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ORIGINAL ARTICLE

Understanding Therapeutic Benefits of Overground Bionic Ambulation: Exploratory Case Series in Persons With Chronic, Complete Spinal Cord Injury

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Abstract

Objective: To explore responses to overground bionic ambulation (OBA) training from an interdisciplinary perspective including key components of neuromuscular activation, exercise conditioning, mobility capacity, and neuropathic pain.

Design: Case series.

Setting: Academic research center.

Participants: Persons (N=3; 2 men, 1 woman) aged 26 to 38 years with complete spinal cord injury (SCI) (American Spinal Injury Association Impairment Scale grade A) between the levels of T1 and T10 for ≥1 year.

Intervention: OBA 3d/wk for 6 weeks.

Main Outcome Measures: To obtain a comprehensive understanding of responses to OBA, an array of measures were obtained while walking in the device, including walking speeds and distances, energy expenditure, exercise conditioning effects, and neuromuscular and cortical activity patterns. Changes in spasticity and pain severity related to OBA use were also assessed.

Results: With training, participants were able to achieve walking speeds and distances in the OBA device similar to those observed in persons with motor-incomplete SCI (10-m walk speed, .11−.33m/s; 2-min walk distance, 11−33m). The energy expenditure required for OBA was similar to walking in persons without disability (ie, 25%−41% of peak oxygen consumption). Subjects with lower soleus reflex excitability walked longer during training, but there was no change in the level or amount of muscle activity with training. There was no change in cortical activity patterns. Exercise conditioning effects were small or nonexistent. However, all participants reported an average reduction in pain severity over the study period ranging between −1.3 and 1.7 on a 0-to-6 numeric rating scale.

Conclusions: OBA training improved mobility in the OBA device without significant changes in exercise conditioning or in neuromuscular or cortical activity. However, pain severity was reduced and no severe adverse events were encountered during training. OBA therefore opens the possibility to reduce the common consequences of chronic, complete SCI such as reduced functional mobility and neuropathic pain.

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The desire to walk ranks among the most prevalent concerns related to mobility identified by people with paraplegia caused by spinal cord injury (SCI).[1-4] Other complications related to the injury include muscle atrophy, reductions in bone mineral density, skin breakdown, urinary tract infections, spasticity, impaired lymphatic, vascular, and digestive function, and reduced cardiorespiratory capacity.[5] Beyond these complications, persistent pain may negatively affect mobility and activity levels.[6,7]

Approaches to mitigate these issues now include so-called bionic devices such as robotic exoskeletons. Fully powered lower extremity exoskeletons that facilitate movement with electric motors are being developed by several groups.[8,9] Different aspects

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of structural stability (ie, supporting persons with various neurologic levels of injury), device weight, and functional capacity (eg, feedback, stair stepping, incline walking) are emphasized by the various systems.[9,10] Commercially available exoskeletal walking devices must be used in conjunction with assistive devices for balance, such as a walker or crutches.

The structure and mechanics of bionic exoskeletal walking devices have been described from an engineering perspective, and potential applications for civilian and military use have been proposed.[11,12] However, clinical data on user performance and physiological responses to walking in these devices are limited. Only a few studies[13-18] have been published in the peer-reviewed literature to date, none of which reported training that had been standardized with regard to walking time, walking distance, or pretraining values to assess potential pre-post changes with training. While these studies represent a reasonable first attempt at evaluating robotic exoskeletons, the available data are limited to device use for mobility. Unexplored issues include whether secondary complications of SCI are influenced by overground bionic ambulation (OBA), specifically, whether these devices will be most effective for improving neuromuscular activation, exercise conditioning, or as assistive technology to improve mobility. We therefore adopted a cross-disciplinary approach with the objective to explore multifaceted responses to OBA training with a bionic exoskeleton in a convenience sample of 3 participants with chronic, complete SCI. Key components focused on were brain and muscle electrical activity, exercise conditioning as measured by peak oxygen consumption (Vo_2peak), and the potential effects on markers of cardiometabolic risk, mobility capacity (ie, walking speeds as assessed by the 10-m walk test and distances as assessed by the 2-minute walk test achieved while using the device), and neuropathic pain.

