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TECHNICAL PERSPECTIVE Efficacy of a New Rehabilitative Device for Individuals With Spinal Cord Injury

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Abstract

Background/Objective: Regular exercise is required in persons with spinal cord injury (SCI) to reduce the deleterious effects of chronic paralysis. The primary aims of the study were to examine responses to passive and active exercise on a new rehabilitative device for persons with SCI and to examine reliability of these responses over 2 days of testing.

Methods: Nine men and women with chronic SCI completed the study, 2 with a complete injury and 7 with an incomplete injury. The level of injury ranged from thoracic (T4-T6 and T10) to cervical (4 with C5-C6 and 3 with C6-C7 injuries). They completed 2 30-minute sessions of active lower-body and passive upper-body exercise, during which heart rate (HR), blood pressure (BP), gas exchange data, rating of perceived exertion (RPE), and oxygen-hemoglobin saturation were continuously assessed.

Data Analysis: One-way ANOVA with repeated measures was used to examine differences in all variables over time.

Results: Results demonstrated significant increases (P < 0.05) in HR, systolic BP, RPE, and oxygen uptake (Vo_2) from rest to exercise. No change (P > 0.05) in diastolic BP or oxygen-hemoglobin saturation was evident. Cronbach's alpha values for HR, systolic BP, and Vo_2 recorded over both days of testing ranged from 0.79 to 0.97, indicating adequate consistency.

Conclusions: Data demonstrated that exercise on this device significantly increases HR, Vo₂, and systolic BP compared to rest. However, its efficacy for long-term rehabilitation, especially in regular exercisers with SCI, is unknown.

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Key Words: Spinal cord injuries; Rehabilitation, physical; Tetraplegia; Paraplegia; Exercise; Aerobic fitness

INTRODUCTION

It has been reported (1) that more than 200,000 persons with spinal cord injury (SCI) reside in the United States, and there are more than 2,000,000 worldwide. With life expectancy of these individuals approaching that of the able bodied (2), the importance and application of proper care and rehabilitation to improve quality of life, enhance function, and prevent disease cannot be understated.

Persons with SCI typically lose voluntary neural control of the limbs, leading to marked reductions in activity (3). This tends to elicit spasms, as well as atrophy of skeletal

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JSCM 586 muscle (4) and reductions in exercise tolerance and activities of daily living. In SCI, reduction in overall physical function leads to loss of strength and endurance (5), greater incidence of fractures (6), and chronic pain. Consequently, individuals with SCI require effective rehabilitation to slow the deterioration in physical function.

Various equipment exists in the rehabilitation of the SCI. Modalities including cycle (5) and arm ergometry (7), Nautilus-type machines, circuit training (8), and electrical stimulation (9,10) have been traditionally employed to promote cardiovascular and strength training in these individuals. In 17 individuals with paraplegia (8), circuit training increased heart rate (HR) and oxygen uptake (Vo₂) compared with rest. Electrically induced leg cycling in patients with complete SCI (9) demonstrated similar HR yet higher whole-body Vo₂ compared with the Nash et al (8) study. In response to 10 minutes of electrically stimulated knee extensions, it was reported that HR did not change from rest to exercise, yet

systolic and diastolic blood pressure (BP) was enhanced with exercise, suggesting improved circulation in the paralyzed limb (10). A brief bout of passive leg exercise in persons with SCI increased Vo_2 , stroke volume (SV), and ventilation (V_E), which was explained by augmented venous return (11,12). This suggests that exercise in people with SCI stresses the cardiovascular system, leading to elevated HR, Vo_2 , SV, and/or BP. However, such modalities as circuit training and electrical leg cycling are typically found in rehabilitation centers or hospitals, leaving housebound patients with limited means of rehabilitation.

A new piece of in-home exercise equipment has recently been designed, called the Flexiciser (Flexiciser International Corp, Carlsbad, CA). According to the manufacturer, "virtually anyone who has lost the ability to control their body's movement can benefit from using the Flexiciser." This includes individuals injured in an accident or who have SCI, multiple sclerosis, Parkinson disease, muscular dystrophy, cerebral palsy, and degenerative diseases. Exercise using this device has been claimed to enhance endurance, range of motion, circulation and muscle tone, weight control, and pain while reducing spasticity, stress, depression, and swelling. However, the accuracy of these claims needs to be tested via scientific investigation.

Consequently, the primary aim of this study was to assess acute responses to exercise on the Flexiciser in individuals with SCI. Furthermore, the reliability of physiological responses to multiple bouts of exercise on this device was examined. Data will elucidate whether this new device is effective for rehabilitating persons with SCI.

