The Editors

The training

The patients underwent a 90-day period of HAL exoskeleton (Cyberdyne, Inc.) training (five per week), including a mean number of sessions of 51.75±5.6. The training was performed on a treadmill with individually adjustable body weight support and speed, recording walking speed, time, and distance. It included a 10-m walk test (10MWT) before and after each session and regular physiotherapy that lasted approximately 90 minutes. The training was supervised by a physiotherapist and a medical doctor.

Measurements

Walking capabilities and neurologic status

All patients were assessed on admission by medical doctors involved in this trial. The outcomes were assessed

Table 1
Subject demographics and clinical characteristics

Case	Sex	Age (y)	Time since trauma, y	Etiology	Level	ASIA/ZPP	WISCI II	Ashworth
1	M	40	13	# T7/T8	T8	C	13	4
2	M	63	1	# T12	L1	B/L3	6	0
3	M	36	1.16	# T11/T12	T12	A/L3	6	0
4	F	55	1.08	# L1	L1	C	13	0
5	M	42	16	# L1	L1	A/L3	9	0
6	M	52	10	# L3	L2	A/L3	6	0
7	F	40	19	# L1	T11	A/S1	9	0
8	M	53	3	# T12	T12	D	18	0

M, male; F, female; #, fracture; ASIA, American Spinal Injury Association; ZPP, zones of partial preservation; WISCI, walking index for spinal cord injury; T, thoracic; L, lumbal; S, sacral.

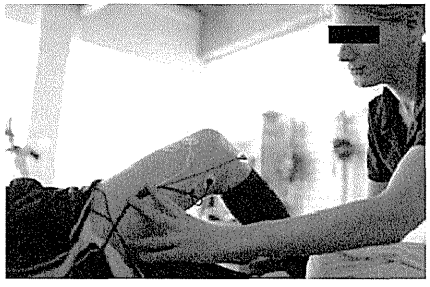

Fig. 1. Positioning of the electromyography electrodes on the knee extensor and flexor muscles.

by physiotherapists neither involved in the study design nor analysis after 45 days and on discharge from the training period. An assessment through the ASIA classification was already done on admission and on discharge from the SCI department, Bergmannsheil, Bochum, within the initial therapy after acute SCI. The 10MWT, done before and after each session, detected the needed time, the number of steps, and the required assistance to walk a 10 m distance [19,20]. The timed-up and go test (TUG test) describes the time and assistance required for standing up from the wheelchair, walk 3 m, turn around, walk back, and sit down. It was performed every 2 weeks. The 6-minute walk test (6MWT) was done at the beginning, at half time, and at the end if possible, depending on the patient. It evaluates the distance and assistance while walking for 6 minutes [21]. The main outcome was the functional motor assessment by the walking index for SCI II (WISCI II) [22,23]. The WISCI II score is a 20-item scale, measuring the walking capabilities of a patient based on the requirements of assistance because of walking aids, personal assistance, or braces. Grade 0 means that the patient has neither standing nor walking abilities. Grade 20 means that no assistance is needed to walk a distance of 10 m. The neurologic status was assessed using the ASIA Impairment Scale modified from the Frankel classification and classifies motor and sensory impairments that result from a SCI [3]. The lower extremity motor score (LEMS) acquired in this study was obtained by the addition of the impairment scores (0–5) of the lower extremity key muscles of both sides. Muscle volume was assessed by manual measurements, 20/10 cm above and 15 cm below inner knee gap.

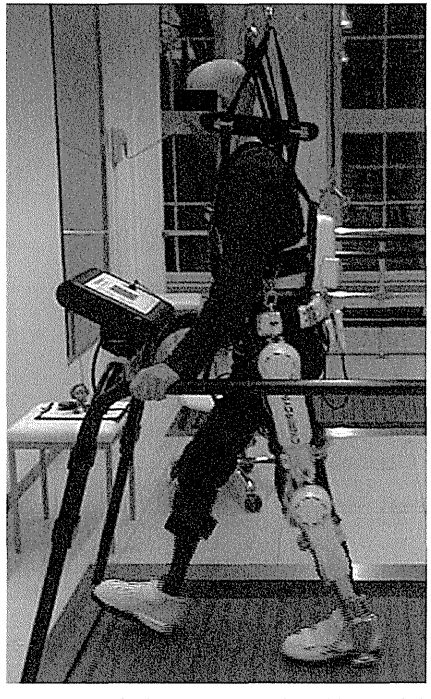

Fig. 2. Patient performing treadmill locomotion training with body weight support and hybrid assistive limb exoskeleton.

Statistical analysis

Descriptive analysis of the demographic and injury characteristics was done using frequency distribution for categorical data and mean for continuous variables. Differences between pre- and posttraining sessions were assessed by a paired t test (for continuous variables). Treatment effects on functional performance as the WISCI II are all ordinal scales. Medians were used as descriptive statistics for these outcomes, and nonparametric tests were used to assess the relative effect of the treatments.

Results were considered statistically significant when the p value was ≤.05.

Results

Treadmill associated results

All patients improved in treadmill training by using HAL (Cyberdyne, Inc., Japan). The mean walking speed increased from 0.91±0.41 m/s (0.5–1.8 m/s) in the first session up to 1.59±0.5 m/s (0.8–2.1 m/s) in the last session after 3 months. The progress in speed after 6 weeks of training was lower than in the first weeks. The range was located between 0 km/h and 0.8 km/h. The mean walking time at the beginning was 12.37±4.55 minutes. The average walking time at the

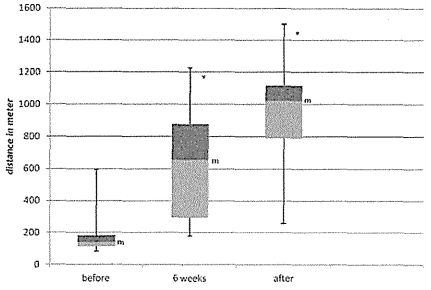

Fig. 3. Changes in treadmill-associated walking distance in pre-, mid-, and postevaluations. m, median. *pre-post difference, p<.05.

end was 31.97±9.45 minutes. The mean ambulated distance at the first session was 195.9±166.7 m and increased to 954.13±380.4 m on discharge (Fig. 3).

Functional outcome

Although the mean improvement concerning the WISCI II score was not statistically significant, three patients showed functional improvement in gait abilities. Two subjects needed braces, a walker, and support by a physiotherapist at the beginning and were able to walk after the training series only with a walker and braces (WISCI II score increased from 6 to 9). One patient increased from 9 to 12 and, therefore, was able to walk with two crutches and a brace compared with a walker and a brace before the training. At baseline, the mean WISCI II score was 10±4.3. At the end of the 90 days trial, the mean WISCI II was 11.13±6.68. Improvements in speed and endurance in over-ground gait assessments in all participants have been achieved. The 10MWT showed a significant increase in mean gait speed at the end of the training period compared with baseline (0.28±0.28 m/s vs. 0.50±0.34 m/s) (Fig. 4).

The improvement corresponded to a 44% faster walking than in initial evaluation. It also includes the reduction of

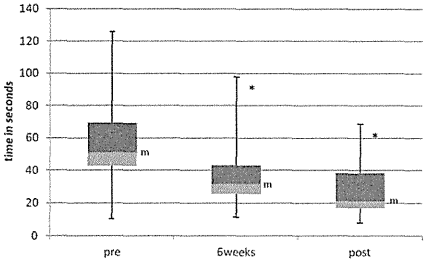

Fig. 4. Changes in 10-m walk test in pre-, mid-, and postintervention evaluations. m, median. *pre-post difference, p<.05.

Table 2
Comparison of pre- and postinterventions

Outcome measurements	Before training	After training	n
10MWT speed (m/s)	0.28±0.28	0.5±0.34*	8
Number of steps	29.88±7.85	19.38±3.16*	8
6MWT distance (m)	70.1±130	163.3±160.6*	8
TUG test (s)	55.34±32.20	38.18±25.98*	8
Distance (m)	195.88±166.71	954.13±380.35*	8
WISCI-II	10±4.34	11.12±3.68	8

10MWT, 10-m walk test; 6MWT, 6-minute walk test; TUG, timed-up and go; WISCI, walking index for spinal cord injury.
Note: Values are means±standard deviation.
* Pre-post difference, p<.05.

support needed detected by the WISCI II score. The mean number of steps decreased from 29.8±7.85 to 19.4±3.16. We observed significant increase in gait speed from pre- to midtraining and from mid- to posttraining assessments. Similar results were detected for the TUG test. The mean time needed for the TUG test decreased from 55.34±32.2 seconds to 38.18±25.98 seconds. The 6MWT was done with a constant walking time of 6 minutes without any break. Only three patients were able to perform the 6MWT before the training with a mean walking distance of 187±162.2 m. The subjects in this subgroup improved their performance and increased the walking distance to 287.3±229.4 m. After completing the training, all eight patients could be evaluated, therefore the overall mean distance increased from 70.1±130 m to 163.3±160.6 m (Table 2).

