Robotic Walking to Mitigate Bone Mineral Density Decline and Adverse Body Composition in Individuals With Incomplete Spinal Cord Injury

A Pilot Randomized Clinical Trial

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Objective: The aim of the study was to determine whether 24 wks of robotic locomotor training or activity-based training was sufficient time to induce bone mineral density and body composition changes in individuals with spinal cord injury. This study reports the secondary analysis of a randomized pilot trial.

Design: Participants with chronic motor incomplete tetraplegia ($N = 16$) were recruited. Interventions involved 60-min sessions, 3× per week, over 24 wks. Robotic locomotor training involved walking in the Ekso GT suit. Activity-based training involved a combination of resistance, cardiovascular, and weight-bearing exercise.

Results: Hip bone mineral density was maintained during robotic locomotor training; however, it was significantly reduced ($P = 0.04$, effect size = 0.86) during activity-based training by 0.03 (−0.29 to 0.23) g/cm^2 after intervention. Both interventions improved arm fat-free soft tissue mass, but neither group experienced changes in leg fat-free soft tissue mass. The activity-based training group had a significant decrease in visceral adipose tissue ($P = 0.04$, effect size = 0.72) and gynoid fat mass ($P = 0.01$, effect size = 0.62).

Conclusions: Twenty-four weeks of robotic locomotor training is possibly a sufficient duration to prevent the progressive decline of bone mineral density usually occurring in this population. A longitudinal period of activity-based training serves as an effective rehabilitation strategy to reduce indices of fat mass in individuals with spinal cord injury.

Key Words: Rehabilitation, Spinal Cord Injuries, Bone Mineral Density, Body Composition

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What Is Known

- It is possible that robotic locomotor training (RLT) may improve bone density, as the weight-bearing activity stimulates and creates an ideal stress environment to promote physiologic bone remodeling. The effect of RLT on body composition is currently unclear. There is a lack of randomized controlled trials addressing the influence of RLT on bone health and body composition, especially trials involving a homogenous spinal cord injury (SCI) population and a longer-length intervention of more than 6 wks. The feasibility of these types of clinical trials within a low-middle income setting is understudied and poorly understood.

What Is New

- A 24-wk robotic walking program is feasible and safe within a low-middle income country, but costs and resources remain a limiting factor. Robotic locomotor training may serve as an effective rehabilitation tool for preventing the progressive decline of bone mineral density usually occurring in the SCI population group. Activity-based training is effective in reducing total body fat and improving adiposity distribution in individuals with SCI.

Spinal cord injury (SCI) leads to a reduction in muscle contractions and a redistribution of gravitational forces applied to the skeleton. As a consequence, bone mineral density (BMD) decline and adverse changes in body composition are common secondary complications associated with SCI.[1] The rate of bone resorption is accelerated and bone formation is decreased after SCI, resulting in a significant decrease in BMD of up to 50% within the first 3 yrs.[2] The dramatic bone loss after SCI leads to an increased risk of bone fractures, serving as a significant health risk for this population.[3] After SCI, the body also undergoes changes in composition and metabolism due to decreased physical activity levels and, consequently, reduced daily energy expenditure. As a result, individuals with SCI have significantly decreased fat-free soft tissue mass (FFSTM) and increased fat mass (FM) compared with the average population.[4,5] In addition, there is a tendency for central obesity characterized by deposition of subcutaneous adipose tissue and visceral adipose tissue.[4,5] Greater adiposity is closely related to an increased risk of cardiovascular and metabolic diseases.[3,4]

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Bone mineral density loss after SCI is partly caused by a decrease in mechanical loading as a result of reduced or complete loss of muscle function and weight-bearing activity.[3] Resistance exercises, functional electrical stimulation–assisted exercises, and weight-bearing activities are suggested to promote bone health and density after SCI.[1,6–8] The current global standard of care for SCI rehabilitation, activity-based training (ABT),[4,9] has been proposed as a vital therapy to prevent BMD decline by mechanically reloading the lower extremity and stimulating the osteogenic effects for bone mass deposit.[1,6,10]