METHODS

Nine men and women with SCI participated in the study; their characteristics are presented in Table 1. Pain was measured on a 0-4 verbal rating scale. Seven participants completed weekly rehabilitation, and the other 2 remained inactive. Two participants had complete SCI, and 7 maintained an incomplete injury. Level of injury ranged from thoracic (T4-T6 and T10) to cervical (4 with C5-C6 and 3 with C6-C7 injuries). There were 2 participants with paraplegia and 7 with tetraplegia, respectively. Participants were recruited by word of mouth and flyers distributed at rehabilitation centers in Southern California. Participants were free of known cardiac, pulmonary, or metabolic disease and were not taking medications that affect cardiovascular or metabolic function. They filled out a health history questionnaire and provided informed consent before participating in the study. All experimental procedures were approved by the University Institutional Review Board.

Exercise Protocol

After refraining from consuming caffeine and alcohol and from exercising for 24 hours, the participants arrived at the Human Performance Laboratory for the first trial.

Table 1. Demographic Characteristics of Study Participants (N=9)

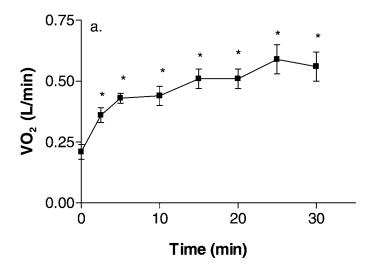
Parameter	Mean ± SE	Range
Age (y)	40.6 ± 3.4	26–54
Height (m)	1.7 ± 0.3	1.6–1.8
Weight (kg)	74.5 ± 3.4	52.5-84.0
Injury duration (y)	5.4 ± 1.9	1.3-20.0
Training (y)	2.6 ± 0.8	0.0-6.0
Pain (0-4 scale)	0.8 ± 0.2	0.0-2.0
Resting heart rate (bpm)	67.4 ± 3.2	53.0-77.0
Resting systolic blood		
pressure (mmHg)	113.0 ± 5.7	78.0–128.0

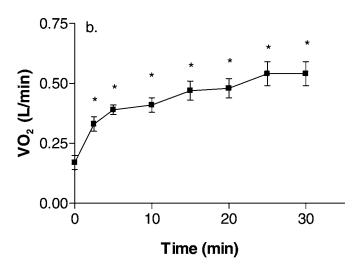
They remained seated in their wheelchairs with no weight bearing, and their wheelchairs were secured inside the rails of the Flexiciser. Their feet were attached to the machine's foot pedals with Velcro straps, and participants were required to grab the handgrips with the arms extended in front of them. The machine, powered by a motor, simulates simultaneous upper- and lower-body extremity movement similar to walking at cadences ranging from 0 to 60 revolutions per minute (rev/min). There is additional trunk rotation and core involvement as well. There is no resistance setting on this machine.

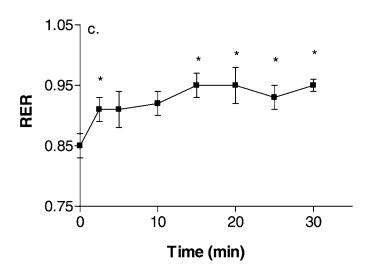
Study participants initially completed 3 to 5 minutes of passive warm up on the Flexiciser at 30 rev/min, during which the machine, via the motor, executed simultaneous movement of the arms and legs. This was followed by 30 minutes of exercise, during which participants were required to resist the foot pedals with their legs, yet passively use their arms and upper body. Upper-body resistance was not added, because only some participants had use of their upper body. Cadence of the machine was set at 15 rev/min for the first 10 minutes and increased to 30 and 45 rev/min at minutes 10 and 20. This protocol was repeated 1 week later at the same time of day, and each participants' diet and exercise status in the 24 hours before the second trial was similar.