The LEMS increased in all patients. The mean LEMS before the training increased significantly from 21.75±8.3 to 24.38±7.6 after the intervention (Fig. 5).

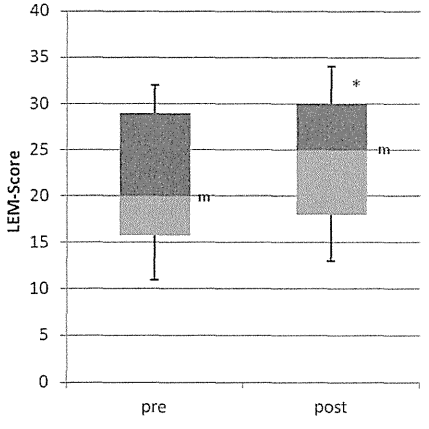

Fig. 5. LEMS in pre- and postevaluation. LEM, lower extremity motor score; m, median. *pre-post difference, p<.05.

One patient switched in the ASIA scale from ASIA B to C, he was at the beginning of the training 12 months posttrauma.

Others

To describe muscle volume, measurements of the circumferences 10/20 cm cranial of the inner knee joint gap and 15 cm distal of it have been done before and after the 90 days of training. Seven participants showed a gain of muscle circumference from 5 mm up to 50 mm. In one participant with edema in his lower legs, we observed a loss of circumference up to 25 mm. One patient suffering from a thoracic SCI presented a significant spinal spasticity. For spastic motor behaviors, we used the modified Ashworth scale to evaluate the involuntary resistance to passive stretch of the quadriceps muscle group. At pretraining evaluation, he showed an extensor spasm with high resistance to passive stretch according to Ashworth 4. After the training sessions, the resistance was reduced according to Ashworth 2. This level lasted for about 6 to 8 hours with a new maximum level at the next morning. All other patients showed no spastic motor behaviors.

Discussion

The objective of the study was to determine whether locomotor training with the exoskeleton HAL is feasible and safe in application, improves functional mobility, and increases motor functions in chronic paraplegic patients after SCI. The results obtained revealed a highly significant improvement for over-ground walking abilities evaluated by the 10MWT, the 6MWT, and the TUG test and the partial reduction of physical assistance and walking aids in the WISCI II score. Muscle strength, measured with the LEMS increased in all patients.

The results acquired in this clinical trial imply that HAL-supported locomotion training can improve walking abilities in terms of speed, gait, and distance. Furthermore, it improves motor functions.

Thus far there is insufficient evidence and only a few articles addressing the main hypothesis of this study that locomotor training improves walking function for patients with SCI [24].

The present study is according to the knowledge of the authors the first to investigate the impact of HAL-supported locomotor training in chronic SCI patients, where referring to the current state of knowledge no further functional improvements are to be expected.

In the subject population consisting of eight patients including patients suffering from SCI from 1 to 19 years (8.03±7.4 years), all patients improved significantly regarding treadmill-associated walking distance and speed and functional improvement was detected in the over-ground walking tests.

Although no significant influence was seen on the requirements of assistance in the 10MWT, three patients attained improvement in walking abilities according to the WISCI II, under condition of a comfortable and stable gait. A further reduction of assistance was not forced because of more pathologic gait or higher risk of falling [24].

Although the evidence is still insufficient, the effectiveness of automated locomotor training using the DGO in patients with chronic SCI is being investigated and considered promising in several systematic reviews including a Cochrane review [25,26]. The results mentioned previously add to the wealth of that data presuming that HAL-assisted locomotion training is useful in terms of functional mobility and a safe adjunct to the treatment of patient with chronic SCI.

Our study had several limitations: the relatively small number of patients (n=8) and the mixture of complete and incomplete SCIs.

However, all the patients were treated in the same facility by the same multidisciplinary team, according to a standardized protocol.

In summary, our study provides the first data demonstrating the clinical potential of HAL-locomotor training based on voluntary drive in patients suffering from chronic SCI.

It was proven to be a safe device for locomotion therapy as neither adverse nor severe adverse events occurred.

However, continued research in the form of large randomized trials to compare the efficacy of HAL-assisted training with well established, conventional therapies is necessary.

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技術論文

装着型歩行補助ロボットのリスク管理方法
ロボットスーツ HAL® 福祉用の事例

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Risk Management for Wearable Walking Assistant Robot
A Case Study of Robot Suit HAL® for Well-being

Cota Nabeshima*1, Masahiro Shingu*1, Hiroaki Kawamoto*2 *and* Yoshiyuki Sankai*2*3

In this paper, we provide a essence of the risk management sheet that was used to obtain the world-first certificate of ISO/DIS 13482:2011 for "Robot Suit HAL® for Well-being," and discuss how it could be applicable to more common wearable walking assistant robots. We hope our experiences and knowledge will help overcoming the so-called "valley of death" towards commercialization of the personal care robots.

Key Words: Robot Suit HAL®, Physical assistant robot, Risk management, Quality management, International safety standards

1. はじめに

CYBERDYNE 株式会社 (以下, CD 社) は, 筑波大学のサイバニクス研究から生まれた装着型ロボット "ロボットスーツ HAL®" [1] (以下, HAL) を実用化し, 広く社会に貢献すべく 2004 年に設立された. 2008 年には, CD 社初の製品となる "ロボットスーツ HAL® 福祉用" [2] (以下, HAL 福祉用) のレンタル・リース販売を開始した.

CD 社はその当初より, 安全を最優先に HAL の研究開発, 製造, 販売に取り組んできた. しかし当時は装着型ロボットの安全標準が確立されておらず, HAL 福祉用の安全性について, 第三者評価, すなわち, 認証を受けられずにいた. そのため安全標準への適合という簡便な安全性の証明を利用できず, CD 社は, 顧客に都度, HAL 福祉用の安全性について説明する必要があった.

安全標準への適合をもって安全性の証明を簡便に行うことは, メーカーだけでなく, 消費者, 規制当局にも便益をもたらし, 産業化を促進すると考えられる. そのため CD 社は筑波大学とともに, HAL 福祉用を主なプラットフォームとして, 新エネルギー・産業技術総合開発機構 (NEDO) が 2009 年〜2014 年の期間で実施する生活支援ロボット実用化プロジェクト [3] に参画し, 装着型ロボットの安全技術と安全性検証手法の研究開発を行い, また, その成果を国際標準化すべく活動してきた.

2011 年には, これらの活動の成果として, 国際安全規格原案 ISO/DIS 13482:2011 "Robots and robotic devices - Safety requirements for non-industrial robots - Non-medical personal care robot" [4] が, ISO/TC184/SC2/WG7 により発行, 公開された†. これにより初めて, HAL 福祉用の安全性について第三者評価が可能となった. CD 社は現行モデルの HAL 福祉用に対する ISO/DIS 13482:2011 認証を, 一般財団法人 日本品質保証機構 (JQA) に依頼し, 2013 年 2 月に, ISO/DIS 13482:2011 の世界初の認証を得ることができた [5].

ISO/DIS 13482:2011 では, [6]〜[9] などの国際安全規格と同様に, リスクアセスメントが要求されている [10]. そのためメーカーが認証を取得する際には, 対象となる機器のリスク管理表を認証機関に提出する必要がある. 本論文では, Sec.2 で HAL 福祉用の特徴を述べたのち, Sec.3 で, 実際に認証機関に提出した HAL 福祉用のリスク管理表の一部を示し, CD 社がどのようにリスク管理を実施したかを述べる. HAL 福祉用のリスク管理表の構成は, 一般的な装着型歩行補助ロボットに対しても, 標準的に適用できると考えられる (Sec.4). 本論文が, 装着型歩行補助ロボットのみならず, 装着型ロボット, ひいては, 生活支援ロボットの実用化および産業化の一助となることを期待する.

原稿受付
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†ISO 規格は, その策定の段階に従って, 委員会原案 (CD), 国際規格原案 (DIS), 最終国際規格原案 (FDIS), 国際規格 (IS) と発行される. DIS 以降は一般に入手可能となり, 認証が可能となる. ただし, FDIS 発行後は DIS が入手できなくなるため, DIS での認証は行われなくなる. ある製品が DIS で認証を取得していた場合, IS 発行後には必要に応じて, 改めて IS による認証を取得することになる. 一般的には DIS 以降, 要求が大きく変わることは少ないため, DIS 認証を取得した製品の IS に対する適合性評価は, 差分的に行われる.

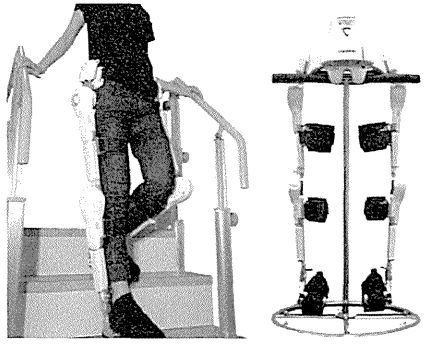

Fig. 1 The Robot Suit HAL® for Well-being.