Subsequently, it has been hypothesized that robotic locomotor training (RLT) may also ameliorate the progressive loss of BMD in people with SCI,[3] as the weight-bearing activity stimulates and creates an ideal stress environment to promote physiologic bone remodeling.[3,11] However, as RLT is a relatively new rehabilitation technology, there is currently a lack of adequately powered studies, including randomized control trials (RCTs), addressing the influence of robotic walking on bone health in the SCI population.[2,8,12] In addition, there is a lack of published evidence-based guidelines defining the optimum time and frequency of weight-bearing activity required to maintain bone health during SCI rehabilitation.[13–15] Evidence for impact on BMD is somewhat mixed with descriptive evidence mainly suggesting benefits for early initiation of higher-dose standing programs.[16] However, in general, there is a paucity of studies evaluating the benefits of longer-length exercise interventions on BMD after SCI, with most studies consisting of 6-wk interventions only.[2,12,17]

There is currently no evidence that supports the effectiveness of any intervention in preventing fragility fractures after SCI.[2,18,19] Furthermore, although there is supporting evidence that regular physical activity, including ABT, is associated with greater lean mass and lower adiposity for individuals with SCI,[5] RLT has not been thoroughly investigated for its utility in improving these indices of health.[12,20] There is a need to strengthen the current level of evidence linked to longer-term rehabilitation interventions, particularly RLT, and to explore their potential effectiveness in overcoming SCI-related changes in bone density and body composition before performing a full-scale RCT. This pilot study would be the first to provide preliminary evidence to support the design of effective interventions that target body composition and attenuate the rapid decline in bone microstructure and geometry. Thus, in support of a larger-scale RCT, this pilot study aims to explore whether a longer-term (24-wk) robotic walking intervention mitigates BMD and body composition in individuals with chronic SCI.

METHODS

Study Design

This study is a secondary analysis from a pilot RCT, for which information on recruitment, retention,[21] methods, and sample size determination[22] has previously been reported. Primary outcomes including functional capacity and cardiovascular changes from the original RCT have been previously reported.[21,22] Additional measures related to bone density and indices of body composition, not determined in the original study, were analyzed by the authors of this article. The additional measures were *Z* scores, BMD, and body composition indices of FFSTM and FM. Randomization and group allocation (assigned via computer generation) was performed by the project manager after participants completed preintervention testing. Each participant provided written informed consent before the study. This study was approved by the Faculty of Health Sciences Human Research Ethics Committee (HREC 718/2017) and is a secondary analysis of a registered trial in the Pan African Clinical Trial Registry (PACTR201608001647143). The study was performed in accordance with the principles of the Declaration of Helsinki as revised in 2008, ICH Good Clinical Practice, and the laws of South Africa. This study conforms to all CONsolidated Standards of Reporting Trials guidelines and reports the required information accordingly (see Supplementary Checklist, Supplemental Digital Content 1, http://links.lww.com/PHM/B444).

Participants

Participant recruitment ensured the following inclusion criteria: chronic (>1-yr) traumatic motor incomplete tetraplegia, individuals 18–65 yrs, motor incomplete injury (AIS C, D), with a neurological level of injury between C1 and C8 (tetraplegia), must be reliant upon a wheelchair as the primary mode of mobility, sufficient anthropometrics and range of motion to achieve a normal, reciprocal gait pattern within the Ekso GT suit, had to be medically stable and cleared by a physician for full weight-bearing locomotor training including 15-min standing frame trial to assess standing tolerance.

Exclusion criteria included: nontraumatic SCI, have trained in a robotic exoskeleton in the past 12 mos or currently performing any other form of locomotor training, Modified Ashworth Scale = 4 in any of the lower extremity joints, skin integrity issues in areas that contact the device, pregnancy, severe osteoporosis, any medical issue that in the opinion of the investigating team precludes full weight-bearing locomotor training, including but not limited to: heart or respiratory comorbidity, spinal instability, acute deep vein thrombosis with activity restrictions, severe, recurrent autonomic dysreflexia requiring medical intervention, heterotopic ossification in the lower limbs resulting in range of motion restrictions at the hips or knees, any medical issue that in the opinion of the investigating team would affect participant safety either due to cognitive deficits/impulsivity, intolerance to mild exercise or other factors, and any issue that in the opinion of the investigating team would confound results such as a concurrent neurological injury or disorder (other than SCI). All participants were recruited from the Western Cape region of South Africa. One hundred ten participants were screened for eligibility, of whom 25 were physically assessed and 17 deemed eligible. One RLT participant dropped out because of a tibial stress fracture.