Measurements

Throughout exercise, gas exchange data were obtained every 15 seconds using indirect calorimetry (ParvoMedics True One 2400, Sandy, UT). This metabolic cart was recently validated (13) against the Douglas bag method for Vo_2 measurement. Because of the inherent noise of BXB data due to shallow breaths, coughs, etc., all Vo_2 values \pm 3 SD from the mean Vo_2 value for each person were excluded (14). Expired volume was measured using a Hans Rudolph Pneumotach flowmeter (Hans Rudolph, Shawnee, KS) and then integrated. Vo_2 and carbon dioxide production (Vco_2) were measured using the Servomex paramagnetic O_2 analyzer and infrared CO_2 analyzer, respectively (Servomex Co, Sugarland, TX). Before exercise, the metabolic cart was calibrated to gases of known concentration (16% O_2 and 4% CO_2), as







well as to room air $(20.93\% O_2 \text{ and } 0.03\% CO_2)$, and a 3-L syringe was used to calibrate flow. Pilot testing revealed a test/retest correlation of Vo_2 across multiple days equal to 0.92. HR was assessed during exercise via telemetry (Polar Electro, Woodbury, NY). Rating of perceived exertion (RPE) was assessed every 5 minutes using a 1–10 scale (15).

Assessment of Blood Pressure and Oxygen Saturation

Systolic and diastolic BP was assessed at rest, during the warm up, and throughout exercise by the primary investigator using manual sphygmomanometry (adult-size cuff, Omron HealthCare Inc, Vernon Hills, IL). The first and fourth Korotkoff sounds were recorded to represent systolic and diastolic BP. Test-retest correlations for resting and exercise BP were 0.98 and 0.93, respectively. Oxygen-hemoglobin saturation (S_aO₂) was assessed at similar intervals using finger pulse oximetry (BCI Model 3301, Watford, UK).

Data Analysis

Data were expressed as mean \pm SE and analyzed using SPSS Version 14.0 (Chicago, IL). One-way ANOVA with repeated measures was used to examine gas exchange data (Vo₂, Vco₂, ventilation [V_E], and respiratory exchange ratio [RER]), HR, BP, RPE, and S_aO₂ across time during exercise. If a significant F ratio was obtained, Tukey's posthoc test was used to locate differences between means. Cronbach's alpha was used to examine the consistency of responses (HR, Vo₂, and systolic BP) across 2 days of testing. Because variables examined across days of testing were consistent, all data reported are the average of 2 trials. Statistical significance was set at P < 0.05.

RESULTS

Testing was well tolerated by all participants without reports of pain or discomfort. Because of personal issues, one participant did not complete his second trial, resulting in a total sample of 8 men and women.

Gas Exchange Data

Exercise on the Flexiciser elicited significant increases in Vo $_2$ compared with rest (0.21 \pm 0.03 L/min, 95% CI = 0.14–0.29 L/min), F (7,56) = 24.9, P < 0.01. Vo $_2$ significantly increased (P < 0.05) during exercise compared with the previous cadence. These data are demonstrated in Figure 1a.

 Vco_2 was significantly increased with exercise, F (7,56) = 32.4, P < 0.01. A twofold increase (P < 0.05) in Vco_2 was observed from rest (0.17 \pm 0.03 L/min, 95%

Figure 1. Responses of (a) oxygen uptake, (b) carbon dioxide production, and (c) respiratory exchange ratio to acute exercise on the Flexiciser. *, P < 0.05 compared with rest.

CI = 0.10–0.24 L/min) to warm up (0.33 \pm 0.03 L/min, 95% CI = 0.27–0.39 L/min), with sustained increases in Vco₂ demonstrated as cadence increased from 15, 30, and 45 rev/min (Figure 1b). However, at a cadence of 45 rev/min, Vco₂ did not significantly increase compared with 30 rev/min.

RER was significantly increased (F (7,56) = 2.5, P < 0.05) from 0.85 ± 0.07 (95% CI = 0.8–0.91) at rest to 0.91 ± 0.06 (95% CI = 0.87–0.96) during warm up to 0.95 ± 0.04 (95% CI = 0.92–0.98) at 45 rev/min (Figure 1c). However, only exercise at 30 and 45 rev/min demonstrated significant (P < 0.05) increases in RER compared with the warm up or exercise at 15 rev/min.

 V_E was significantly augmented with exercise, F (7,56)=32.9, P<0.01. V_E values at all time points were significantly different (P<0.05) from each other, with the exception of V_E at 10 and 15 minutes, 15 and 20 minutes, and 25 and 30 minutes.

RER was significantly increased with exercise on the Flexiciser, F (7,56) = 17.5, P < 0.01. For example, it increased from 14.4 \pm 4.0 breath/min at rest to 24.1 \pm 5.3 breath/min at 30 rev/min and 28.5 \pm 6.7 breath/min at 45 rev/min. Tidal volume was augmented (F (7,56) = 5.4, P < 0.01), yet significant increments were observed only between rest and values at 10, 20, and 30 minutes of exercise.