2. HAL 福祉用の特徴

HAL 福祉用は, 装着者の下肢運動の支援を意図した外骨格型の装着型ロボットであり, 歩行や立ち座りの際の主要な関節 (股関節と膝関節) に沿う形で能動軸を有している. 装着の様子および外観を Fig.1 に, 構造の模式図を Fig.2 に示す. HAL 福祉用のフレームは足裏で床面に接地しており, HAL 福祉用の重量が装着者の負荷にならないと同時に, 装着者の体重がフレームの負荷にならない構造となっている.

詳細には立ち入らないが, HAL 福祉用では, 装着者の膝と大腿に貼り付けられた電極から読み取った生体電気信号を利用し, 装着者の筋肉が動くより早くモーターを駆動することでアシストを行う "サイバニック随意制御" と, 装着者の関節角度, 姿勢, 体重移動の情報から推定した歩行フェーズに基づくアシストを行う "サイバニック自律制御" を混合した制御方式が用いられている.

以上の特徴から, その意図する使用において, HAL 福祉用と装着者は電気的に接続されるだけでなく, 互いに接触し, 力学的エネルギーをやりとりする. つまり本質的に, 機械的, 電気的, 熱的, 音響的なハザード源となる機器を装着者から隔離できない. これは産業用ロボットで一般的な "隔離の原則" を単純には適用できないことを意味し, 特に装着型ロボットにおいては, その安全性が懸念される原因となっている. HAL 福祉用では, Sec.3 のようにリスク管理を実施し, 個別のハザードごとに十分なリスク低減を講じることで, 安全性を確保している.

3. HAL 福祉用のリスク管理

HAL 福祉用は 2013 年 9 月末の時点で, 国内 160 施設, 400 台以上が稼働しており, 累積の利用者は 4,000 人以上†に上っている. HAL 福祉用において, これまでに有害事象は発生しておらず, 安全面での実績を有していると言える. このことは, 以下で示す HAL 福祉用に適用されたリスク管理の有効性を示していると考えられる.

†CD 社による, 稼働ログに基づく推計.

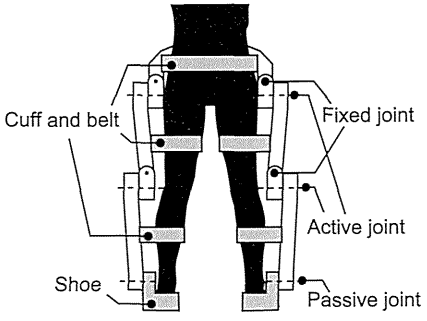

Fig. 2 The abstract structure of Robot Suit HAL® for Well-being.

3.1 CD 社のリスク管理体制

製品の安全は品質の一部 [7] であり, 製品のライフサイクルのすべて (初期の構想, 設計開発, 仕入れ, 製造, 引き渡し, 保守サービス, 苦情, 回収・廃棄など) に係わる. CD 社では, リスク管理システムが組み込まれた一般的な品質管理システムを有しており, 組織的にリスク管理プロセスに取り組んでいる. その結果として, CD 社は 2012 年 12 月に, 医療機器の品質マネジメントシステムの国際規格である ISO 13485:2003 の認証を, 株式会社 UL Japan より取得している [11].

3.2 HAL 福祉用のリスク管理表

HAL 福祉用のリスク管理には表を用いた (リスク管理表). これは特定したハザード, 推定した初期リスク, 特定したリスク低減方法, 期待されるリスク低減後のリスクについて一覧性を持たせるためである. ハザードの特定, 初期リスクの推定, リスク低減方法の特定は, ISO 14971:2007 [7] をベースに, HAL 福祉用の開発, 製造, 販売および市場からのフィードバックにより得られた知見を利用して行った.

初期リスクの推定にあたって, 当初は加算法を用いていたが, 現在ではよりリスク低減方法の効果を表現しやすいマトリクス法を用いた [12]. リスク管理にあたって定義したリスクマトリクスを Table 1, Table 2 に示す. なお, 通常のマトリクス法では, 危害の重大さと危害の頻度のマトリクス (Table 2) のみを用いるが, 危害に至る事象の発生と遷移を表現できなかったため, Table 1 を追加した.

Table 1, Table 2 では, 加算法や積算法を用いずにレベルを割り当てている. これは,

- 一度死亡に至る危害が特定された場合, リスク低減をいくら講じても, リスクを受容可能にできない
- 算出されたリスクの値が, 必ずしもリスク低減の優先度に一致しない
- 発生頻度や遷移可能性に割り当てた数値自体に任意性があり, 加算あるいは積算によって求められる数値に対して, 実質的な意味付けが難しい

といった, 数値化に起因する問題を避けるためである. また, リスクグラフは, 加算法や積算法同様, リスクの値にリスク低減の

優先度を反映しにくく，さらに，事象の遷移を表現すると複雑化することから，不採用とした．実際の製品開発では，ALARP 原則に従って網羅的にリスク低減を講じるため，その指針となる，直感に合ったレベル付けができれば十分と言える．そのため，HAL 福祉用では，Table 1，Table 2 から構成されるマトリクス法を採用した．

Table 1 は，発生頻度 Fx の { ハザード，危険状態 } が発生した結果として，遷移可能性 Tx で別の { ハザード，危険状態，危害 } が発生するときの発生頻度 Fx' を割り当てるマトリクスである．Table 2 は，発生頻度 Fx で危害が発生するとして，その危害の重大さが Sx のときのリスクレベルを，I から IV の 4 段階で割り当てるマトリクスである．HAL 福祉用では，リスクレベルが I なら受容可能なリスク，II なら受容可能だが追加のリスク低減を検討するリスク，III，IV なら受容できないリスクとした．

HAL 福祉用のリスク管理表は，危険状態表とハザード表の 2 表構成とした．HAL 福祉用に関するリスクの構造として，危害に至る事象の遷移 (ハザード ⇒ 危険状態 ⇒ 危害) を想定した場合，

- 危害は，必ず危険状態，すなわち “有害なエネルギーが人体にさらされる状況” を経て発生する
- 危険状態の種類はそれほど多くないが，危険状態に遷移するハザードの種類は多い

という特徴がある．リスク管理表を 2 表構成とすることで，リスクの構造を活かし，見通しの良いリスク管理表を作成できると考えられた．なお，ISO/DIS 13482:2011 の認証取得に用いたリスク管理表には，危険状態 16 種，および，ハザード 170 種が含まれていた．

HAL 福祉用のリスク管理を進めていく上で，2 表構成のリスク管理表には，以下の利点があった:

Table 1 Occurrence frequency and its transfer possibility of {hazard, hazardous situation, harm}

		Transfer possibility			
		T1	T2	T3	T4
Occurrence frequency	F1	F1'	F1'	F2'	F2'
	F2	F1'	F2'	F2'	F3'
	F3	F2'	F2'	F3'	F3'
	F4	F2'	F3'	F3'	F4'

Fx, Fx' are the occurrence frequencies of {hazard, hazardous situation, harm} as,
x=1: “never,”
x=2: “rare,”
x=3: “occasional,”
x=4: “often.”

Tx is the transfer possibility (avoidability) from {hazard, hazardous situation} to {hazard, hazardous situation, harm} as,
x=1: “never” (“easy to avoid”),
x=2: “rare” (“possible to avoid”),
x=3: “occasional” (“difficult”),
x=4: “often” (“impossible”).

[利点 1] ある一つのリスク低減方法が，

- ハザードが起こるのを防ぐ
- ハザードが危険状態に遷移するのを防ぐ
- 危険状態が起こるのを防ぐ
- 危険状態が危害に遷移するのを防ぐ
- 危害の重大さを下げる

のいずれの効果を持つかを検討しやすい．

[利点 2] 危害に至る事象の遷移において，

- 故障や誤使用など，異なるハザードが 1 つの危険状態に遷移する場合，
- 故障検出などが機能して，ハザードが危険状態に遷移しない場合，
- 危険状態が生じても，人が容易に回避できる場合，
- 危険状態でも人に印加されるエネルギーが低い場合

などを表現しやすい．

[利点 3] 安全規格で言及されている危険状態，ハザード，リスク低減方法の対応関係を表現しやすい．

HAL 福祉用のリスク管理表全体では，危害をトップノードとしたツリー構造を成したため，FTA のようなトップダウンの性質を有し，また一方では，ソフトウェアと電気系に対してシステムレベルの FMEA を行い，故障や機能失敗のハザードをハザード表に列挙したため，ボトムアップの性質も同時に有することになった．

具体例として，感電リスクがどのようにリスク管理表で管理されるかを，Table 3 (危険状態表)，Table 4 (ハザード表) に示す．感電リスクは，HAL 福祉用と装着者が電気的に接続されているために，その評価と低減を適切に実施すべきリスクである (Sec.2 参照†)．

Table 3 の 2 行目は，危険状態 A “装着者が触れる部位に電位差が現れる/漏れ電流が流れる” について，初期リスクの評価を行っている．該当部位に装着者が気付かずに触ることで，感電による火傷が生じると想定している．初期リスクのリスクレベルは III であり，受容できないリスクとなっている．このリスクを

Table 2 Definition of risk level

		Severity of harm			
		S1	S2	S3	S4
Occurrence frequency of harm	F1	I	I	I	II
	F2	I	I	II	III
	F3	I	II	III	IV
	F4	II	III	IV	IV

I, II, III, IV are the risk levels.