Twenty-Four–Week Intervention

An overview of testing timeline, procedures, and intervention has been described[22] and is further summarized. The exercise intervention consisted of 24 wks of supervised RLT and ABT. Both interventions consisted of three sessions per week, 60 mins each, for 24 wks, and were overseen by trained healthcare professionals. Robotic locomotor training involved solely walking in an Ekso GT Variable Assist Model exoskeleton (Ekso Bionics, Richmond, CA), which has been used in previous research.[23,24] This model of exoskeleton is equipped with variable assist software, which provides three different levels of walking

assistance and is further divided into four modes of stepping. Intensity levels were determined by the attending therapist and ranged from standing and walking time of 10–50 mins and between 50 and 1800 steps taken.

The ABT intervention (therapy and beyond rehabilitation program) was adapted from the beyond therapy model used by the Shepherd Centre and can be described as a six-stage process focusing on neurological recovery below the level of lesion, including: prehabilitation, muscle recruitment, posture and joint stability, resistance and endurance training, pregait, and gait training. The stages of ABT were not linear in design but rather recursive, where progression went back and forth as needed. Progress was determined by the treating therapist according to the ability of the participant to meet the demands required within each stage of rehabilitation. Activity-based training consisted of a combination of resistance, cardiovascular, and flexibility training in various positions as well as gait retraining, without a treadmill or robotic assistance. Upper and lower body resistance training was performed using bodyweight exercises and various apparatus, including bands, wrist weights, dumbbells, and cables. The approximate standardized time allocation for each ABT session was as follows: warm-up and mobility (5 mins), resistance training (20–30 mins), and cardiovascular training (20–30 mins). Five minutes were allocated for transfers and the setting up of various apparatus. Participants were monitored using the PARA-SCI tool and advised not to change their physical activity habits or dietary habits outside of the trial.

Preintervention and Postintervention Testing Procedures

The design of this pilot clinical evaluation composed pre-post assessment of the intervention effect on bone density and indices of FFSTM and FM. Specific methods pertaining to the bone density and body composition outcome measures are provided hereinafter.

Body Weight

Body weight of the participants was measured in kilograms on a 900 × 600-mm AMTI force platform (AMTI, Watertown, MA) at baseline (week 0) and postintervention (week 24).

Dual Energy X-ray Absorptiometry

Dual-energy x-ray absorptiometry (DXA; Hologic QDR, MA) was used to measure bone density and body composition. The DXA scans were performed during baseline (week 0) and again postintervention (week 24). Participants were required to remove all clothing and jewelry, wearing only their undergarments and a cotton gown for the scan. All scans were performed by the same radiographer who followed standardized procedures given by the DXA device manufacturers. Site specific least significant change indicating the technician's precision error: AP spine = 0.030 g/cm^2, total hip = 0.025 g/cm ^{2}, whole body = 0.025 g/cm^2.

Bone Mineral Density

Bone mineral density was measured at the following specific sites: lumbar spine, left and right hip, and left and right femoral neck. The specific details of the DXA setup for each body site can be found in the Supplementary Material (Supplemental Digital Content 2, http://links.lww.com/PHM/B445). Bone mineral density of each region was analyzed in grams per square centimeter. *Z* scores were assessed as a preintervention screening tool to ensure that participant's bone density was within safe ranges as prescribed by Ekso. The recommended guidelines regarding bone density for safe walking within the exoskeleton are a *Z* score less than −2. This is an Food and Drug Administration–approved value to ensure minimal risk of stress fracture while walking in the suit. However, there is a lack of evidence to support a *T* score or *Z* score cutoff as a contraindication for safe participation in rehabilitation interventions.[25] There is contradictory evidence on the risk of gait training on fracture risk, with some studies having reported fractures due to upright weight-bearing and gait training activities, whereas other studies using these gait training modalities reported no fractures.[17] Thus, fracture risk should be evaluated on a case-by-case basis by the rehabilitation team based on BMD and clinical risk factors of the individual participant.[17] In the current study, participants with low BMD *Z* scores (<−2) were referred for clinical assessment to the study physician who, after clinical evaluation, confirmed it possible to proceed with the rehabilitation interventions.

