ORIGINAL ARTICLE

Effects of cycling and/or electrical stimulation on bone mineral density in children with spinal cord injury

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Study design: Randomized clinical trial.

Objectives: To determine the effect of cycling and/or electrical stimulation on hip and knee bone mineral density (BMD) in children with spinal cord injury (SCI).

Setting: Children's hospital specializing in pediatric SCI.

Methods: A total of 30 children, aged 5–13 years, with chronic SCI were randomized to one of three interventions: functional electrical stimulation cycling (FESC), passive cycling (PC), and non-cycling, electrically stimulated exercise (ES). Each group exercised for 1 h, three times per week for 6 months at home. The hip, distal femur and proximal tibia BMD were examined via dual-energy X-ray absorptiometry (DXA) pre- and post-intervention.

Results: In all, 28 children completed data collection. The FESC group exhibited increases in hip, distal femur and proximal tibia BMD of 32.4, 6.62 and 10.3%, respectively. The PC group exhibited increases at the hip (29.2%), but no change at the distal femur (1.5%) or proximal tibia (–1.0%). The ES group had no change at the hip (–0.24%) and distal femur (3.3%), but a loss at the proximal tibia (–7.06%). There were no differences between groups or within groups over time. Significant negative correlations were found between baseline BMD and the amount of BMD change.

Conclusion: Although not achieving statistical significance, hip BMD changes observed were greater than the reported 0.9–10% gains after exercise for children with and without disability. Thus, cycling with and without electrical stimulation may be beneficial for skeletal health in pediatric SCI, but further research is needed with a larger sample size.

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Introduction

Pediatric spinal cord injury (SCI) occurs in approximately 1.99 per 100 000 children.¹ As children with SCI age, they face the typical health problems of aging and additional complications impacting cardiovascular, respiratory and neuromuscular health. These factors can lead to decreased quality of life and increased medical costs.²

One complication is loss of bone mineral density (BMD). Following adult-onset SCI, approximately 1/3 of the BMD below the injury is lost within the first year.³ When this loss occurs in a child, long-term consequences can be detrimental, as childhood and early adolescence are 'windows of opportunity' for physical activity to improve bone health, and 25% of the adult bone mineral content is attained between 11 and 13 years of age.⁴ Decreased BMD can

increase fracture risk to 19% in adults with pediatric-onset SCI,⁵ four times greater than the risk in adult-onset SCI.⁶

Cycling with functional electrical stimulation (FES) improves lower-extremity BMD for adults with SCI;^{7–9} however, results are mixed^{10,11} and outcomes hampered by inadequate load applied to the bone.^{12,13} There has been less research focused on passive cycling (PC),¹⁴ with no known studies examining BMD after PC in SCI. PC has potential to lead to increased BMD, as passive exercise in premature infants led to increased bone turnover markers and bone mineralization.¹⁵ Passive motion in rabbits improved the bone density¹⁶ and cyclic compression enhanced fracture healing.¹⁷ Electrical stimulation alone also has the potential to impact BMD; however, loads of 1.4 times body weight may be needed.¹³

FES cycling, PC and electrically stimulated exercise have not been studied in pediatric SCI. The purpose of this study was to examine the effects of a 6-month program of lower extremity cycling and/or electrical stimulation on BMD in children with SCI. It was hypothesized that FES cycling

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would have the greatest impact, followed by PC, and that electrically stimulated exercise (ES) would have little effect owing to the low load. These groups were also chosen as controls for each other to separate the effects of electrical stimulation and cycling in order to determine if one or both of these techniques lead to positive effects.

Materials and methods

Subjects and exercise protocol

A randomized, controlled study was conducted with 30 children with C4-T11 SCI, aged 5–13 years. Parents and children signed institutional review board-approved informed consent and assent forms, respectively. Inclusion criteria were 12 months post injury, cervical or thoracic SCI with American Spinal Injury Association Impairment Scale A, B or C, age 5 to 13 years, and an upper motor neuron injury. Exclusion criteria included chronic steroid treatment, seizure history, cardiac disease, ventilator dependency, severe spasticity, lower limb fractures of unknown origin, uncontrolled autonomic dysreflexia, heterotopic ossification and hip dislocation. Children were excluded if they participated in electrical stimulation, cycling or treadmill training within the previous 3 months.

