Protocol: Development of Walk Assist Device to Improve Community Ambulation

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I. Overview

We will assess a walk assist device (WAD) which assists flexion and extension at the hip joint to assist community walking/ambulation. Prototype model of this device has been developed by Honda Motor Corporation ®, Japan. This device: 1) will be simple to use in the clinical setting; 2) will be easily adjustable to alter the requirement of each subject; and, 3) will be able to quantify the amount of assistance required to facilitate normal community walking patterns. With the use of this device we will evaluate adaptations in walking performance following both over ground and body weight supported treadmill walking (BWSTT) in individuals with stroke. This information will help us identify the impact of an automated walking assistance device on lower extremity muscle activity, motor performance (kinematics), and corticospinal excitability after chronic neurological injury.

The assessment of WAD will be undertaken to determine the optimal use of the device tested on the treadmill and over ground in individuals with chronic motor unilateral stroke.

Testing procedures and informed consent procedures are described below.

II. Subject Population

Subject sample size of 12 stroke subjects will be sufficient to detect a significant difference, however considering attrition 15 subjects will be recruited. For the objective measures, power analysis yielded a sample size of 12 will be sufficient to detect a significant difference, however considering attrition 15 subjects will be recruited.

Subjects will be chosen to participate in this study, drawn from the Rehabilitation Institute of Chicago Research Registry.

Specific inclusion for participation of subjects includes:

a. Stroke subjects with a history of unilateral, supratentorial, ischemic or hemorrhage stroke will be recruited, with lesion location confirmed by radiographic findings.

b. All subjects who score > 10 on the Lower Extremity Motor Score (LEMS) developed previously to measure strength in SCI. For the LEMS criteria, preliminary data indicate that subjects with LEMS < 10 in the chronic stages do not recover walking.

c. All subjects will be required to walk > 10 m over ground without physical assistance at self-selected walking speeds ≤ 0.8 m/s using assistive devices and bracing below the knee as needed. A criterion of 0.8 m/s is utilized to target participants with limited or minimal ambulation in the community. Subjects will be further stratified into those who walk < 0.4 m/s and > 0.4 m/s, identified as household vs. limited community ambulators, respectively.

d. Range of motion (ankle: -10 to 30 deg, knee: 0 to 90 deg, hip: -10 to 40 deg) consistent with gait;

e. Medically stable with medical clearance to participate (absence of concurrent illness, including unhealed decubiti, infection, cardiopulmonary disease, osteoporosis, active heterotrophic ossification or peripheral nerve damage in the lower limbs, history of traumatic head injury);

f. Able to tolerate 30 minutes of upright (standing) position without orthostasis (decrease in blood pressure by 20 mmHg systolic and 10 mmHg diastolic; minimized with ambulatory population);

g. Must not be undergoing concurrent physical therapy to eliminate effects of additional interventions;

h. Patients prescribed medications for spasticity will not be excluded from participation but will be asked to maintain current levels of medication or inform the researcher if changes are necessary.

Specific exclusion for participation of subjects includes:

a. Women of childbearing potential will not be excluded, although women who are pregnant will be excluded due to potential forces at trunk from BWS or pelvic assistance;

b. Significant cardiorespiratory or metabolic disease that may limit exercise participation.

c. Weights limit > 250 lbs (limit of most counter-weight safety systems).

d.   History of previous orthopedic or neurological conditions which may impair walking.

e. Exclusion for TMS: pacemaker, metal implants in the head region, history of epilepsy or seizures, skull fractures or skull deficits, concussion within the last 6 months, unexplained recurring headaches, medications that lower seizure threshold, and pregnancy.

f. Subjects with scores < 23 on the Mini Mental Status Exam will be excluded.

III. Evaluation of motor and walking performance using walk assist device

A. *Clinical Assessment of motor and walking performance*

For evaluation purposes and measures of walking progression, reliable and valid measures will be utilized to assess: a) lower extremity voluntary control; b); degree of walking independence; and, c) walking speed, endurance and temporal-spatial parameters.