Body Composition

Parameters of body composition, including estimates of appendicular and total body FFSTM (in kilograms) and FM (in kilograms), percent FM (in percentages), trunk/limb FM ratio, android/gynoid ratio, trunk FM (in kilograms), percentage trunk fat (in percentages), visceral adipose tissue (in square centimeter), and subcutaneous adipose tissue (in square centimeter) were obtained based on total body DXA data acquisition. In vivo precision, expressed as a percentage coefficient of variation, was 0.7% and 1.67% for FFSTM and FM, respectively.

Statistical Analysis

All data were analyzed using statistical software (R; R Core Team, Auckland, New Zealand; Prism 8; GraphPad Software, Inc, CA). Nonparametric statistical tests, Mann-Whitney *U* and Wilcoxon signed rank, were used to determine the group and time main effects on bone density and body composition between premeasurements and postmeasurements. The Mann-Whitney *U* assessed whether the change in premeasurements and postmeasurements were different between the ABT and RLT group; Null hypothesis (H_0): The distribution of the change between premeasurements and postmeasurements is the same for both groups. The Wilcoxon signed rank test was used to determine differences between pre– and post–time points within a group; in null hypotheses (H_0), the median difference, between two paired samples, is equal to zero. Significance was accepted at a *P* value less than 0.05. Effect sizes were calculated according to the nonparametric tests, the Wilcoxon signed rank for paired samples and the Mann-Whitney *U* for independent samples ($r = z/\sqrt{N}$).[26] Effect size estimates of zero denote no effect, whereas ranges from 0.2 to 0.5, 0.5 to 0.8, and greater than 0.8 represent small, medium, and large effects, respectively.[27]

RESULTS

Participant Characteristics and Compliance

A total of 16 participants, aged 19–60 yrs (mean ± SD = 38.4 ± 14.3) completed the trial, which are presented in Table 1

TABLE 1. Descriptive characteristics of the RLT and ABT groups

Group	Participant	Age, yr	Sex	TSI, yr	Neurological Level of Injury	AIS Category	Etiology	Body Weight, kg	Total Body Fat, %	Whole-Body *Z* Score
RLT (n = 8)	1	27	M	9	C6	D	Stabbing	63.6	27.3	−1.6
	2	33	M	15	C6	C	MVA	64.8	19.0	−1.4
	3	32	M	3	C5	D	MVA	62.5	14.9	−0.7
	4	46	M	26	C4	D	Gunshot	85.1	33.1	−3.2
	5	55	M	4	C5	D	MVA	81.7	43.2	−1.4
	6	43	M	23	C6	C	MVA	71.3	34.9	−2.3
	7	56	M	15	C4	C	MVA	73.8	38.2	−2.3
	8	32	M	15	C7	C	Sport—rugby	52.4	18.4	−2.2
	Average	40.5 ± 11.2		13.8 ± 8.2				69.4 ± 10.7	28.6 ± 10.4	−1.89 ± 0.77
ABT (n = 8)	9	26	M	2	C6	C	MVA	84	40.6	−2.6
	10	46	F	20	C6	D	MVA	63	28.4	−1.5
	11	50	M	8	C7	D	MVA	95.8	31.8	−0.3
	12	19	M	2	C5	C	MVA	63	28.4	−1.5
	13	47	M	3	C4	D	Motorcycle	99.7	43.3	−1.4
	14	29	M	10	C5	C	MVA	51.7	24.4	−1.2
	15	60	M	2	C5	C	Mountain bike	108.5	34.0	−2.5
	16	30	M	11	C4	C	Diving	81.9	43.9	−3.7
	Average	38.4 ± 14.3		7.3 ± 6.4				81.0 ± 20.2	34.4 ± 7.4	−1.84 ± 1.05

Values are presented as mean ± SD. No significant difference between groups for age and TSI (P = 0.10), body weight (P = 0.18), and body fat (P = 0.23). Participants with low BMD *Z* scores (<−2) were referred for clinical assessment to the study physician who, after clinical evaluation, confirmed that it was possible to proceed with the rehabilitation interventions.