After enrolling, children were assigned to one of three groups using a block randomization schedule: FES lower extremity cycling, passive lower extremity cycling and non-cycling electrical stimulation. Children exercised at home with parental assistance for 1 h, 3 times per week, and parents received training on equipment use from the same investigator. Before exercising, children participated in lower-extremity passive range of motion exercises. Children could continue previous therapeutic activities, such as standing and walking with braces, but were not permitted to participate in other lower-extremity repetitive motion tasks or ES. Although the effects of standing and walking with braces on the bone are unknown for children with SCI, it was decided not to alter pre-study exercise as declines from baseline could potentially occur if activities were stopped because of decreased weight bearing.

The functional electrical stimulation cycling (FESC) group cycled at 50 revolutions per minute (r.p.m.) using the RT300-P (Restorative-Therapies, Inc., Baltimore, MD, USA) while seated in their wheelchairs (Figure 1). Bilateral cyclical stimulation was delivered to the quadriceps, hamstring and gluteal muscles using the largest surface electrodes (Axelgaard Manufacturing Co., Inc., Fallbrook, CA, USA) appropriate for the child. Resistance was progressively increased throughout the exercise, while maintaining 50 r.p.m. The cycle provided 10 min of passive warm-up, 40 min of FESC, and 10 min of passive cool-down. Stimulation frequency was fixed at 33 Hz, and pulse duration between 150 and 300 μ s. The amplitude was increased automatically up to 140 mA to generate sufficient force to maintain cadence. This maximum was decreased for smaller children based on individual muscle response.

The PC group used the RT100 (Restorative-Therapies, Inc.) motorized cycle, which passively moved the limbs at

Figure 1 Child with paraplegia using the FES cycle. A full color version of this figure is available at the *Spinal Cord* journal online.

50 r.p.m. for 1 h with children seated in their wheelchairs. The ES group used a two-channel surface stimulation unit (Empi 300PV, Empi, St Paul, MN, USA) to create strong contractions of bilateral hamstrings, quadriceps and gluteal muscles for 20 min per muscle group with a duty cycle of 5:15 s with stimulation parameters of 33 Hz, 300 μ s and a maximum amplitude of 100 mA. The amplitude was set individually for each muscle to achieve optimal response based on muscle size and response to stimulation. Children exercised in supine, working against zero resistance.

Children could miss up to 12 sessions over the 6 months. If sessions were missed, parents were instructed to add one session per week to make up these sessions. Parents logged each session on a log sheet that was sent to the investigators monthly. Phone calls were made to parents every 2 weeks to receive information on progress.

Data collection

Dual-energy X-ray absorptiometry (DXA; Delphi W; Hologic, Bedford, MA, USA) was used to measure areal BMD (g cm^{-2}) at the hip, distal femur and proximal tibia in supine pre and post intervention. The initial scan was performed after randomization and the post-intervention scan was performed within 1 week after the intervention ended. Scans were performed by certified radiation technicians blinded to group assignment and checked for accuracy by a blinded radiologist. During the test, the hip was positioned in neutral rotation, and the distal femur and proximal tibia were aligned with the fan beam parallel to the long axis. Only the left side was scanned to reduce radiation exposure. Technicians identified the regions of interest, and analytic software automatically performed BMD calculations. For the distal femur and proximal tibia, the lumbar spine algorithm as described by Shields *et al.*¹⁸ was used. Manual image correction was performed to include all appropriate bone pixels.

Statistical analysis

Two-way analyses of variance with Bonferroni corrections for multiple comparisons ($\alpha=0.0167$) were used to compare

BMD for the hip, distal femur and proximal tibia across time and group. *Post hoc*, one-tailed paired *t*-tests were used to examine changes within groups. To allow comparisons with published results for children with typical development, percent changes in total hip, distal femur and proximal tibia BMD were calculated per child and then averaged per group. Pearson's correlation coefficients were performed to examine relationships between baseline BMD and BMD change in order to determine if baseline BMD was important to consider. All data are presented as mean $\pm$ s.d.