- Assessment of strength, spastic motor behaviors and functional ambulation will be performed by a licensed physical therapist at the initial evaluation and during walking protocols. Assessment includes:

- Lower Extremity Motor Scores: to determine strength in the lower extremities

- Functional Independence Measure (FIM): extent of disability and societal limitations linked with functional limitations of ambulation.

- 10m walk: gait speed

- 6min walk: gait speed and distance

- GaitMat II (Equitest, Chalfont, PA): to detect temporal-spatial gait patterns.

B. *Objective measure of motor and walking performance*

Evaluation of the changes in walking performance with the use of the proposed WAD will be assessed using computerized gait analysis during independent stepping on an instrumented treadmill and during over ground walking. Specific outcome measures include: a) extent of lower extremity loading and ground reaction forces during independent treadmill stepping; c) peak treadmill speed at minimal body weight support; c) lower extremity kinematics during stepping, including peak hip, knee, and ankle joint kinematics during walking, and temporal-spatial gait parameters, and, d) timing of lower extremity EMG activity during treadmill stepping. In addition, metabolic costs will be determined. Metabolic costs will be collected using a portable metabolic system (K4b2, CosMed USA, Inc., Chicago). Metabolic measures will be obtained in sitting for 5 minutes prior to walking. Metabolic measures will be taken during un-assisted walking and device assisted walking for comparison. Subjects will return to their metabolic baseline between the walking trials. Metabolic measures will always be measured at sub-maximal levels and will be stopped 75% of target heart rates. Written approval from subject's physician will be obtained before allowing subjects to participate in sub-maximal graded treadmill test. Non-approval from physician will exclude the subject's participation only in the sub-maximal graded treadmill test; however they will be allowed to participate in the other tests involved in the study. Gait analysis

will be performed with use of a motion analysis system (Motion Analysis Corp, Santa Rosa, CA), which includes eight strategically positioned charge-coupled device video cameras (VC491; Oxford Metrics), a minicomputer (PDP 11/73; Digital Equipment, Maynard, Massachusetts), and software for the collection and analysis of the data. Twenty-one, 1-inch diameter spherical reflective markers will be placed over pre-determined anatomical landmarks on the trunk and extremities. The patient will walk on a treadmill with embedded bilateral force plates, and the position coordinates for the markers on both sides of the body will be recorded simultaneously at 120 Hz using phase-locked cameras. The recording technique and the software allow for the three-dimensional reconstruction of the motion of all of the major joints of the upper and lower extremities. All of the patients will wear comfortable shoes, and each will walk at pre-determined (0.5 km/hr increments) and maximal speed. A harness attached to the suspension system will be used for all patients to prevent the patient from falling. Data will be collected at least three times for 30 sec at various speeds. In cases of visual occlusion of reflective markers during walking with assistance and/or devices, gait kinematics at the knee and hip will be detected by electrogoniometers placed bilaterally (Biometrics, Ltd, UK).   The electrical activity of the TA, SOL, MG, VL, RF, and MH will be recorded bilaterally with a 32-channel dynamic EMG telemetry system (Noraxon Inc., Scottsdale, AZ), with surface electrodes sampling at 960 Hz. Force-plates (OR6; AMTI, Newton, Massachusetts) that are embedded in the treadmill will sample the ground-reaction forces at 960 Hz.

