Reviewer's report

Title: Pilot study of locomotor training using Hybrid Assistive Limb in chronic stroke patients

Version: 1 Date: 5 June 2013

Reviewer: Federica Tamburella

Reviewer's report:

Major Compulsory Revisions

Background:
- 2° paragraph
  o “Locomotor training based on gait motion has been suggested for task-specific training programs aimed at restoring walking ability [3-5]”. These references are too old, there are few more recent papers about task-specific motor learning
  o “Indeed, body weight-supported treadmill training is widely used in clinical practice”. Please add references
  - Last paragraph.
  o Please try to clarify which are the differences between the still available exoskeleton and HAL
  o Reference 22 refers to paraplegic patient. Please try to justify the rationale behind the hypothesis that HAL could be also useful for stroke subjects

Methods:
“Patients”:
- in the background authors declare 10 stroke patients, while in this paragraph “Eight patients had hemiplegia, one had quadriplegia, and one had ataxia.”. This is not a uniform group.
- Inclusion criteria are not well specified
- Table 1: please add some informations about clinical features of each patient such as Barthel Index and about Trunk control and sitting balance, by using Trunk Control Test. Furthermore, if the objective is to evaluate gait performances, it is useful to classify patients according to a validated clinical scale used for stroke subjects, such as Functional Activity Ambulation (FAC). Also data about the degree of pain, the degree of muscle activity, such as Manual Muscle Test, or the degree of spasticity, by means of Modified Ashworth Scale, are not reported.
- Last paragraph: How do you quantify the “limiting the range of motion of the lower limb, and severe spasticity.”? Which is the threshold value for range of motion and for spasticity? Do you use some clinical scales, such as Ashworth?
- As concerns body weight, the body weight reduction was different between
patients? The phrase “the patient’s body weight was partially unloaded using the suspension system” indicate different level of suspension.

“Intervention”:
- Please clarify if patients underwent other rehabilitation therapies or not.
- “When excessive knee flexion during the stance phase or toe dragging during the swing phase was observed, the patient’s body weight was partially unloaded using the suspension system.” In any table are reported in detail for the 10 patients data about body weight unloading during training sessions. According to the literature body weight unloading is a key point for the effectiveness of rehabilitation, such as the “walking speed and distance” that are modified for each subject according to “patient’s tolerance”. Also these data are missing.
- “Blood pressure and heart rate were measured at the start and end of each training session, and during the rest periods. At the end of each session, the patients stated their fatigue level after training and their level of satisfaction with the robotic assistance during movement.” How these parameters are quantified? No results are reported also for the level of satisfaction.

“Outcome measures”
- Please add some clinical scales such as FAC, 6 Minute Walking Test, some data about Physiological Cost Index, the level of Mood, Motivation, Satisfaction

“Statistical Analyses”
- No distribution data analysis have been performed, but it has to be done according to the population enrolled into the study. No patients for the control group have been enrolled.

Results - Discussion:
- According to my opinion, results section is too much poor, due to the reduced number of parameters/data collected. No crucial clinical scales have been used, as reported above. Furthermore a goal of the study is to define the improvement of balance performances, but besides BBS, no instrumental assessment, such as stabilometry, has been used. In line with these missing data, also discussion section is without an high degree of consistency. Furthermore, without a control group, even if patients have chronic lesion is not possible to conclude “walking ability may be improved by the HAL”. Furthermore the sentence “… HAL generates torque that is varied according to the bioelectrical signal generated when the wearer exerts force. The HAL user controls the voluntary drive to accomplish walking motion. This control is performed by a perceptual feedback based on visual and/or proprioceptive sense” is not discussed and it’s not clear how the user can voluntary drive the HAL. Also the concept of visual and/or proprioceptive feedback is not clearly discussed.

Minor Essential Revisions
Background
- 1° paragraph “is a major cause of paralysis and other physical or cognitive
disabilities, …” please add more references
- 3° paragraph “Robots are better able to provide cyclic support of the patient’s leg motion compared with therapists.” Please add some papers in order to justify these phrase

Methods:
“Intervention”:
- Please clarify if patients underwent other rehabilitation therapies or not.
- Protocol is not clear: “Early training sessions for individuals with severe gait impairment involved simple flexion/extension movements of the lower limb and dynamic postural tasks (i.e., sit-to-stand task) with HAL assistance”. Which is the progression of the treatment?

“Outcome measures”
- Please clarify when all the measurements have been collected
- “The best time of the two trials was used in the analysis.”. Please justify these sentence according to some references.

**Level of interest:** An article of insufficient interest to warrant publication in a scientific/medical journal

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**
I answe no to all questions reported above.