F, female; M, male; MVA, motor vehicle accident; TSI, time since injury.

with several variables previously published.[22] Participants had an average adherence of 93.9 ± 6.2% of all available sessions.[21] During the recruitment for the trial, the mean total hip BMD across those recruited was a *Z* score of −2.25 ± 0.73. One participant discontinued the intervention after being enrolled in the RLT group for 3 wks. Persistent right leg weakness necessitated a magnetic resonance imaging study, which provided images consistent with the diagnosis of a tibial stress fracture. Only baseline measures had been recorded for the participant, which may have been confounded by an existing stress fracture. Thus, the participant was excluded from all analyses and received treatment for the fracture outside of the trial protocol.

Bone Density in Response to the 24-Wk Intervention

There were no significant changes in spinal BMD for either group over time (P = 0.86). However, there was a significant decrease in BMD in the ABT group for both the total hip (P = 0.04, effect size [ES] = 0.43) and femoral neck (P = 0.04, ES = 0.86) measurements, with a mean difference of 0.03 (−0.29 to 0.23) g/cm^2 (3%) and 0.06 (−0.34 to 0.22) g/cm^2 (5%) from preintervention to postintervention, respectively (Table 2). No significant changes in these BMD sites were found for the RLT group over the 24-wk intervention (P = 0.55, ES = 0.31).

Body Composition in Response to the 24-Wk Intervention

There was a significant 7% increase in arm FFSTM over time for both the RLT (P < 0.01, ES = 0.87) and ABT (P < 0.01, ES = 0.87) group, with a mean increase of 0.34 (−0.86 to 1.54) kg and 0.35 (−1.32 to 2.02) kg from preintervention to postintervention, respectively (Table 2). However, no change in leg FFSTM occurred for either group over time (P = 0.32). The ABT group showed a significant 15% decrease in visceral adipose tissue (P = 0.04, ES = 0.72) and 13% decrease in gynoid FM (P < 0.01, ES = 0.62) over time, with a mean decrease from preintervention to postintervention of 23 (−108.39 to 62.39) cm^2 and 0.54 (−1.77 to 0.69) kg, respectively.

DISCUSSION

This secondary analysis explored the impact of a 24-wk exercise intervention on bone density and body composition in people with chronic incomplete SCI during a randomized pilot trial. The results provide preliminary evidence to support the effectiveness of a longer-term intervention of RLT in preventing BMD decline and ABT for improving indices of adiposity in individuals with SCI.

The main clinical finding of this study showed that there was a significant reduction in hip and femoral neck BMD in the ABT group over time, whereas the RLT group showed no changes in these BMD measures across the 24 wks. Despite both interventions involving regular standing and weight-bearing, BMD was only preserved in the RLT group. As passive standing was not sufficient to produce BMD changes, the results of this study support that dynamic muscular loads in stance are needed to offer a bone-sparing stimulus to the lower limbs after SCI.[3,28] The repetitive, dynamic, and mechanical loading of RLT is likely to provide sufficient mechanical stress to stimulate cortical bone at the site of greatest mechanical strain.[6,11] In addition, studies suggest that BMD benefits for people with SCI rely

TABLE 2. A summary of BMD and body composition characteristics between the RLT and ABT groups