C. *Objective measure of corticospinal excitability during walking:*

Transcranial magnetic stimulation (TMS) will be performed while walking with and without the WAD. TMS is a safe, non-invasive, painless method of brain stimulation that has been widely used to study the physiology of the representations of muscles in the motor cortex in healthy and neurologically disordered individuals. Very short duration (< 1 ms) magnetic pulses are applied via an insulated wire coil placed on the intact scalp overlaying the motor cortical. Each pulse induces a motor evoked potential (MEP) in a target muscle that can be readily monitored by recording EMG from the muscle. Magnetic stimuli will be delivered from a Magstim 200 unit via a Magstim double cone coil (Magstim Company, Boston MA). Self adhesive disposable electrodes (Suretrace) with an inter-electrode distance of 2 cm will be applied over the muscle bellies of the quadriceps, hamstrings, ankle dorsiflexors and ankle plantar flexors in the lower extremities. A ground electrode will be applied over the patella. Standard skin preparation techniques (light abrasion and cleansing with alcohol) will be completed prior to application of the electrodes. EMG recordings will be amplified (Octopus AMT-8; Bortec Biomedical, Calgary, Alberta), band-pass filtered (10-1000 Hz), and sampled at 5000 Hz. Electromyographic (EMG) activity will be collected from all muscles bilaterally. TMS will be delivered with the stimulating coil positioned over the vertex at intensities ranging from 70 – 140% of "walking threshold". This threshold is a better estimate of excitability than conventional thresholding because during walking, EMG burst patterns and EMG amplitude differ between subjects, and walking threshold is typically lower than tonic contraction threshold, and much lower than rest threshold. Walking threshold is the stimulus intensity that results in MEPs just visible as time locked waveforms emerging out of background EMG. Pre-burst onset MEPs will also be recorded at an intensity that results in a MEP of ~ 500 μV. This measure is important because we expect when the WAD is providing assistance, the
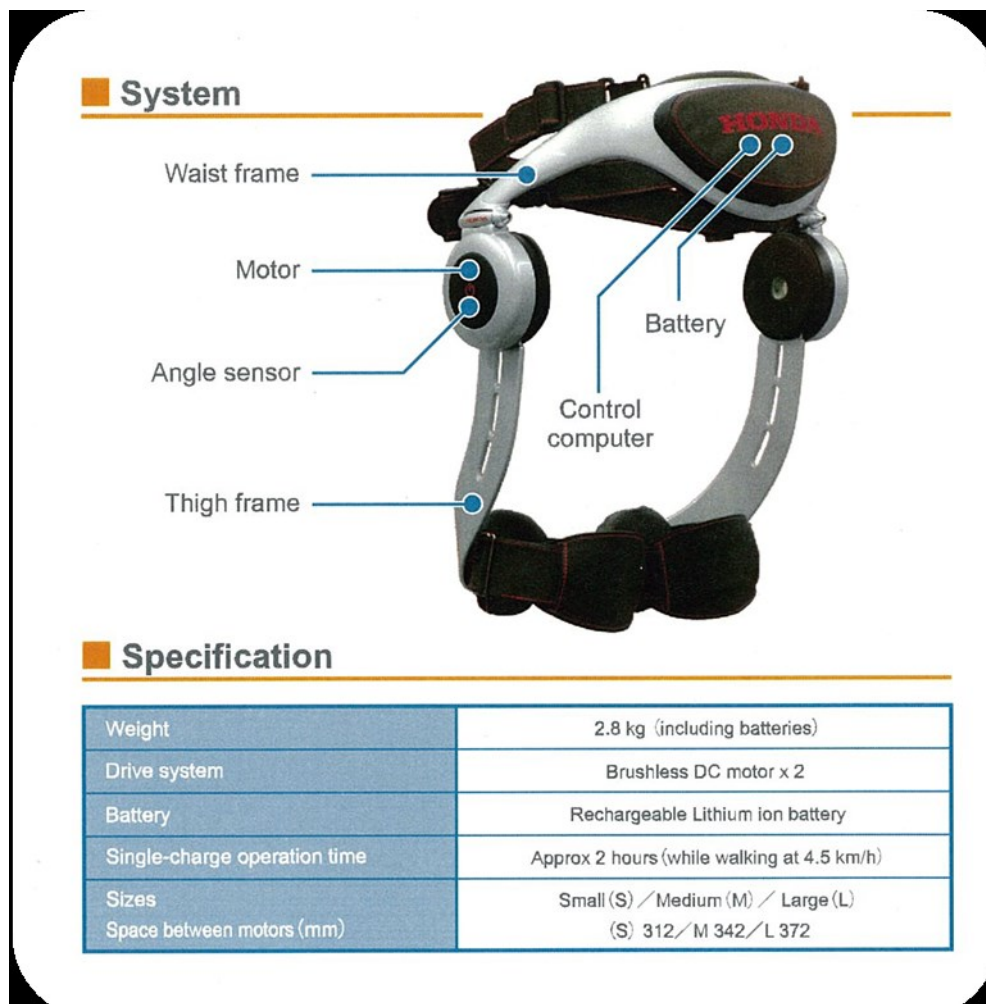
EMG burst amplitude may change, making it difficult to interpret changes in MEP amplitude assessed during the EMG burst. Subjects will be walking on a treadmill when magnetic stimulation is delivered. An optical motion switch will detect when a limb is in mid-swing and sends a pulse to software that in turn delays a TMS trigger pulse to coincide with a chosen cycle phase. Motor cortex excitability changes during walking will be examined by calculating the mean amplitude of 10 MEPs recorded from each muscle with and without WAD. A harness will be placed around the subject's pelvis and lower torso. The harness is attached to a rope and pulley system that is capable of supporting the subject's entire body weight in the upright position. A physical therapist (PT) will be in attendance at all times. Use of the harness and handrails, and the PT in attendance, will ensure that the subject is comfortable and secure at all times. Subjects will be provided with sufficient breaks between walking to avoid fatigue.