Sx is the severity of harm as,
x=1: “no injury,”
x=2: “curable or minor injury”
e.g. cut or scrape of skin,
x=3: “incurable or serious injury”
e.g. loss of fingers or limbs,
x=4: “mortal injury.”

†機械的な接触によるリスクの評価と低減は，[13] [14] を参照．

低減できたかは，最終的に漏れ電流試験を行うことで確認するとしている．

Table 3 の 3 行目では，リスク低減方法として安全電圧を採用し，危害の重大さを軽度 (S2) にできると見積もっている．このとき，危険状態の発生頻度が高くとも，リスクレベルが II となり，受容可能となる．このリスク低減方法の実施は，電源仕様の検査によって確認するとしている．なお，安全電圧の採用は，機械安全における 3 ステップメソッドの本質的安全設計方策にあたり，優先的に検討すべきリスク低減方法である．

危険状態 A の発生頻度を低くし，よりリスクを下げるには，原因となるハザードから遷移する可能性を下げれば良い．Table 3 の 4 行目の受容可否の欄の “OK+” は，リスク低減が追加して行われることを示している．

危険状態 A に遷移するハザードとして，Table 4 の 2 行目と 4 行目それぞれに，ハザードを例示している．ハザード 1 は，電源線が外れて外装に触れるハザードであり，ハザード 2 は，外装の割れから電源線が露出するハザードである．これらのハザードの発生頻度は，関係する部位の強度を高めることで下がると期待できる．それぞれに対するリスク低減方法は，3 行目と 5 行目に記されている．これらのリスク低減方法の実施は，強度計算や，強度試験によって確認できるとしている．なお，これらのリスク低減方法は，機械安全における 3 ステップメソッドの安全防護・付加保護方策にあたる．

Table 4 の 6 行目には，典型的な誤使用として，使用者が機器に水をこぼすハザードが示されている．HAL 福祉用の使用環境は屋内のトレーニング施設であり，また，電子機器に水を掛けないことは一般的となっているため，発生頻度はまれに起こる (F2) としている．7 行目には，水が掛かることで生じる短絡を検出し，電流を遮断するとしている．これは機械安全における 3 ステップメソッドの安全防護・付加保護方策であり，危険状態 A への遷移可能性を T4 から T3 に下げられるとしている．なお，短絡検出による電流遮断は，感電のリスク低減だけでなく，火災のリスク低減にも有効であり，実際のリスク管理表では複数回登場している．

Table 4 の 8 行目には，機器に水をこぼす誤使用のハザードを防ぐために，注意を行うとしている．注意は一般的に取扱説明書に記載されるため，リスク低減方法の実施は取扱説明書の記載によって確認できるとしている．なお，このようなリスク低減は，機械安全における 3 ステップメソッドの使用上の情報にあたる．

Table 4 では，列挙されたハザードが直接危害につながらないため，危害の重大さとリスクレベルの割り当てを行っていない．またこの例では，Table 3 を利用することで，“危険状態 A につながるハザードはすべて受容可能である” ところから初められるため，ハザード表ではリスクレベルの割り当てに悩むこと無く，ハザードを列挙し，追加のリスク低減を講じて行くことができる．

Table 3, Table 4 では，検証に用いる試験の例として，漏れ電流試験，電源線の引張試験，外装の強度試験が挙げられている．これらの試験を実際に行う場合には，適切な安全規格 ([9] など) で定められている試験方法と合格基準を利用できる．

3.3 リスク低減方法の検証と妥当性確認

HAL 福祉用では，リスク管理表に記載したリスク低減方法のすべてについて CD 社で検証を実施した．特に受容できないリスクを受容可能なレベルまで下げているリスク低減方法については，重点的に安全性試験を行うようにした [13] [14]．ISO/DIS 13482:2011 の認証を受ける際は，認証機関が第三者として，規格の要求に対する適合性を評価すべく，検証を行った．

具体的な検証方法としては，レビュー，検査，試験の他に，安全規格に定められた安全性評価法を採用した．例えば生物学的安全性や EMC，材料，バッテリーなど個別の安全規格が存在する場合には，規格適合を検証方法として採用した (Sec.3. 2 参照)．

HAL 福祉用では，最終的なリスク低減方法となる情報提供を，取扱説明書の記載と表示における禁止，警告，注意によって行った．禁止，警告，注意の別は，その情報によって低減されるリスクの程度をリスク管理表から特定し，決定した．情報提供に関する検証はチェックリストを用いて行い，必要な情報の記載に漏れが無いかを確認した．

全体的なリスク管理の妥当性を確認するために，リスク管理表に記載したリスク低減方法を個別に検証したのちに，実際のユースケースを模擬した試験を実施した．この妥当性確認において，新たなハザードが生じないことを確認した．

4. おわりに

本論文は，NEDO が実施する生活支援ロボット実用化プロジェクトの成果の一部として，CD 社が HAL 福祉用に対して実施したリスク管理の方法を，リスク管理表を中心に述べた．このリスク管理の方法はあくまで現状を示したものであり，今後の改善の結果として変更される可能性がある．例えばリスク管理を表からデータベースに移したり，情報システムを利用して市場からのフィードバックを得やすくすることで，リスク管理にかかる労力を低減できると考えられる．

本論文では，HAL 福祉用のリスク管理に適用した，2 表構成のリスク管理表を示した．この方法は，危険状態の種類が把握可能な程度に収められ，かつ，ハザードが瞬時に危害に発展しない場合に有効と考えられる (Sec.3. 2 参照)．人が危害を受ける対象であれば，“有害なエネルギーが人体にさらされる” 危険状態の種類は，{ 機械的，熱的，電気的，化学的 } エネルギーの授受など，あまり多くないと言えるため，本論文のリスク管理方法を適用しやすいと思われる．そのため，本論文のリスク管理方法は，主に使用者/装着者が危害を受けることになる生活支援ロボット，特に装着型ロボットのリスク管理に有効と考えられる．本論文が，装着型ロボットのみならず，生活支援ロボットの実用化および産業化に必須となるリスク管理において，有益な情報となることを期待する．

謝辞 本研究は，独立行政法人新エネルギー・産業技術総合開発機構 (NEDO) の委託業務および，内閣府最先端研究開発支援プログラム「健康長寿社会を支える最先端人支援技術研究プログラム」の支援により行われた．

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Table 3 A part of the risk management sheet for hazardous situation against electrical shock

ID	Hazardous situation	Possible harm	Risk control measure	F	T	F'	S	R	Acceptability	Verification method
A	Potential difference / leakage current between touchable parts	electrical burn injury	-	F4	T3	F3'	S3	Ⅲ	NG	Leakage current test
-	-	-	Application of safety voltage	F4	T3	F3'	S2	Ⅱ	OK	Inspection of specification of the power supply
-	-	-	Reduction of transfer possibility from hazards resulting in the hazardous situation A	F2	T3	F2'	S2	I	OK+	Inspection of the risk management sheet for hazards

Table 4 A part of the risk management sheet for hazard against electrical shock

ID	Hazard	Possible hazardous situation	Risk control measure	F	T	F'	Verification method
1	Power wire that came off touches to the enclosure.	Hazardous situation A	-	F4	T4	F4'	-
—	-	-	Application of double fixation	F1	T4	F2'	Inspection of assembling manual / tensile test
2	Power wire exposures through the broken enclosure.	Hazardous situation A	-	F4	T4	F4'	-
—	-	-	Sufficient mechanical strength of enclosure	F1	T4	F2'	Inspection of the strength calculation / strength test
3	A user spills water on the equipment.	Hazardous situation A, electrical short	-	F2	T4	F3'	-
—	-	-	Short circuit detection and current interruption	F2	T3	F2'	Inspection of the drawings / short-circuit test
—	-	-	Precaution by instruction for use	F1	T3	F2'	Inspection of the user manual

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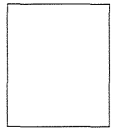

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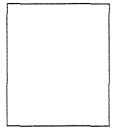

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Article

Wearable Gait Measurement System with an Instrumented Cane for Exoskeleton Control

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Abstract: In this research we introduce a wearable sensory system for motion intention estimation and control of exoskeleton robot. The system comprises wearable inertial motion sensors and shoe-embedded force sensors. The system utilizes an instrumented cane as a part of the interface between the user and the robot. The cane reflects the motion of upper limbs, and is used in terms of human inter-limb synergies. The developed control system provides assisted motion in coherence with the motion of other unassisted limbs. The system utilizes the instrumented cane together with body worn sensors, and provides assistance for start, stop and continuous walking. We verified the function of the proposed method and the developed wearable system through gait trials on treadmill and on ground. The achievement contributes to finding an intuitive and feasible interface between human and robot through wearable gait sensors for practical use of assistive technology. It also contributes to the technology for cognitively assisted locomotion, which helps the locomotion of physically challenged people.