We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

Results and discussion

In all, 28 children underwent baseline and 6-month dual-energy x-ray absorptiometry testing (Table 1). The CONSORT flow diagram is published elsewhere.¹⁹ Two children had incomplete data post intervention; therefore their data were not included. Intervention adherence rates, accounting for allowed missed sessions, were 95.2 ± 18.1 , 107.2 ± 16.2 and $105.5 \pm 19.6\%$ for the FESC, PC and ES groups, respectively. Without the allowance, adherence rates were 81.6 ± 15.5 , 91.9 ± 13.9 and $89.6 \pm 17.4\%$.

Following intervention, there were no significant increases in BMD between or within groups. (Figure 2 displays effect sizes and 95% confidence intervals.). The FESC group exhibited non-significant increases in hip, distal femur and proximal tibia BMD of 32.4, 6.62 and 10.3%, respectively

(Figure 3). The PC group exhibited a non-significant increase in hip BMD (29.2%), but no change at the distal femur (1.5%) and the proximal tibia (-1.0%). The ES group exhibited no change in hip (-0.24%) and distal femur (3.3%) BMD, and a non-significant loss at the proximal tibia (-7.06%). It is not known why percent increases were higher for the hip than for the knee in the FESC and PC groups. Using FESC for 30 min, 3 times per week for months, adults with chronic SCI showed distal femur BMD gains but not femoral neck changes.⁸ It is unknown how age impacts BMD response to either exercise.

Individual BMD changes are presented in Table 2. Analysis indicated that there are no hip BMD differences between groups with respect to time ($P=0.754$) using two-way analyses of variance or percent change ($P=0.33$) using one-way analyses of variance. *Post hoc* within-group analyses indicated trends toward increased hip BMD over time in the FESC and PC groups (FESC $P=0.10$, PC $P=0.11$, ES $P=0.32$). The distal femur and the proximal tibia analyses indicated no statistical differences between groups (distal femur, $P=0.963$, proximal tibia, $P=0.577$) over time or for average percent change (distal femur, $P=0.89$, proximal tibia, $P=0.17$). *Post hoc* within-group analyses indicated trends toward increased distal femur BMD over time in the FESC and PC groups (FESC $P=0.03$, PC $P=0.07$, ES $P=0.52$), and a trend for proximal tibia loss for the ES group (FESC $P=0.19$, PC $P=0.26$, ES $P=0.08$). Pearson analyses between baseline BMD values and BMD change showed significant negative correlations: hip -0.717 ($P<0.001$), distal femur -0.407 ($P<0.032$) and proximal tibia -0.567 ($P=0.001$).

Table 1 Demographics for the 28 children with complete data

Age	Gender	Level of SCI	AIS class	Years post SCI	Etiology	Height (cm)	Weight (kg)
5	F	C7	A	4	MVA	116.5	24
6	F	T7	A	1	MVA	118	20.7
7	F	T4	A	5	MVA	119	27.5
7	F	T8	C	7	Ischemia	120	24.1
7	M	C4	B	6	Transverse myelitis	122	23.1
7	M	T1	A	5	MVA	120.5	20.2
7	M	T3	A	3	MVA	118.5	19.7
7	M	T7	C	1	MVA	118.5	17.7
8	M	C7	A	6	MVA	121.5	24.6
8	M	C8	B	6	MVA	122.5	26.8
8	M	T1	A	5	MVA	134.7	37
8	M	T5	B	8	Atresia	120	19.7
9	F	C7	A	5	MVA	130	23.7
11	F	C8	B	7	MVA	139	41.6
11	F	T5	A	7	MVA	146	45
11	M	C7	A	8	MVA	144.5	29.1
11	M	T1	A	5	MVA	138.5	27.5
11	M	T11	B	7	Chemotherapy	156	49.1
12	F	T1	A	1	MVA	156.5	89.4
12	F	T11	A	2	MVA	160.5	57.8
12	F	T4	A	1	MVA	149	38
12	M	C7	A	12	Birth	146	33.9
12	M	C7	A	10	MVA	153	37.7
12	M	T5	A	2	MVA	167	75.4
12	M	T7	A	8	MVA	161.3	72.6
13	F	T10	C	3	MVA	156	66
13	M	T4	A	7	MVA	171.4	70.2
13	M	T5	A	1	Transverse myelitis	165.5	67.6

Abbreviations: AIS, ASIA (American Spinal Injury Association) Impairment Scale; MVA, motor vehicle accident; SCI, spinal cord injury;.

