



EFFECT ON BODY COMPOSITION AND BONE MINERAL DENSITY OF WALKING WITH A ROBOTIC EXOSKELETON IN ADULTS WITH CHRONIC SPINAL CORD INJURY

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Objective: To examine the effect on body composition and bone mineral density of locomotor training using a robotic exoskeleton in individuals with spinal cord injury.

Study design: Interventional study.

Subjects/methods: Five adults with a non-progressive traumatic complete sensorimotor spinal cord injury who were using a wheelchair as a primary mode of mobility. Participants performed a personalized 6-week progressive locomotor training programme using a robotic exoskeleton 3 times/week for up to 60 min. Body composition measures were determined using dual energy X-ray absorptiometry and peripheral quantitative computed tomography.

Results: A significant increase in leg and appendicular lean body mass and a decrease in total, leg and appendicular fat mass was observed after the intervention. Furthermore, the calf muscle cross-sectional area increased significantly after the intervention. Finally, although not statistically significant, there was an increase of 14.5% in bone mineral density of the tibia, which may be clinically significant. A decrease of >5 % was also noted for subcutaneous adipose tissue and intramuscular adipose tissue.

Conclusion: Locomotor training using a robotic exoskeleton appears to be associated with improvements in body composition and, potentially, bone health.

Key words: dual energy X-ray absorptiometry; peripheral quantitative computed tomography; fat mass; lean body mass; physical activity and rehabilitation.

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People with spinal cord injury (SCI) usually use a powered or manual wheelchair as their primary mode of locomotion indoors and outdoors. However, this often results in a sedentary lifestyle (1), which is associated with a 3–4%/month decline in bone mineral density (BMD) in the lower extremities in the first year after a SCI, leading to an increase risk of fractures

(~25–46%) (2, 3). Moreover, individuals with a SCI gain weight at the rate of ~2.0 kg/year and 40–66% become overweight or obese (4). In addition, muscle mass atrophy (~30%) develops, as well as increases in intramuscular adipose tissue (~100%) with a SCI (5, 6). Overall, these changes increase the risk of metabolic complications (7).

The use of recently-developed robotic exoskeleton systems for ambulation may represent a promising alternative, which might overcome unfavourable changes in BMD and body composition. To date, these systems have been used primarily for studying walking parameters and performance (8). The potential for these systems to increase weight-bearing in the lower extremities and physical activity needed to overcome some secondary health complications is plausible (9). There is a need to strengthen the current level of evidence linked to robotic exoskeleton systems and to explore their potential effectiveness in overcoming SCI-related complications prior to developing a large-scale randomized controlled trial. Accordingly, a recent review has advocated more research on the effect of locomotor training programmes using robotic exoskeleton systems in order to gain a better understanding of their related health benefits (10, 11). The purpose of the present pilot study was therefore to examine the effect of a 6-week locomotor training programme using a robotic exoskeleton on body composition and BMD in individuals with a chronic SCI.

METHODS

Participants

Five adults (4 men and 1 woman) with a non-progressive traumatic complete sensorimotor SCI (American Spinal Injury Association Impairment Scale A) below the 6th cervical vertebra were recruited. These subjects had no ambulatory capacity and used a wheelchair as their primary mode of mobility. Inclusion criteria were: over 18 years of age; discharged from an intensive rehabilitation programme for at least 18 months; and no musculoskeletal upper limb impairment. Exclusion criteria were: other nervous system damage aside from the SCI; impaired skin integrity; concomitant or secondary musculoskeletal impairment; cardiovascular disease; and cognitive dysfunction. All procedures were approved by the Research Ethics Committee of the Centre for Interdisciplinary Research in Rehabilitation of

Greater Montreal and of the Université du Québec à Montréal. All participants were fully informed about the nature, goal, procedures and risks of the study and gave their informed consent in writing prior to the study. All applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

Measurements

Body composition. Total body weight, percentage fat mass (FM) and lean body mass (LBM in kg) of the arms, legs and trunk, as well as total and leg BMD were measured using dual energy X-ray absorptiometry (DXA) (General Electric Lunar Prodigy, standard mode, software version 12.30.008; Madison, WI, USA). Height was measured using a tape measure in a lying position. Body mass index (BMI) was calculated (kg/m^2). Furthermore, BMD of the tibia, as well as the cross-sectional areas of the calf muscle, subcutaneous adipose tissue and intramuscular adipose tissue, were assessed with peripheral quantitative computed tomography (pQCT) (Stratec Medizintechnik XCT 3000, software version 6.20; Pforzheim, Germany). The cross-sectional areas and densities were determined at the 66% tibia site of the right leg. Scans were acquired with a voxel size of 0.8 mm and a scan speed of 10 mm/s.