Keywords: wearable sensors; motion intention; exoskeleton robot; hemiplegia; cane

1. Introduction

Lower limbs exoskeleton robots offer major possibilities for support and rehabilitation of locomotion affected people [1–3]. Active exoskeleton robots can be used to augment human power [1], to support the locomotion of locomotion affected people [2,4,5], and to assist the process of rehabilitation as well [6–9]. Exoskeleton robots act directly on the human body, and are meant to assist human locomotion. Therefore, the design and control of these robots should be completely based on human characteristics, not only from ergonomics perspectives but also from motor control perspective as well. Also, compliance between the control system and different users is important. Thus, it is important to explore various human-machine interfaces and human motion intention estimation techniques, and to develop flexible control systems based on human motor control for the effective and proper use of exoskeleton robots.

For assistance of locomotion affected people outside the laboratory environment, issues of human-machine interfacing, safety, wearability, and feasibility of the system should be considered. This paper addresses the development of a wearable gait measurement system with its underlying human gait characteristics and application to control of exoskeleton robot (Robot Suit HAL [1]). Robot Suit HAL is a wearable powered exoskeleton for support and rehabilitation of motor function in locomotion affected people. In recent studies the feasibility of rehabilitation training with HAL has been verified for stroke and spinal cord injury patients [8], and the locomotion improvement in chronic stroke patients after training with HAL was demonstrated as well [9]. The system in this work is designed for assistance of Hemiplegic persons with the single leg version of Robot Suit HAL. The single leg version is worn around the waist and on the affected leg, with straps around the thigh and shank segments to transfer the assist power to the leg. Power assist is provided through actuators at the hip and knee joints of the robot, while the ankle joint remains passive (Figures 1 and 2 show a person wearing the single leg version of Robot Suit HAL).

Figure 1. Illustration of the measured joint angles in the proposed system, and the concept of synergy based control.

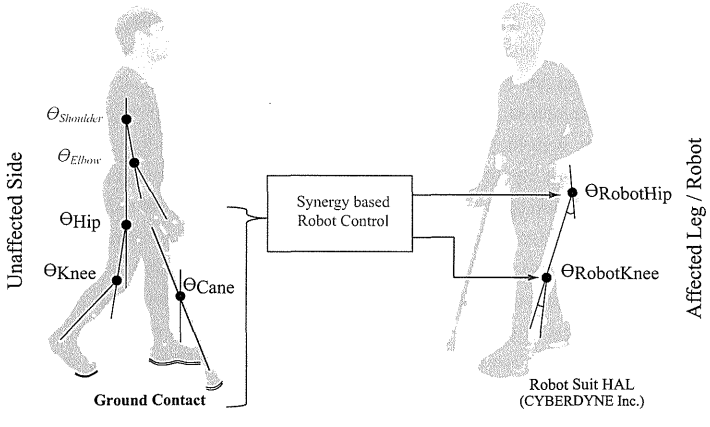
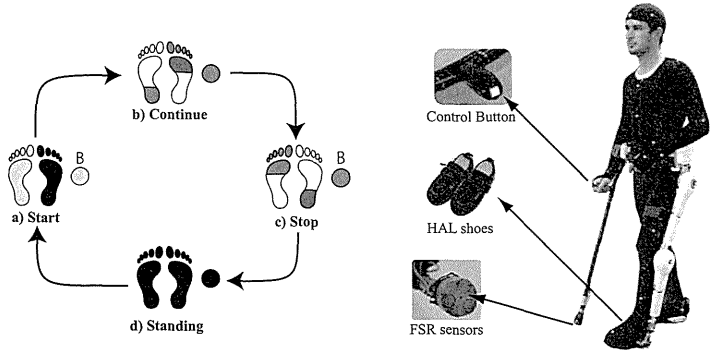


Figure 2. Start, walk and stop support based on ground contact patterns.



In recent years wearable systems for gait measurement and analysis gained significant improvements in feasibility and application [10–15]. These systems use inertial measurement sensors such as gyroscopes, accelerometers, and magnetometers for measuring the motion of limb segments and body parts. Also, force sensors embedded in shoe insole or underneath it are used for measurement of ground reaction forces and center of pressure in stance phases. Wearable sensors installed on the shoes [10–12] enable measurement and analysis of gait variables such as the stride length and width, single and double stance time, foot placement, and gait phases. Other wearable systems comprising inertial motion sensors fixed on lower limb segments [13,14] enable capturing the kinematics of lower limbs such as joints angles and limb orientation during ambulation.

The system we propose in this paper based on wearable technology is intended as an interface for real-time control of an exoskeleton robot by hemiplegic people. For the purpose of exoskeleton control application we consider inertial measurement sensors fixed on lower limb segments and force sensors embedded in the shoe insoles to capture lower limbs kinematics and ground contact information. Also, we consider using an instrumented cane as a mean for motion capture and motion intention estimation. While in other wearable systems the cane is not considered, we propose that in the case of hemiplegia the cane is incorporated in gait and, therefore, can provide valuable information for motion intention estimation and interfacing with an exoskeleton robot.

1.1. Related Work

Few interfaces have been developed for lower limbs exoskeleton robots, with the target pathology being hemiplegia or paraplegia. The bioelectrical signals are reliable information to estimate human motion intention [1]. However, in the case of neuronal injury/dysfunction such as Spinal Cord Injury (SCI) or stroke related paralysis, bioelectrical signals are different from that of healthy people or even not available. Therefore, reference trajectory for the assisted limb(s) needs to be computed, and the motion intention need to be estimated in different ways [2,4,5].

Kawamoto *et al.* [4] developed a control system for single leg version of Robot Suit HAL by using FRF (Floor Reaction Force) sensors to detect the gait phase shifting intended by the user. The readings

from FRF sensors embedded in the shoe insole of the wearer were used to determine the current phase and phase shifting during gait, and the robot is then operated by assembling segments of reference trajectories extracted from healthy people to restitute the motion of the impaired limb. The reference trajectories are beforehand adjusted according to the user's physical conditions. More extended work has been realized for the case of paraplegia in [5]. In this work gyroscope, accelerometer and level sensors measure the tilting angle of the user's torso according to his anatomical lateral plane. And this information is also used for detecting the phase sequence intended by the wearer.

Krausser and Kazerooni [2] developed a Human Machine Interface for SCI people with an exoskeleton robot (eLEGS) and two crutches. The user convey his/her intention to the robot using the two crutches to perform Four-Point gait with assistance from the robot and the crutches. The sensor suit comprises load measurement mechanism on the crutches, inertial sensors on the arms, force sensors in the shoe insole, and angle sensors on the robot's actuators. The robot uses hip and knee angle measurements, foot pressure, arm angle, and crutch load to determine the current state and state transition in a state machine controller customized for Four-Point gait.

1.2. Proposal

Human Locomotion Synergies: The methods mentioned previously do not consider human inter-limb synergies in gait. Human gait is not only a function of the lower limbs, but also a coordination between upper and lower limbs as well [16–20], adding to balance and cognitive functions. Research on human locomotion have shown evidence for the existence of a task-dependent neuronal coupling of upper and lower limbs [21,22]. Also, research on inter-limb coordination after stroke [23] indicated that stroke patients in the acute stage have close to normal synergies in the unaffected side, and that synergies in the chronic stage depend on the level of recovery. It was also demonstrated that high functioning stroke patients preserve the ability to coordinate arm and leg movements during walking [24].

Proposed Approach: In this work we propose a system for control of exoskeleton robot by fusing sensory information from upper and lower limbs. We developed a wearable gait measurement system based on inertial measurement sensors and force sensors, and we fuse the sensory information for control of single leg version of Robot Suit HAL in real time. The system is targeted at persons with hemiplegia. In case of Hemiplegia, the person usually uses a cane in the unaffected arm (contralateral to the affected leg) to support body weight and balance [25,26]. Therefore, we propose to utilize an instrumented cane ,forearm-type crutch, as a part of the interface with the robot. We equip the cane with motion and force sensors to capture its motion, while it is still supportive for the user's balance and somatosesnory as a traditional walking aid.