Figure 2 Effect sizes and 95% confidence intervals for the three groups (FES, solid line; PC, dashed line; ES, dotted line).

Figure 3 Percent change in BMD per group.

BMD in pediatric SCI is of concern as childhood represents the window of opportunity for essential bone formation. FES cycling has potential for increasing BMD. Likewise, PC has the potential to modify muscle structure,¹⁴ and thus the bone, after SCI. This study indicates trends toward improvement in hip BMD with either paradigm. Although not statistically significant, gains observed (33 and 29% for the FESC and PC groups, respectively) were larger than would be expected owing to growth.²⁰ In children with typical development, hip BMD increases approximately $0.01\text{--}0.04\text{ g cm}^{-2}$ per year until age 11 years (approximately 3% per year), after which increases can be greater (approximately $0.02\text{--}0.10\text{ g cm}^{-2}$).²⁰ Using these guidelines and assuming children gain $\frac{1}{2}$ of the yearly increase, the FESC and PC group averages exceeded these values. However, when looking at individual changes, some children had increases whereas some children had decreases that exceeded these values. The decreases are concerning and suggest that some children with SCI may be losing BMD.

Hip BMD increases were greater than gains reported in other pediatric exercise studies. Hind and Burrows²¹ found a mean increase in the bone of $0.9\text{--}4.9\%$ after 6 months of exercise in prepubertal children with typical development. For children with cystic fibrosis,²² BMD improvements of $2\text{--}10\%$ were achieved following 6 months of exercise. These findings suggest that the hip BMD changes in the FESC and PC groups may be clinically meaningful.

Examination of individual changes (Table 2) indicates a potential threshold for the hip BMD of 0.03 g cm^{-2} (Figure 4), below which substantial increases could be achieved with cycling. The threshold values are not as distinct for the distal femur (Figure 5) and the proximal tibia (Figure 6); however, all areas (hip, distal femur, proximal tibia) showed significant negative correlations between baseline BMD and BMD change. Therefore, children with the lowest baseline BMD values had greater gains. Further study is warranted to ascertain if one treatment is better for children with low baseline BMD. The existence of a BMD threshold level and correlation between baseline values and response to treatment have not been reported. A threshold level may exist for adults with SCI; however, it has not been reported. Therefore it is unknown if the threshold level is unique to pediatric SCI. It is also unknown if ES would have similar effects, as no child in the ES group had starting hip BMD values below threshold. As children were randomized before measurement, the distribution of children with low BMD into the two cycling groups was unintentional.

Individual hip BMD changes for the 25 children with values $>0.300\text{ g cm}^{-2}$ indicated no to modest improvements. This finding is consistent with adult FES cycling literature that found no change in the hip BMD with a 3–4-month FES cycling paradigm.^{10,11} It may be that above the threshold, other interventions, such as calcium or vitamin D or other pharmacological therapies, are needed to achieve

Table 2 Baseline and post-intervention bone mineral density (BMD) values (in g cm^{-2}) for each child