Robotic exoskeleton system. The Ekso robotic exoskeleton system (Ekso Bionics, Richmond, CA, USA) is a battery-powered, motor driven, robotic pair of legs generating active motion at the hip and knee joints, in a properly sequenced manner. Information gathered by different sensors attached to the lower extremities and trunk feed the decisional algorithm loop when walking, while requiring individuals with a SCI to control forward and lateral trunk body shifts to activate steps.

Locomotor training programme. Participants first attended 2 familiarization sessions, each 45–60-min in duration, over a 2-week period. During these sessions, participants were fitted with the Ekso before performing walking-related (e.g. sit-stand and transfer) and walking tasks, in order to familiarize themselves with the system. Subsequently, participants learned to ambulate the Ekso safely at a self-selected speed. Following these 2 sessions, participants had to complete a personalized 6-week progressive locomotor training programme 3 times/week for up to 60 min on free overground walking. The workload was periodically adjusted using walking distance, duration and speed parameters to continually maintain 60–70% of heart rate reserve. All sessions were under the direct supervision of an Ekso-certified physiotherapist.

Statistical analysis

Results are presented as means and standard deviation (SD). The paired-sample Wilcoxon signed-rank test was used to identify differences after the intervention. The 2-tailed test was set at $\alpha=0.10$ and the statistical significance was considered when the normalized p -value was <0.05 . In addition, the number of subjects (n) presenting positive or negative differences, as well as the negative and positive rank sums, were reported. A relative change of 5% or more was considered clinically significant for all variables. Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 22 (IBM Corp., Armonk, NY, USA).

RESULTS

Mean time since the SCI was 7.6 years (SD 4.6). The American Spinal Injury Association Impairment Scale (AIS) of the SCI neurological level ranged between C7 and T10. The mean AIS motor scores were 45.6/50 (SD 9.8) and 0.0/50 (SD 0.0) for the upper and lower extremities, respectively, whereas the mean AIS sensory scores were 52.6/112 (SD 18) and 51.6/112 (SD 16.9) for the pinprick and light touch discrimination tests, respectively. Moreover, the modified Ashworth Scale (scored on a 0–5 scale) confirmed minimal spasticity in the lower extremity (tested on 14 hip, knee, ankle and toe muscle groups) with a mean score of 5.4/140 (SD 4.8) pre- and post-locomotor training. No changes in the AIS scores were observed after the locomotor training programme. Mean standing time, walking time and steps taken per session were 48.4 min (SD 7.4), 27.0 min (SD 5.4) and 904 steps (SD 260), respectively. Mean attendance for the exercise sessions was 93%. No serious injuries were reported during the intervention and none of the participants dropped out of the study.

Body composition and BMD characteristics of the participants before and after the intervention are shown in Table I. A significant improvement was noted for leg and appendicular LBM, total, leg and appendicular FM, as well as the cross-sectional area of the calf muscle mass after the intervention. Total body weight and BMI increased significantly. No changes were observed for all of the other variables. Finally, after the intervention, the 1 participant who started the study with a diagnosis of osteoporosis improved his status to osteopaenia.

DISCUSSION

Participants in the present pilot study exhibited a favourable improvement in body composition measures, i.e. an increase in calf muscle and a decrease in leg and total FM were observed after the intervention. In addition, a tendency for an increase in BMD of the tibia was noted. An increase of 14.5% would be highly relevant from a clinical perspective, especially as the training programme lasted only 6 weeks. Similar improvements of $>5\%$ were also observed for subcutaneous adipose tissue and intramuscular adipose tissue. These results suggest that the proposed locomotor training programme could be an effective rehabilitation intervention for musculoskeletal and bone health. Furthermore, there was no participant dropout, there was very good compliance with the locomotor sessions (93%), and no

Table I. Body composition and bone mineral density characteristics of the participants (n = 5) before and after the intervention