Blood Pressure, Heart Rate, and Oxygen-Hemoglobin Saturation

A significant change in systolic BP (F (7,56) = 8.2, P < 0.05) was observed over time, yet was not significantly increased from rest (109.3 \pm 6.2 mmHg, 9% CI = 94.2–124.4 mmHg) to any other time point (Figure 2a). No change in diastolic BP was demonstrated with exercise on the Flexiciser, F (7,56) = 0.6, P > 0.05 (Figure 2b).

HR was significantly augmented from rest (63.5 \pm 3.4 bpm, 95% CI = 55.4–71.6 bpm) to exercise at all cadences, F (7,56) = 21.1, P < 0.01 (Figure 2c). However, it was significantly increased (P < 0.05) from the warm up only at 30 and 45 rev/min.

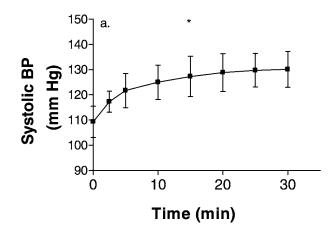
 S_aO_2 did not change in response to exercise, F (7,56) = 1.3, P>0.05. A maintenance in S_aO_2 was observed from rest (96.4 \pm 0.5%, 95% CI = 95.3–97.6%) to minute 10 (96.3 \pm 0.4%), 20 (96.3 \pm 0.5%), and 30 (95.1 \pm 0.6%) of exercise.

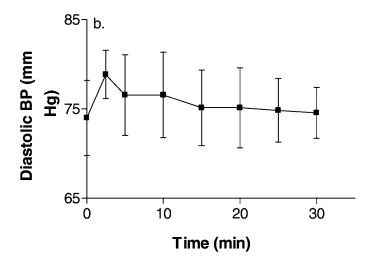
Rating of Perceived Exertion

Figure 3 reveals significant changes in RPE from warm up to initiation of exercise, F (6,48) = 21.9, P < 0.05. A consistent increase in RPE was observed as cadence was increased and lower body resistance was added, reaching a value of 5.0 ± 1.3 at minute 30, representing "somewhat hard" effort.

Reliability Data

Over both days of testing, Cronbach's alpha was calculated for systolic BP, HR, and Vo₂ recorded at





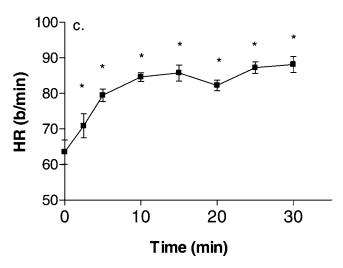


Figure 2. Responses of (a) systolic blood pressure, (b) diastolic blood pressure, and (c) heart rate to acute exercise on the Flexiciser. *, P < 0.05 compared with rest.

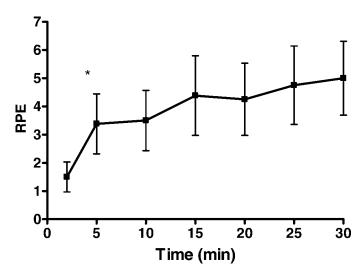


Figure 3. Responses of rating of perceived exertion to acute exercise on the Flexiciser. *, P < 0.05 compared with rest.

minute 15 of the protocol, during exercise at 30 rev/min. This coefficient of reliability was equal to 0.97, 0.79, and 0.88 for these variables, suggesting high consistency across multiple bouts of exercise.

DISCUSSION

The primary aim of the study was to assess the efficacy and reliability of combined passive and resistive exercise on a new rehabilitative device in persons with SCI. Results demonstrated significant increases in Vo₂, HR, systolic BP, and RPE from rest to exercise but no change in diastolic BP or S₂O₂. Yet the magnitude of increments in these variables was small, and in some cases insignificant, when cadence was increased and lower-body resistance was added after the warm up. Because gains in cardiovascular function are typically elicited by a progressive increase in frequency, duration, and eventually intensity of exercise, the long-term effectiveness of this device for enhancing cardiovascular fitness in individuals with SCI is questionable. In its current iteration, the Flexiciser may be most practical for patients with acute injury and those with chronic SCI who do not typically complete rehabilitation.