Group	Age	Gender	Level of SCI	Hip B/L	Hip post	Change	Femur B/L	Femur post	Change	Tibia B/L	Tibia post	Change
FESC	7	F	T4	0.163	0.462	0.299	0.264	0.319	0.055	0.318	0.337	0.019
FESC	7	M	T1	0.614	0.472	-0.142	0.383	0.263	-0.12	0.371	0.359	-0.012
FESC	7	M	C4	0.472	0.464	-0.008	0.359	0.263	-0.012	0.368	0.398	0.03
FESC	8	M	C8	0.57	0.431	-0.139	0.341	0.367	0.026	0.399	0.425	0.026
FESC	8	M	T5	0.611	0.588	-0.023	0.439	0.414	-0.025	0.357	0.362	0.005
FESC	9	F	C7	0.28	0.623	0.343	0.243	0.36	0.117	0.225	0.358	0.133
FESC	11	M	T1	0.413	0.45	0.037	0.313	0.386	0.073	0.283	0.382	0.099
FESC	12	F	T11	0.616	0.583	-0.033	0.561	0.53	-0.031	0.465	0.445	-0.02
FESC	12	F	T1	0.458	0.532	0.074	0.468	0.493	0.025	0.411	0.387	-0.024
FESC	13	F	T10	0.665	0.724	0.059	0.729	0.769	0.04	0.648	0.63	-0.018
FESC group, means $\pm$ s.d.				0.486 $\pm$ 0.164	0.533 $\pm$ 0.095	0.047 $\pm$ 0.162	0.410 $\pm$ 0.147	0.425 $\pm$ 0.144	0.015 $\pm$ 0.066	0.385 $\pm$ 0.115	0.408 $\pm$ 0.084	0.024 $\pm$ 0.053
PC	5	F	C7	0.145	0.221	0.076	0.347	0.359	0.012	0.305	0.325	0.02
PC	7	F	T8	0.562	0.58	0.018	0.481	0.465	-0.016	0.451	0.451	0
PC	7	M	T3	0.435	0.465	0.03	0.372	0.315	-0.057	0.358	0.339	-0.019
PC	7	M	T7	0.417	0.399	-0.018	0.305	0.337	0.032	0.279	0.339	0.06
PC	8	M	T1	0.664	0.601	-0.063	0.451	0.452	0.001	0.415	0.429	0.014
PC	8	M	C7	0.191	0.363	0.172	0.488	0.305	-0.183	0.449	0.279	-0.17
PC	11	F	C8	0.653	0.679	0.026	0.519	0.527	0.008	0.471	0.499	0.028
PC	11	M	C7	0.126	0.28	0.154	0.181	0.285	0.104	0.354	0.348	-0.006
PC	12	F	T4	0.58	0.565	-0.015	0.598	0.576	-0.022	0.477	0.471	-0.006
PC group, means $\pm$ s.d.				0.419 $\pm$ 0.216	0.461 $\pm$ 0.156	0.042 $\pm$ 0.079	0.416 $\pm$ 0.127	0.402 $\pm$ 0.106	-0.013 $\pm$ 0.077	0.395 $\pm$ 0.074	0.387 $\pm$ 0.077	-0.009 $\pm$ 0.065
ES	6	F	T7	0.483	0.496	0.013	0.33	0.341	0.011	0.383	0.399	0.016
ES	11	F	T5	0.496	0.537	0.041	0.29	0.352	0.062	0.322	0.307	-0.015
ES	11	M	T11	0.583	0.531	-0.052	0.407	0.508	0.101	0.348	0.422	0.074
ES	12	M	T7	0.563	0.394	-0.169	0.451	0.312	-0.139	0.511	0.345	-0.166
ES	12	M	C7	0.524	0.612	0.088	0.337	0.404	0.067	0.36	0.4	0.04
ES	12	M	T5	0.479	0.553	0.074	0.421	0.389	-0.032	0.408	0.282	-0.126
ES	12	M	C7	0.444	0.449	0.005	0.29	0.321	0.031	0.483	0.458	-0.025
ES	13	M	T4	0.615	0.469	-0.146	0.435	0.361	-0.074	0.461	0.364	-0.097
ES	13	M	T5	0.458	0.532	0.074	0.468	0.493	0.025	0.411	0.387	-0.024
ES group, means $\pm$ s.d.				0.516 $\pm$ 0.059	0.508 $\pm$ 0.064	-0.008 $\pm$ 0.095	0.381 $\pm$ 0.070	0.387 $\pm$ 0.071	0.006 $\pm$ 0.076	0.410 $\pm$ 0.064	0.374 $\pm$ 0.056	-0.035 $\pm$ 0.079

Abbreviations: B/L, baseline; ES, electrical stimulation; FESC, functional electrical stimulation cycling; PC, passive cycling; Post, Post 6 months of training; SCI, spinal cord injury.