Variables	Pre	Post	% Δ	Negative/positive differences (n)	Negative/positive differences (rank sum)	Normalized p-value	Normalized p-value
Age, years, mean (SD)	60.4 (6.1)						
Sex, n	♀=1, ♂=4						
Height, m, mean (SD)	1.80 (0.1)						
Body weight, kg, mean (SD)	79.7 (12.5)	81.7 (13.7)	2.4 (1.3)	0/5	0/15	0.06	0.04
Body mass index, kg/m ² , mean (SD)	24.5 (1.7)	25.1 (2.0)	2.4 (1.3)	0/5	0/15	0.06	0.04
DXA measurements							
Total lean body mass, kg, mean (SD)	50.2 (6.8)	51.4 (9.2)	1.7 (5.7)	1/4	4/11	0.38	0.34
Arm lean body mass, kg, mean (SD)	7.8 (1.9)	7.9 (2.0)	1.1 (5.1)	2/3	5/10	1.00	0.50
Leg lean body mass, kg, mean (SD)	14.1 (2.5)	15.6 (3.0)	6.7 (5.1)	0/5	0/15	0.06	0.04
Appendicular lean body mass, kg, mean (SD)	22.4 (4.1)	23.5 (4.5)	4.7 (2.8)	0/5	0/15	0.06	0.04
Trunk lean body mass, kg, mean (SD)	23.1 (4.0)	23.8 (4.3)	3.0 (3.5)	1/4	1/14	0.38	0.08
Total fat mass, %, mean (SD)	35.4 (7.1)	34.1 (4.0)	-3.7 (2.8)	5/0	15/0	0.06	0.04
Arm fat mass, %, mean (SD)	28.1 (8.1)	26.8 (7.9)	-4.9 (3.9)	4/1	14/1	0.38	0.08
Leg fat mass, %, mean (SD)	40.9 (7.9)	38.1 (7.1)	-6.8 (2.6)	5/0	15/0	0.06	0.04
Appendicular fat mass, %, mean (SD)	34.5 (7.5)	32.5 (7.1)	4.7 (2.8)	5/0	15/0	0.06	0.04
Trunk fat mass, %, mean (SD)	35.2 (9.0)	35.2 (8.7)	0.4 (7.2)	3/2	8/7	1.00	0.89
Total bone mineral density, g/cm ² , mean (SD)	1.188 (0.12)	1.168 (0.10)	-1.7 (5.2)	2/3	7/8	1.00	0.89
Prevalence of osteoporosis, n, %	20 (1/5)	0 (0/5)					
Prevalence of osteopaenia, n, %	0 (0/5)	20 (1/5)					
Leg bone mineral density, g/cm ² , mean (SD)	1.108 (0.12)	1.114 (0.13)	0.5 (1.9)	1/4	4/11	0.38	0.34
pQCT/tibia measurements							
Bone mineral density, mg/cm ³ , mean (SD)	466.2 (75.4)	532.6 (92.4)	14.5 (11.2)	1/4	1/14	0.38	0.08
Cross-sectional area of the calf							
Muscle, mm ² , mean (SD)	385.8 (96.6)	445.7 (117.3)	16.2 (21.2)	0/5	0/15	0.06	0.04
Subcutaneous adipose tissue, mm ² , mean (SD)	211.2 (16.0)	196.0 (53.1)	-6.9 (24.6)	2/2	5/5	1.00	1.00
Intramuscular adipose tissue, mm ² , mean (SD)	341.4 (77.4)	295.6 (77.6)	-6.5 (41.8)	3/2	10/5	1.00	0.50

Statistical significance was set at $p < 0.05$. A relative change of 5% or more was considered clinically significant. SD: standard deviation.

injuries or adverse events were reported, suggesting that a locomotor training programme may be feasible and secure for this type of population. Therefore, healthcare professionals could consider locomotor training with a robotic exoskeleton system as an option during the implementation of rehabilitation training programmes. However, these results need to be replicated with a larger sample size in a randomized controlled study to strengthen the level of evidence. Future studies should compare the effects of locomotor training using a robotic exoskeleton system with other training models, such as functional electrical stimulation cycling, in order to gain understanding of which training model is more effective on body composition and BMD.

Collectively, in order for the overground exoskeleton system to become a large-scale alternative for clinical practice, careful consideration of the financial costs, equipment, personnel and time may be warranted. In addition, sustainability of the beneficial effects may be another key issue to consider. Similar issues have been raised in the past regarding functional electrical stimulation (FES) cycling. However, when compared with FES training, which can be completed only within a rehabilitation or adapted physical activity setting, the use of an overground exoskeleton walking system appears to be a promising avenue over time, since some devices are now approved for use at home or in the community in different countries (e.g. ReWalk, ReWalk Robotics, Inc., Marlborough, MA, USA).

Moreover, the development of the next generation of this mobility technology has been initiated. That is, numerous research teams around the world are currently working on the development of lightweight personally fitted robotic walking exoskeletons with sophisticated balance controllers for safe and efficient use at home and in the community. Hence, if the potential health benefits of the exoskeleton system are confirmed, healthcare utilization and costs, as well as caregiver burden, will decrease, while social participation and life satisfaction will increase. Future studies investigating locomotor training using robotic exoskeletal systems will provide a better understanding of the balance between health and social benefits as well as the economic costs.

In conclusion, this is the first study to indicate that locomotor training using a robotic exoskeleton system is associated with improvements in body composition and, potentially, bone health. Indeed, these findings should be considered preliminary, but they may stimulate additional research on the impact of locomotor training using a robotic exoskeleton on metabolic diseases in individuals with a SCI.

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