	RLT (n = 8)				ABT (n = 8)				Between Group	
DXA Outcomes	**Pre**	**Post**	**Δ (95% CI)**	**ES**	**Pre**	**Post**	**Δ (95% CI)**	**ES**	***P***	**ES**
Bone mineral density (g/cm^2)										
Spinal BMD	0.97 ± 0.09	0.97 ± 0.10	0.00 (−0.09 to 0.09)	0.09	0.98 ± 0.13	0.98 ± 0.15	0.00 (−0.14 to 0.14)	0.09	0.96	0.03
Hip BMD	1.25 ± 0.07	1.24 ± 0.08	0.01 (−0.08 to 0.06)	0.31	1.23 ± 0.27	1.20 ± 0.25	0.03 (−0.29 to 0.23)[a]	0.43	0.13	0.12
Femoral neck BMD	1.15 ± 0.14	1.13 ± 0.14	0.02 (−0.16 to 0.12)	0.31	1.21 ± 0.30	1.15 ± 0.27	0.06 (−0.34 to 0.22)[a]	**0.86**	0.16	0.09
Fat mass										
Whole-body FM, kg	18.53 ± 9.18	18.29 ± 8.32	0.24 (−8.83 to 8.34)	0.17	25.93 ± 10.60	23.46 ± 9.57	2.47 (−12.37 to 7.43)	0.42	0.38	0.35
Appendicular FM, kg	7.86 ± 3.20	7.85 ± 3.03	0.010 (−3.06 to 3.04)	0.07	12.15 ± 4.28	11.03 ± 3.11	1.12 (−4.79 to 2.55)	0.47	0.44	0.46
Trunk FM, kg	10.67 ± 6.19	10.37 ± 5.60	0.30 (−6.79 to 6.19)	0.32	13.78 ± 6.91	12.43 ± 6.74	1.35 (−8.04 to 5.34)	0.52	0.28	0.25
Whole-body fat, % FM	28.62 ± 10.36	28.18 ± 9.56	0.44 (−10.25 to 11.3)	0.22	34.79 ± 7.13	32.47 ± 5.33	2.32 (−4.43 to 9.07)	0.67	0.40	0.20
Appendicular fat, % FM	44.56 ± 6.35	44.76 ± 6.90	0.20 (−6.29 to 6.69)	0.10	49.04 ± 9.20	49.97 ± 9.69	0.93 (−8.33 to 10.19)	0.40	0.57	0.24
Trunk fat, % FM	55.44 ± 6.35	55.24 ± 6.90	0.20 (−6.69 to 6.29)	0.10	50.96 ± 9.20	50.03 ± 9.69	0.93 (−10.19 to 8.33)	0.40	0.57	0.24
Gynoid FM, kg	2.84 ± 1.13	2.82 ± 1.21	0.20 (−1.17 to 1.13)	0.22	4.16 ± 1.45	3.62 ± 1.03	0.54 (−1.77 to 0.69)[a]	**0.62**	0.28	0.28
Subcutaneous fat, cm^2	172 ± 103	170 ± 100	2 (−101.48 to 97.48)	0.42	244 ± 115	227 ± 108	17 (−126.32 to 92.32)	0.22	0.88	0.30
Visceral fat, cm^2	144 ± 100	142 ± 104	2 (−101.98 to 97.98)	0.12	152 ± 92	129 ± 82	23 (−108.39 to 62.39)[a]	**0.72**	0.08	0.01
Fat-free soft tissue mass (kg)										
Whole-body FFSTM	41.34 ± 3.96	41.94 ± 4.63	0.60 (−3.62 to 4.82)	0.52	43.11 ± 11.45	43.91 ± 12.51	0.80 (−10.95 to 12.55)	0.27	0.96	0.04
Appendicular FFSTM	17.96 ± 2.26	18.30 ± 2.38	0.34 (−1.93 to 2.61)	0.22	19.65 ± 6.32	20.01 ± 6.73	0.36 (−6.04 to 6.76)	0.27	0.88	0.06
Leg FFSTM	12.78 ± 2.03	13.20 ± 2.35	0.42 (−1.73 to 2.57)	0.17	14.50 ± 4.79	14.77 ± 5.16	0.27 (−4.61 to 5.1)	0.32	0.51	0.12
Arm FFSTM	5.10 ± 1.21	5.44 ± 1.24	0.34 (−0.86 to 1.54)[a]	**0.87**	5.24 ± 1.65	5.59 ± 1.75	0.35 (−1.32 to 2.02)[a]	**0.87**	0.96	0.01

Data are presented as mean ± SD and mean difference ± 95% CI. Medium to large effect sizes are indicated in bold.

[a] Statistical significance is accepted at $P < 0.05$.