Bold type indicates a non-significant ($P > 0.05$) increase in BMD. In children with typical development, BMD around the hip increases approximately $0.01\text{--}0.04\text{ g cm}^{-2}$ per year until the age of 11 years (approximately 3%/year), after which the increase can be greater (approximately $0.02\text{--}0.10\text{ g cm}^{-2}$).¹⁶ Using the higher range of these guidelines and assuming that children gain $\frac{1}{2}$ of the yearly increase as the intervention was of 6 months duration, the FESC and PC groups exceeded these values.

Figure 4 Relationship between baseline BMD and BMD change at the hip (Pearson's correlation coefficient -0.717 , $P < 0.001$). Of the children below the threshold baseline value of 0.3 g cm^{-2} , two were in the FESC group and three in the PC group. A full color version of this figure is available at the *Spinal Cord* journal online.

Figure 5 Relationship between baseline BMD and BMD change at the distal femur (Pearson correlation coefficient -0.407 , $P < 0.032$). Using a cutoff of 0.4 g cm^{-1} at baseline, 14 children were below this value (6 FESC, 4 PC, 4 ES). A full color version of this figure is available at the *Spinal Cord* journal online.

Figure 6 Relationship between baseline BMD and BMD change at the proximal tibia (Pearson correlation coefficient -0.567 , $P = 0.001$). Using a cutoff of 0.4 g cm^{-1} at baseline, 15 children were below this value (7 FESC, 4 PC, 4 ES). A full color version of this figure is available at the *Spinal Cord* journal online.

normal BMD. Another potential mechanism to increase BMD is to increase the load during FES cycling. Shields and colleagues indicated that larger loads (1.2–1.4 times body weight) are required to achieve lower-extremity BMD gains.^{12,13} While the FES cyclists in this study were working against progressive resistance, the goal was to maintain 50 r.p.m. Thus, load applied to the bone was likely low. However, a lower cadence paradigm²³ could allow for higher loads, and may have greater impact on BMD. Finally, the use of dual-energy X-ray absorptiometry may underreport the positive effects of exercise on the bone,¹³ and thus may have impacted the results. Peripheral quantitative computed tomography (pQCT) or magnetic resonance imaging analysis offers information on multiple determinants of bone strength (bone geometry, cortical vs trabecular compart-

ments, volumetric bone density) and may be more responsive to change. Using pQCT, Frotzler *et al.*⁹ showed significant gains in trabecular bone and overall distal femoral epiphysis BMD following FES cycling, but no change in the femoral shaft or tibia.

Examination of the knee BMD values indicates a trend towards improvement with FESC and PC at the distal femur, a primary fracture site in SCI. What is of concern was the observed loss of the proximal tibia BMD in the ES group. Reasons for this decline are unknown. As children in this study were prepubertal and are expected to continue growing, these declines could increase the fracture risk. Thus, interventions such as passive and FES cycling may be warranted to positively affect long-term bone health, and intervention may need to be maintained in order

to prevent the declines observed after intervention withdrawal.²⁴

There are several limitations to this study. As parental reports were used to assess adherence, adherence percentages could be inflated. In addition, developmental changes in BMD for children with SCI are not known, especially if children with chronic SCI attain new bone or show slow declines as seen in adult SCI. If children show similar declines, then slowing this decline would be beneficial. In pediatric SCI, effects of growth cannot be separated from the effects of an intervention, as longitudinal bone data are lacking in pediatric SCI, and the BMD change needed for clinical significance is unknown. Finally, even though 30 children participated, sample size was small, making statistical changes more difficult to obtain. This limitation is inherent in working with children with SCI owing to the small population and geographical distances from pediatric specialty medical facilities.

In conclusion, hip BMD values demonstrated trends for gains with a 6-month intervention using PC or FESC. Furthermore, there appeared to be a threshold level for hip BMD in children with SCI, above which modest improvements in BMD values could be achieved. Non-significant increases at the distal femur were achieved with passive and FES cycling, whereas the proximal tibia changes were only observed with FES cycling. As hip BMD changes were greater than those reported for exercise modalities in other pediatric populations, FESC and PC may be good choices for improved bone health. However, further research with a larger sample size is warranted.

Conflict of interest

The authors declare no conflict of interest.

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