Instrumented Cane: The cane as a walking aid does not only provide biomechanical support but also an augmentation to somatosensory, and therefore leads to enhanced posture control. John J Jeka [27] showed in a series of studies that "sensory input to the hand and arm through contact cues at the fingertip or through a cane can reduce postural sway in individuals who have no impairments and in persons without a functioning vestibular system, even when contact force levels are inadequate to provide physical support of the body". Jeka's studies [27] were in quiet stance case. However, other studies

showed similar benefits during ambulation. Rumpa *et al.* [28] showed that touch cue through the cane at weight acceptance of the paretic leg provides mediolateral pelvic stability for stroke persons.

The system devised by Krausser and Kazerooni [2] utilized two canes for motion intention estimation. The HMI they developed utilizes the ground contact of the cane and feet to allow four-point gait for paraplegic persons with an exoskeleton robot. Jang *et al.* [29] also explored walking intention estimation with a cane, but rather through motion sensors fixed on the hands (glove module) and contact force between the palm of the hand and the cane's handle. The mentioned examples utilize sensory information through the cane only for estimating the stepping intention. Thus, control of the exoskeleton is step-wise and segmented according to Three-Point or Four-Point gait patterns, considering the case of paraplegia. In the case of hemiplegia, on the other hand, the person has a nearly unaffected side on which he/she uses the cane. Therefore, we consider that the cane in this case could be used in a continuous manner, and could also accommodate the inter-limb synergies as well.

2. Methodology

2.1. Synergy Analysis

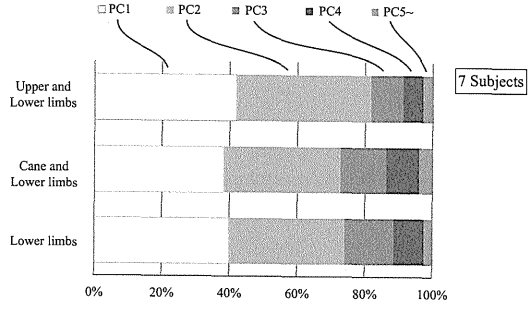
In the proposed system we aim to use the cane to capture the unaffected arm motion, and to utilize it in the human machine interface with the robot based on its coordination with the lower limbs. Therefore, we first conducted an investigation to verify that the cane is incorporated in the joint coordination of upper and lower limbs [30]. In our investigation we asked seven healthy subjects to walk on a treadmill with/without a cane, and captured their kinematics with a 3D-Motion Capture System (see [30] for details). The joint angles and angular velocities of the shoulder, elbow, hip and knee joints for the right and left side limbs, as well as the tilting angle and angular velocity of the cane were computed in the sagittal plane (Figure 1). Three cases were inspected: (i) Joint coupling of the lower limbs; (ii) Joint coupling of the upper and lower limbs; (iii) Coupling of the cane and the lower limbs. We extracted and compared the synergies among the three cases by means of Principal Component Analysis (PCA). The results showed that for each of the three cases the first four synergies (represented by principal components) accounted for about 95% of the data variation (Figure 3). This result indicate that the cane motion falls into the synergies of upper and lower limbs in gait, and thus could be used in a synergy based control approach.

2.2. Motion Intention Estimation

In this work we consider a motion intention estimation method based on synergies of human locomotion. Vallery *et al.* [31,32] suggested a method called Complementary Limb Motion Estimation (CLME). In this method it is possible to compute the reference trajectory for affected limb(s) in real-time from the motion of other healthy (unaffected) limbs and the inter-joint coupling of healthy gait. In our investigation [30] we found that the cane is incorporated into the inter-joint synergies of gait. Therefore, we use the motion of the cane and the unaffected leg (considering the case of hemiplegia) together with the averaged synergies of walking with cane to estimate the motion of the affected leg. In this manner,

the assisted motion will be automatically coordinated with the motion of the healthy leg and the cane (capturing the arm motion).

Figure 3. Group mean ratios of the first 4 principal components to the overall data for three sets of variables: **(i)** upper and lower limbs; **(ii)** cane and lower limbs; **(iii)** lower limbs.



2.3. Start and Stop

Motion intention estimation based on CLME [31,32] generates the reference trajectory for the intended limb(s) based on synergies extracted from continuous walking. However, start and stop motions have different synergies from those of continuous walking. Therefore, it is necessary to provide support for start and stop motions separately, and to switch between start, continuous walking, and stop motions accordingly. Although some researches have shown possible the estimation of gait initiation before heel-off and toe-off [33]. Such studies are based solely on healthy patterns of gait, without consideration of disturbed patterns after pathology. Therefore we decided to build on a more feasible approach for estimation of start and stop intention that depends on the user actively conveying his/her intention. We provide a button on the handle of the cane (Figure 2), close to where the thumb would usually rest, that should be pushed before starting and stopping. Provided that the button is pushed, the system monitors the ground contact pattern on both feet using force sensors embedded in the shoes of Robot Suit HAL, and the cane's ground contact using FSR sensors on the tip of the cane. Start and stop motions are based on segments of trajectories extracted from walking with cane of healthy subjects. The control system switches between assistance of starting, continuous walking, and stopping according to the current gait status, button status, and ground contact patterns (Figure 2). This system will be explained in some more detail in a later section.

3. System Overview

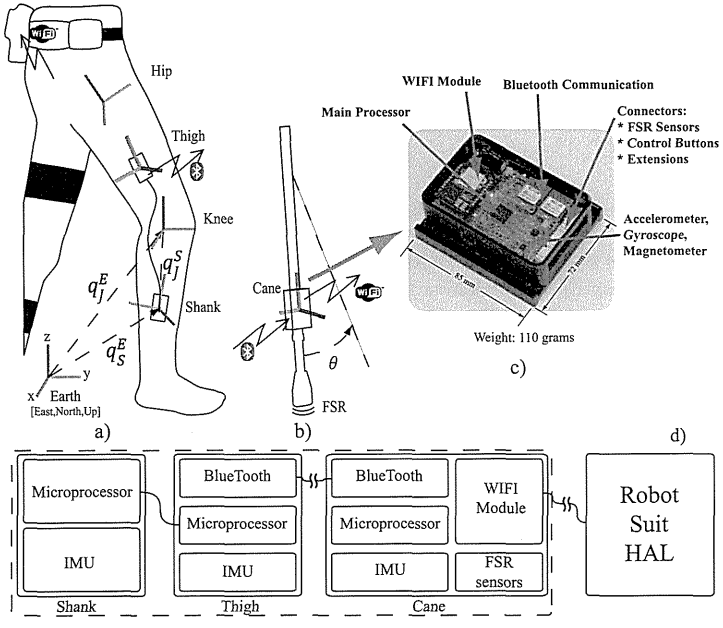
3.1. Wearable System

The motion capture system is currently the most accurate mean for acquisition of human motion. However, systems based on inertial sensors for measurement and analysis of human motion (specially

gait) have been steadily improving [13,14,34]. Using Inertial Measurement Units (IMUs) it is possible to capture the body motion by placing an IMU on each segment and fusing their information.

We developed a wearable gait measurement system based on inertial sensors, force sensors and embedded microprocessors to control exoskeleton robot. The system consists of three IMU modules: two modules fitted on the thigh and shank of the unaffected leg to acquire its motion (Figure 4a), and a main unit fixed on the cane (Figure 4b). Modules on the thigh and the shank acquire the motion (angle and angular velocity) of the hip and knee joints of the unaffected leg. The shank module is connected to the thigh module with wired serial communication, while the thigh module streams motion data from both thigh and shank modules to the main unit on the cane (Figure 4c,d). The module on the cane is the main unit (Figure 4c,d). It receives motion data via bluetooth from the thigh module, acquires the cane's motion (angle and angular velocity) from its own IMU, acquire the ground contact information from force sensors in the shoes of the robot through wireless communication , acquire the cane's ground contact information from FSR sensors, compute the control commands for the robot according to the current status, and stream those commands to the robot via WIFI communication. The force sensors embedded in the shoes consist of floor reaction force sensors under the heel and forefoot for each foot. The sensors provide continuous measurement of the floor reaction forces, and are used together with the FSR sensors on the tip of the cane to monitor the ground contact patterns for start-walk-stop support as well as for modification of control parameters in stance and swing phases (Figure 10).

Figure 4. Wearable system configuration and frame calibration.