IV. Using the Walk Assist Device (WAD)

As part of the testing in this study, subjects will be asked to participate in body weight supported treadmill walking and/or over ground walking with the help of the WAD. All testing procedures will be with a licensed physical therapist or physical therapist assistant as described below.

Device Assisted Walking: The walk assist device (WAD) consists of a waist frame, rechargeable lithium ion batteries, hip actuators / motors, angle sensor and thigh frame. The WAD gently assists both forward and backward movements at a person's hip joints in a very smooth way with the electrical actuators. The electrical actuators are equipped with angular sensors to monitor walking speed, velocity, and the degrees of the forward and backward movement of the hip joints. Using the information from the sensors, the WAD gently assists the person towards normal walking patterns. However, most subjects are unaware of this manipulation because the assistive torque is

small. The WAD stops functioning when the subject stops walking and will in no way control walking or movement of the subject causing tripping or falling. The total weight of the WAS is approximately six pounds. All subjects will receive a thorough explanation of the structure and function of the WAD before the experiment to eliminate any concerns. Individual fitting of the WAD will be performed by the persons who developed the WAD to avoid any kind of discomfort to the subjects. The WAD also helps in conserving the subject's energy consumption during walking as the device utilizes the subject's inertia and gravity to assist walking. The WAD has been successfully used to assist walking in the elderly population and reduce energy consumption during walking in healthy controls.[1, 2]

System	
Waist frame	
Motor	
Angle sensor	
Battery	
Control computer	
Thigh frame	

Specification	
Weight	2.8 kg (including batteries)
Drive system	Brushless DC motor x 2
Battery	Rechargeable Lithium ion battery
Single-charge operation time	Approx 2 hours (while walking at 4.5 km/h)
Sizes Space between motors (mm)	Small (S) / Medium (M) / Large (L) (S) 312 / M 342 / L 372

IV. Statistical Analysis

Paired comparisons of electromyographic, kinematic, kinetics, strength and metabolic data will be made within subjects between groups (un-assisted stepping, device-assisted stepping) using standard parametric (t-test, ANOVA) comparisons. Changes in clinical performance will be assessed using primarily ordinal measures, with statistical comparisons made using non-parametric tests. Correlation (Pearson or Spearman) will be made between clinical/functional assessments and kinematics/kinetics observed during device-assisted walking.

V. References

1. Effects of an automated stride assistance system on walking parameters and muscular glucose metabolism in elderly adults. Shimada H, Suzuki T, Kimura Y, Hirata T, Sugiura M, Endo Y, Yasuhara K, Shimada K, Kikuchi K, Oda K, Ishii K, Ishiwata K. Br J Sports Med. 2008 Nov;42(11):622-9. Epub 2008 Feb 28.

2. The use of positron emission tomography and [18F]fluorodeoxyglucose for functional imaging of muscular activity during exercise with a stride assistance system.Shimada H, Kimura Y, Suzuki T, Hirata T, Sugiura M, Endo Y, Yasuhara K, Shimada K, Kikuchi K, Hashimoto M, Ishikawa M, Oda K, Ishii K, Ishiwata K. IEEE Trans Neural Syst Rehabil Eng. 2007 Sep;15(3):442-8.