Pre, week 0 measurement; post, week 24 measurement.

on exercises that are delivered with enough transitional force, enough frequency, and for sufficiently long durations to stimulate new bone formation.[4,6,7,29,30]

Furthermore, demographic- and injury-related factors such as sex and aging, the level and severity of the lesion, and the duration of injury can effect bone loss in individuals with SCI.[1,2] The highest rate of bone mineral loss occurs in the first 1–2 yrs after injury.[31] Thus, the more severe bone loss in the ABT group may possibly be accounted for by the four individuals who were 3 yrs or less after injury, compared with the single individual in the RLT group. Furthermore, a Z score of less than −2 has been recommended for safe walking within the exoskeleton. The lowest BMD Z score of −3.8 was recorded for an ABT participant in this study who experienced no adverse events. The participant who was excluded after 3 wks because of a right tibial stress fracture had a satisfactory total right hip BMD Z score of −1.1. Consequently, it is apparent that a cutoff BMD value to determine eligibility within the trial is challenging, as values are currently based on able-bodied norms. However, a BMD cutoff value less than 0.6 g/cm^2 of the knee joint has been used in previous SCI studies and may provide a useful absolute cutoff value for future RCTs.[32] No other adverse events or negative side effects were reported. These individualized factors on bone health as well as recognized cutoff values for safety should be considered when implementing rehabilitation interventions in future large-scale studies.

This study found that the ABT group had improved body composition through decreased FM and positive alterations in adiposity distribution, whereas the RLT group did not experience any significant changes in FM or its distribution over the 24-wk intervention. Activity-based training has previously been identified as a promising therapeutic strategy to counter the adverse changes in body fat in different clinical populations, including SCI.[6] However, to our knowledge, no RCTs have examined the effects of overground RLT on body composition in people with SCI. Both the ABT and RLT interventions were successful in promoting positive changes in FFSTM in the upper body over time. Activity-based training is the key strategy used for strengthening the upper limb muscles of people with SCI, and thus, increases in arm FFSTM were expected because of the high levels of upper body utilization within this training modality.[33] Robotic locomotor training participants may have also encountered upper body increases in FFSTM attributed to the performance of an exercise modality that uses the upper limbs for support and to move and use a gait aid while maintaining standing balance. Despite the improvements in upper body FFSTM for both groups during the trial, no changes in lower limb FFSTM were measured for either group over time. As ABT does not solely target the leg muscles, its inability to promote muscle hypertrophy in the lower limbs is not surprising.[33,34] The effect of RLT on FFSTM is less clear, as to our knowledge, no RCTs have evaluated the effect of overground RLT on lower limb body composition outcomes. However, RLT has been suggested to increase FFSTM of the lower limbs, as the repetitive movement of walking promotes neuromuscular activity, which in turn enhances muscle hypertrophy.[35]

We acknowledge that although this study involved a small sample size, the adherence rate was extremely high (despite the low socioeconomic setting this study occurred in) and the group was homogenous. Thus, these results contribute to the body of knowledge on exercise dosage, BMD, and body composition changes using robotic walking therapy, which supports the implementation of a larger-scale RCT.

Limitations

At the time of starting the study (2017), there were no clear guidelines advising distal femur/proximal tibia scans. Thus, this study considered the BMD measurements of the hip and spine only. However, based on recent guidelines[32] and because the distal femur and proximal tibia have recently been shown to be the most common sites of fracture after SCI,[2,17] an effort should be made to assess the impact of interventions at these specific sites. In addition, future research should consider caloric intake or dietary outcomes, as this could affect energy balance and result in excess body fat accumulation. Furthermore, calcium intake, vitamin D concentration, and melatonin concentration were not assessed within this study. As these variables can impact bone resorption and formation, they should be considered in future trials as an additional outcome of interest. Because of a small sample size of this pilot trial, generalizability of these findings should be interpreted with caution.

CONCLUSIONS

This study offers novel insights into the impact of RLT and ABT on bone density and body composition in individuals with traumatic, incomplete SCI over longer intervention length of 24 wks. It is one of two studies to show that RLT may prevent the progressive decline of BMD usually occurring in this population group. Fat mass was significantly reduced over 24 wks using activity-based therapy. These preliminary findings should be confirmed with a full-scale RCT, consisting of a larger sample size and outcome measures targeting appropriate fracture-prone sites. This study also calls for the development of clinical practice guidelines targeting fragility fracture risk assessment linked to the use of overground robotic exoskeletons.

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