3.2. System Calibration

The sensor fusion algorithm for IMU takes readings from 3-axis Gyroscope, 3-axis Accelerometer and 3-axis Magnetometer, and outputs the coordinates of sensor frame relative to reference frame (earth frame) in quaternion form. Performance of the algorithm is described in [35], accuracy; <0.8° static RMS error, <1.7° dynamic RMS error. In order to find the joint coordinates from the sensor coordinates a transformation is needed from the sensor frame to the joint frame. For performing this transformation we followed a procedure similar to that in recent methods [14,34]. The transformation from sensor frame to joint frame is given by Equation (6)

$$q_J^E = q_S^E \otimes q_J^S \tag{6}$$

The quaternions q_J^E, q_S^E and q_J^S represent the orientation of joint frame relative to earth frame, sensor frame relative to earth frame, and joint frame relative to sensor frame, respectively. And operator $\otimes$ is the quaternion multiplication. Therefore, to transform the sensor frame to joint frame we need to find the orientation of joint frame relative to sensor frame q_J^S. To do this we assume an initial position where the joint frame is known relative to earth frame. In our system we consider the initial position as quiet standing with the leg fully extended (leg completely vertical) and the person is roughly facing north. In this pose we assume that the joint frame for both hip and knee joints is identical to earth frame. From this position we can extract the quaternion of joint frame relative to sensor frame as in Equation (7)

$$q_J^S = (q_S^E)^{-1} \otimes q_J^E \tag{7}$$

After calculating q_J^S from the initial position we can use it to find the joint coordinates from the sensors coordinates assuming that the sensor mounting on the limb segment will not change while walking (sensor is attached firmly on the limb segment). We find the knee joint coordinates from the sensor fixed on the shank, and the hip joint coordinates from the sensor fixed on the thigh. Then we extract the joint angles in the sagittal plane since only motion in the sagittal plane is required in our system (the robot only provides assistance in the sagittal plane).

For the cane module this procedure was not required since the module is permanently fixed to the cane and well aligned to its axis. Therefore, just extracting the angle in the sagittal plan from the sensor's frame is adequate to produce the required cane's tilting angle.

3.3. Robot Control

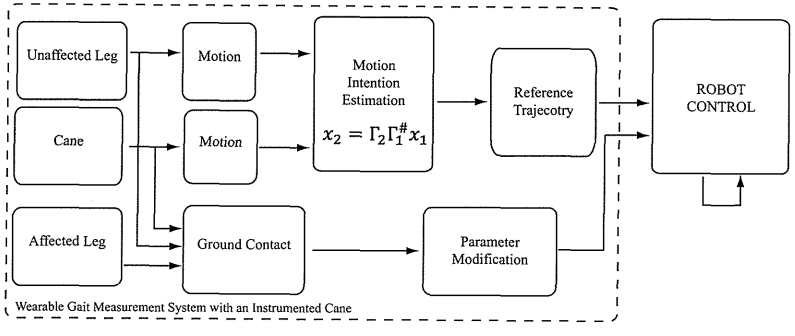
In our work we use the single leg version of Robot Suit HAL. The hybrid control algorithm of Robot Suit HAL [1] consists of a human voluntary control and an autonomous control. The wearer's voluntary muscle activity is obtained from the bioelectrical signals, detected at the surface of the muscles, and then the required assist torque of the actuators is computed from the estimated joint torque. An autonomous control is also implemented based on the pre-determined motion primitives, together with the voluntary control method. In this work we provide the control reference to the robot from the developed wearable measurement system, and the robot's embedded motor control algorithm handles the execution. This modular approach for robot control allows for stacking additional modules of control in the future, allowing the capacity for further considerations such as balance monitoring and head orientation.

Robot control with the developed wearable system will be explained here in detail. The system monitors the status of a start-stop button fitted on the handle of the cane and the ground contact patterns of the feet and the cane to detect start, walk, and stop conditions (Figure 2). We figured the start and stop conditions for this particular version considering the case of left side hemiplegia, where the user would be holding the cane with the right arm (unaffected side), and the robot would be fitted on the left leg (affected side). In this case we consider that the user would typically start with the left leg and the cane, since the right (unaffected) leg is more capable of supporting the body weight and balance requirements for starting. Accordingly, the start assist is triggered when the button is on, the right foot ground contact force is large, and the left foot and cane ground contact forces are small (Figure 2a). Transmission to the continuous walking mode is made at the next heel strike of the assisted leg, a state at which the unaffected leg is near to toe-off, and the cane is at contact with ground or close to it (Figure 2b). From this point assistance would be based on synergies based motion estimation from the cane and unaffected leg. Figure 5 illustrates the signal flow of the control system at this state. Motion of the affected leg's hip and knee joints are estimated from the motion of the cane and the motion of the unaffected leg's hip and knee joints (all motions are angle and angular velocities in the sagittal plane), as in Equation (8)

$$x_2 = \Gamma_2 \Gamma_1^{\#} x_1 \tag{8}$$

where x_2 are the variables to be estimated: affected leg's hip and knee angles and angular velocities, x_1 are the known variables: cane and unaffected leg's hip and knee angles and angular velocities, and $\Gamma_2\Gamma_1^{\#}$ is the rearranged matrix of the eigenvectors extracted from walking with cane trials of seven healthy subjects [30], and rearranged for estimation of x_2 from x_1 [31]. The estimated trajectories are streamed to the robot, and tracked with the actuators on the robot's hip and knee joints with PD controllers. The ground contact information from the robot's feet are used to modify control parameters in different conditions (Stance, Swing). To stop walking the user pushes the handle button again to release, then at the next heel contact of the unaffected leg (Figure 2c), toe-off of the affected leg, the stop motion would start, leading to quiet standing condition (Figure 2d). This pattern is also based on the stopping motion being supported by the unaffected leg, being more proper for hemiplegic persons.

Figure 5. Schematic diagram of the control system in continuous gait.



4. Experimental Evaluation

We devised various experiments to verify the function and feasibility of the proposed approach and the developed system. We test the system here with healthy subjects to verify its function, and to inspect for needed adjustments before trials with persons with hemiplegia. We asked healthy subjects to walk on a treadmill with the proposed method being implemented with the wearable system and with a 3D-Motion Capture System (MOCAP). Experiments were done with a left leg version of Robot Suit HAL, with the cane being used in the right arm. In treadmill trials we only used the continuous walk support, to avoid any fall risks that could result from using the start and stop support on a treadmill. We evaluated the resulting gait variables for each case and compared the results among the two. Also, we asked one subject to test the wearable system on ground with start and stop support to evaluate the feasibility of those functions as well.

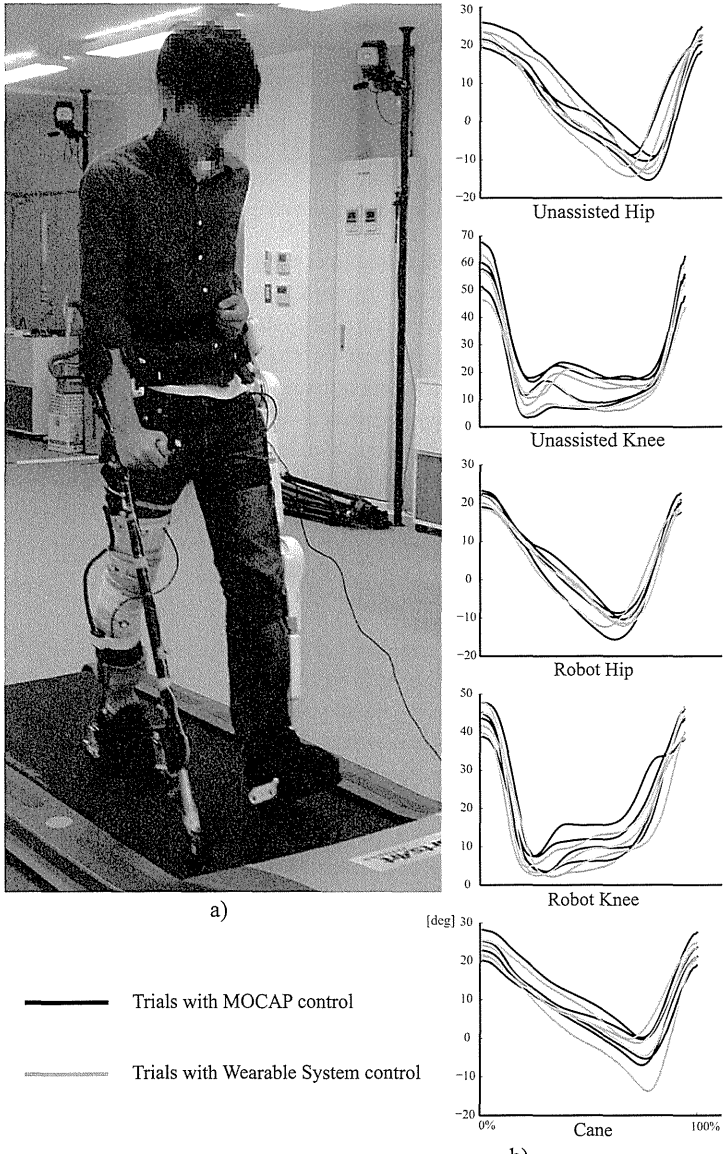
4.1. Subjects

We recruited four healthy male subjects for the experiments. All the subjects participated voluntarily, and neither had any history of locomotion deficits. Subjects had an average age of 26.5 $\pm$ 4.5 years, average weight of 62.6 $\pm$ 2 kg, and an average height of 172 $\pm$ 0.5 cm. All subjects signed a written informed consent, and all procedures were approved by the ethics committee of the University of Tsukuba.