Compared with rest, Vo_2 was increased by 70% with initiation of exercise, most likely mediated by an increase in SV (11) and HR (Figure 2c). Consistent increases in Vo_2 were observed as participants resisted with their legs and cadence was increased (Figure 1a). Peak Vo_2 recorded at 45 rev/min (0.6 \pm 0.1 L/min) was similar to that demonstrated in participants with paraplegia with complete SCI (T4–L1) during circuit training (0.56–0.64 L/min) (8), yet markedly lower than Vo_2 (1.0 \pm 0.1 L/min) reported during electrically induced leg cycling in persons with complete SCI (C5–T7) (9). Nash et al (8) demonstrated Vo_{2max} from arm ergometry equal to 1.58 \pm 0.34 L/min, yet passive leg cycling exercise at 20 and 40 rev/min in 8 individuals with lower-level injuries (T8–L1) demonstrated dramatically lower Vo_2 (0.25 L/min).

This suggests that upper-body passive combined with lower-body resistive exercise on the Flexiciser elicits lower Vo_2 compared with arm ergometry and electrically stimulated cycling, yet higher Vo_2 than other passive leg cycling modes.

Significant increases in systolic BP were demonstrated over time (Figure 2a), yet exercise did not elicit significant increases in systolic BP compared with rest (109.3 \pm 6.2 mmHg). Systolic BP did not change with passive leg cycling in another study (11), which could be attributed to arterial dilatation and consequent reduction in peripheral resistance caused by passive leg cycle exercise in individuals with SCI (16). Yet increased (20 mmHg) systolic BP was demonstrated with electrical stimulation completed in 2 patients with paraplegia and 4 with tetraplegia (10). Overall, lower body exercise may improve circulation and reduce blood pooling in the paralyzed limb (17).

In the present study, exercise significantly increased HR compared with rest (Figure 2c), yet no change in HR was revealed in patients with T8-L1 injuries completing 6 to 7 minutes of passive leg cycling at 20 to 40 rev/min (11,12). The active lower-body combined with passive upper-body exercise required in the present study may have led to significant increases in HR, although peak HR at 45 rev/min (~90 bpm) was lower compared with values previously reported (7,9). In men and women with traumatic SCI at C4 or lower completing 9 months of progressive arm ergometry and resistance training, HR was increased to 145.7 \pm 30.1 bpm at the highest workload (7). The lower HR response in the present study is partially explained because the majority of our study participants had injuries at C5 or higher, which has been reported (18) to elicit lower HR during exercise vs individuals with injury at or below T6. Higher exercise intensity elicits a greater myocardial O2 demand and should lead to greater cardiovascular adaptations during chronic training compared with lower intensities. Passive exercise or requiring the patient to voluntarily resist the machine, as recommended by the manufacturer, may not elicit an adequate cardiovascular stimulus for adaptation over time, especially in persons with injuries lower than C4, in which cardiovascular function is relatively preserved.

RPE was significantly increased with exercise on the Flexiciser (Figure 3), similar to recent findings (19) using arm ergometry. In that study in 42 men and women with complete SCI, data demonstrated significant increments in RPE throughout progressive exercise, reaching values of 16 to 18 on the Borg 6–20 scale (20,21).

One primary limitation of the study is the small sample of only 8 men and women with cervical or thoracic SCI. This reduces the ability to generalize the findings to persons with injury at these regions. The largest increases in HR and BP were observed in the transition from rest to exercise, with minimal increases demonstrated as cadence was increased from 15, 30, and

45 rev/min. Many active participants complained of boredom and stated that their typical training was more intense than intensities prescribed in the study. However, the participants who had been inactive for long periods after SCI believed that exercise on the Flexiciser was more beneficial. The manufacturer must improve the device by implementing alterations in resistance during exercise, because the ability to change cadence does not dramatically increase intensity of exercise. During the study, 5 motors were damaged by active men who could generate more than 60 lb of resistance with their legs, the peak force tolerated by the machine. Overall, the Flexiciser may be of greatest benefit to patients who are initiating rehabilitation immediately after injury and/or prolonged inactivity. In exercisers with SCI, it may not provide a suitable exercise stimulus to elicit adaptation during rehabilitation and may not be able to sustain forces exerted by active men and women with SCI.

CONCLUSIONS

The primary aim of the study was to examine physiological responses to a new exercise device for the SCI. Results demonstrated significant increases in HR, Vo_2 , systolic BP, and RPE with exercise on the Flexiciser. Diastolic BP and S_aO_2 were unaltered during exercise. Reliability of HR, systolic BP, and Vo_2 in response to 2 days of exercise on the Flexiciser was high, indicating a consistent exercise stimulus. This new rehabilitative device has promise for persons with acute SCI and those with chronic SCI who are attempting to initiate a rehabilitation program, yet the device may be ineffective for regular exercisers due to an inadequate exercise stimulus.

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