Methods

Inclusion/exclusion criteria and informed consent

To be included in the study, subjects had to have motor-complete SCI for $\geq$1 year. To fit the exoskeleton, subjects were required to have a height of 1.56 to 1.9m and a weight of $\leq$100kg, with a hip width of $\leq$.45m as measured across the frontal plane. Further details are provided in supplemental appendix S1 (available online only at http://www.archives-pmr.org/). The exclusion criteria were as follows: (1) any surgery within the preceding 3 months (assessed by participant self-report); (2) recent lower extremity fracture (assessed by radiographs of the lower extremity bones and joints in anteroposterior and lateral views); (3) participation in lower limb exercise conditioning within past 3 months; (4) occurrence of a pressure ulcer within past 3 months; (5) upper limb pain that limited weight-bearing on forearm crutches; (6) pregnancy; (7) exercise contraindications of the American College of Sports Medicine; (8) type I or II diabetes defined by American Diabetes Association guidelines (assessed by fasting blood glucose analysis described below); (9) lower extremity spasticity score in any joint exceeding 3 out of 4 (Modified Ashworth Scale[19]); (10) unresolved deep vein thrombosis; (11) uncontrolled autonomic dysreflexia (by self-report); or (12) significant leg length discrepancies (>.13m of the upper leg or >.19m of the lower leg.

Written and verbal informed consent was obtained from all participants. The protocol was approved by the Human Subjects Research Office, Miller School of Medicine, University of Miami.

List of abbreviations:

EEG	**electroencephalography**
MG	**medial gastrocnemius**
MVC	**maximal voluntary contraction**
NRS	**numeric rating scale**
OBA	**overground bionic ambulation**
SCI	**spinal cord injury**
TEE	**total energy expenditure**
Vo_{2peak}	**peak oxygen consumption**

Participants

Participants were 2 men and 1 woman aged 26 to 38 years with complete SCI (American Spinal Injury Association Impairment Scale grade A) between the levels of T1 and T10. Participant details are summarized in supplemental table S1 (found in supplemental appendix S1).

Device description

Detailed descriptions of the bionic device (Esko[a]) have been published elsewhere.[20,21] A brief description is provided in supplemental appendix S1, and the device is shown in supplemental figure S1 (found in supplemental appendix S1).

Protocol

Subjects participated in 18 sessions of OBA, walking around a 24.4-m oblong track (walking direction reversed for each session) for 1 hour per session, 3 times per week using a walker for balance. All subjects walked with close contact guard provided by a trainer, while tethered to an overhead track that would provide support in the event of a fall. Missed sessions because of schedule conflicts or equipment issues were made up during the next week or extending the protocol as needed (all subjects completed the protocol within 47−49d). Subject 1 missed sessions 14, 15, and 18; subject 2 missed sessions 13 through 16; and subject 4 missed sessions 1 and 2. Subjects were encouraged to walk the full hour but were allowed to rest (seated or standing while balanced by investigators) as desired.

The Ekso allows for 3 different modes of walking: (1) FirstStep, wherein the investigator actuates steps; (2) ActiveStep, wherein participants actuate their own steps via buttons on the walker; and (3) ProStep, wherein participants actuate the subsequent step by moving their hips forward and shifting them laterally, upon which the device triggers the step. Participants were progressed through each mode based on their walking quality as assessed by the investigator and the subject's own feedback (ie, expressed desire to progress to the next mode).

Outcome measures

Assessments were performed at baseline, at midpoint, and in the last week to assess functional walking capacity, spasticity, and Vo_2peak, and to analyze blood and diet. Some assessments were performed during the training sessions to evaluate concurrent responses or immediate training-related change. Subjects arrived at the laboratory in the fed state and underwent a series of assessments for pain before and after OBA, and spinal reflex excitability before OBA (see details below). During OBA, muscle and brain activity, as well as metabolic measures, was acquired (details below).