4.2. Experimental Setup and Procedure

The experimental setup for treadmill gait trials is shown in Figure 6a. The motion capture system was used for control and motion capture in the MOCAP trials, and only used for motion capture in trials with the wearable system. All the subjects used the cane in the right arm, and wore single leg version Robot Suit HAL on the left leg. All users used a magnetic safety key attached to the subject's waist and to the treadmill controller, the key will stop the treadmill automatically if a subject lags on the treadmill to avoid falling risk. Also, one of the experimenters constantly watched over the experiment with control over the exoskeleton robot so he could immediately switch the robot to free motion mode, such that it could be easily moved by the subject, in any cases of imbalance. The treadmill speed was set to 1.5 Km/h for all subjects. The length of the cane and the shank and thigh segments of HAL were adjusted to the individual comfort of each subject. Reflexive markers were fitted on the right leg thigh and shank segments, four on each, and the same on robot HAL. Markers were also fixed on the cane to be tracked by the motion capture system. All subjects were introduced to the structure and purpose of the system, and they were all encouraged to modify the cane's motion to reach a gait that is most convenient for them, and each walked at his preferred cadence. Each subject was allowed a test trial of about two minutes to get used to the system, and then we captured 2$\sim$3 trials of walking with the system, each for about two minutes.

Figure 6. Experimental setup and average trajectories for all subjects.



4.3. Treadmill Experiments with the Wearable System and with Motion Capture System

For walking trials on the treadmill with the wearable system, the shank and thigh IMU modules were fitted with rubber bands, and the cane's module was fitted on it using a custom made casing. The wearable units were calibrated as in Figure 4. The control system computed the reference trajectory for the left leg (hip and knee joints) using the the motion of the right leg (hip and knee joints) and the cane, together with averaged synergies of seven healthy subjects acquired from walking with cane trials [30]. The sensor fusion algorithm was run on each module at 128 Hz. The cane module receives motion data from the thigh module at 128 Hz, and is connected to the robot via wireless network for receiving the ground contact readings and streaming control commands at 32 Hz.

Also, we implemented the control system with a motion capture system MAC3D (Motion Analysis Inc.) for comparison with the wearable system. Using the motion capture system we captured the motion of the subject and the cane at 120 fps. From the frames of the motion capture system we computed the angles and angular velocities of the right leg hip and knee joints, and the cane's angle and angular velocity, all in the sagittal plane. The ground contact was obtained from FSR sensors installed at the tip of the cane and force sensors embedded in the shoes of HAL via wireless communication. The control commands were transmitted to HAL through wireless network every other frame of the motion capture system (60 Hz).

4.4. On-Ground Experiment with Start and Stop Functions

To verify the the function of the entire system with start and stop support, we asked one of the subjects to walk with the system on ground and recorded his motion and feet ground contact from robot HAL. The trajectories for start and stop support were extracted from three healthy subjects walking on ground with cane. The subject performed seven steps including the start and stop steps.

5. Results and Discussion

To verify and evaluate the function of the developed wearable system, and the proposed method in general, we extracted and compared the trajectories and step related gait variables from the walking trials. For each subject we extracted 10 consequent gait cycles from a trial of walking with the wearable system and 10 consequent gait cycles from a trial with the MOCAP system. Steps and gait cycles were marked by identifying heel-strikes of the right and left legs from the ground contact data. We selected the cycles as to avoid having more than 5 missing frames at any point. Then we interpolated any missing frames with cubic interpolation, and smoothed the trajectories with a two-pass, 4th order, zero phase shift, 6-Hz cut-off frequency butterworth filter [36].

Figure 6b shows the average trajectories for a complete gait cycle of measured joint angles. The trajectories shown are the averages of the extracted 10 gait cycles for each trial, with the gait cycle duration normalized for all trajectories to compare range differences and trends in those trajectories. The dark lines represent the trajectories for trials with MOCAP control, and the lighter lines represent the trajectories with wearable system control.

Figure 7. Cadence.

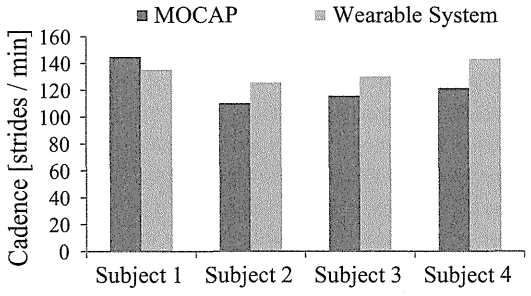


Figure 8. Right and Left Step Lengths.

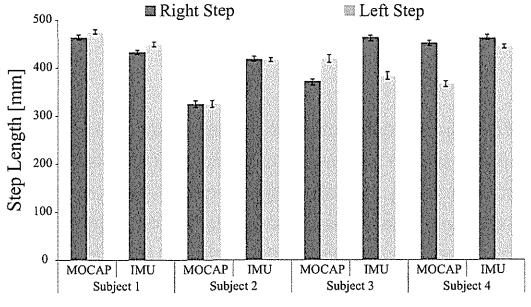
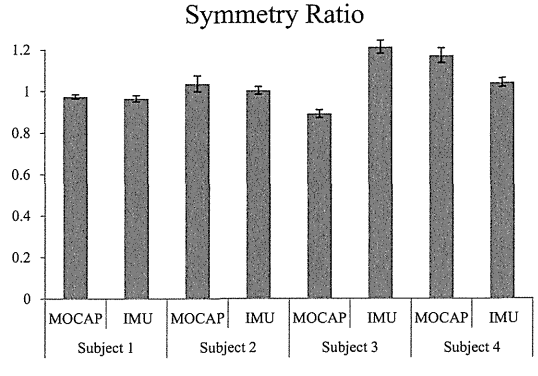


Figure 9. Symmetry Ratio (Right step/left step).



The trajectories show close to normal assisted motion trajectory on the robot's hip and knee joints, compared to that of the unassisted motion on the right leg's hip and knee trajectories. However, the range of motion in the robot's knee was smaller than that on the other side. This observation has several possible underlying causes. One is imperfections in the motion estimation algorithm which is based on linear approximation of the relationships between the variables (PCA) [30]. Another is the change in balance and anatomy resulting from wearing a robot on one side of the body. From the cane's trajectory we note some variation in range between the subjects, as we encouraged subjects to adjust the motion of the cane to reach more comfortable gait.

Figure 10. Start and Stop Support.

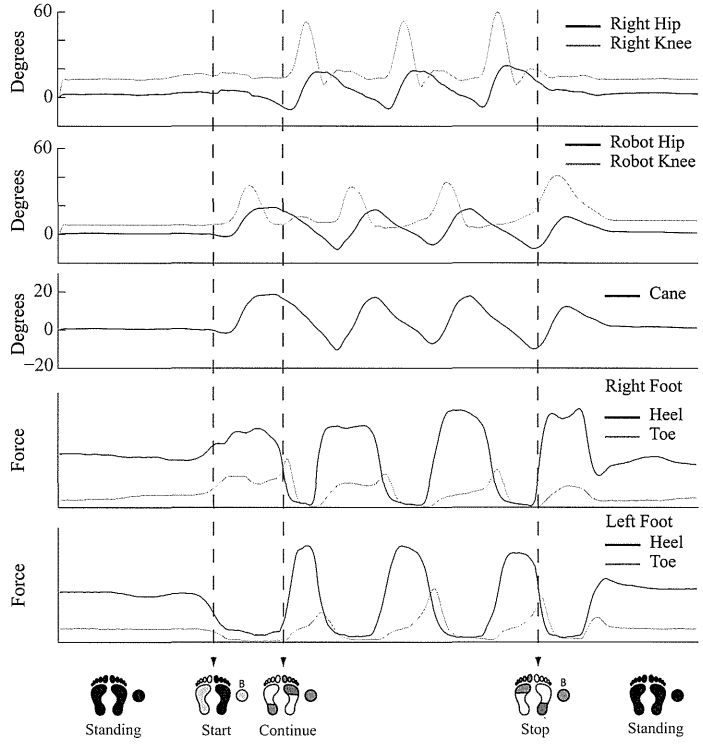


Figure 7 shows the cadence of each trial. Though subjects walked at the same speed on the treadmill, they had different body constitutions and walked at their own preferred cadence. Figure 8 shows the average step length on right and left sides, and Figure 9 shows the symmetry ratio of the trials. Subjects had slightly varying step length between the right and left sides. This is also seen in the symmetry ratio (considered here as the ratio of right step to left step). Figure 9 shows that subjects 1 and 2 achieved close to 1 (more symmetrical gait) ratios for both the wearable system and MOCAP trials, while