# Effectiveness of exercise training program on postural control and quality of life in middle-aged men with unilateral lower limb amputation

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# Abstract

This study aimed to investigate whether the exercise-based amputee rehabilitation program improves postural control and quality of life in people with unilateral transtibial amputation (TTA). Twenty middle-aged men (48.4±3.8 y) with lower limb amputation, in a randomized-controlled longitudinal design, volunteered to participate in the study and were divided into experimental (EXP, n=10) and control (CON, n=10) groups. Before and after 8 weeks of the exercise training program, postural control performance, using one-leg standing (OLS) and Y-balance tests, was measured. The quality of life was also assessed before and after 8 weeks training period using standard questionnaires. Group x time interactions were observed for the EXP group in OLS and Y-balance tests and quality of life scores in comparison to pretraining values and the CON group (p<0.05). People

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with unilateral TTA who received exercise-based amputee rehabilitation program demonstrated significant improvement in balance performance with significant effects on quality of life.

**Keywords** balance • rehabilitation • exercise training • amputation.

## Introduction

Postural control (PC) is generally defined as the ability to maintain the body's center of gravity within its base of support and can be categorized as either static or dynamic balance (Asadi et al., 2015). Poor PC is reported to be associated with injury or falls in daily life activity and, consequently, is considered a critical component of common motor and performance skills throughout life (Gabbard, 2008). Some injuries, which are associated with PC deficits, result in serious health problems and are reported to be associated with high costs for the society as well as suffering (McGuine et al., 2000).

In a physically healthy population, the ankle and lower body musculature play an important role to maintain balance and shift the center of pressure, which result in an appropriate PC (Burke-Doe et al., 2008). Lower limb amputation is a life-changing event. Approximately 45% of the lower limb amputation is caused by traumatic mechanisms (Ziegler-Graham et al., 2008). Persons with an acquired unilateral amputation below the knees experienced sensory impairments including lack of ankle torque penetration to restore equilibrium in the sagittal plane, lack of weightshifting capacity to control posture in the frontal plane and distorted somatosensory input from the side of amputation (Sherk et al., 2010).

Having lower limb amputation in their mind, the physician and physical therapist apply prosthetic limb for optimizing physical function (Ries, & Vaughan, 2007). Besides, some physical and exercise treatments could be used to enhance neuromuscular properties and balance tasks in those individuals (Van Velzen et al., 2006; Studenski et al., 2003; Barthuly et al., 2012). Miller et al. (2001) reported that people with unilateral below-knee amputation experienced a fall during the past year. It has been reported that balance performance is reduced in subjects who had lower limb amputations (Pauley et al., 2014).

Clinicians have used a large number of exercise training approaches (e.g., resistance training, balance training) in rehabilitation in amputees as well as methods to assess PC performance including static and dynamic balance (Pauley et al., 2014; Wong et al., 2016; Wasser et al., 2017; Gailey et al., 2020). However, there is a lack of research about the effects of rehabilitation exercise training program on PC performance and quality of life in persons with lower limb amputation. Moreover, randomized-controlled interventions, with unilateral transtibial amputation (TTA) have not been addressed properly in previous studies. Therefore, to address the gap in research literature, the purpose of this study was to investigate the effects of an 8-week exercise-based amputee rehabilitation program on postural control, using static and dynamic balance tests, and on quality of life in people with TTA.

# Method

#### Participants

Twenty middle-aged individuals with lower limb amputation volunteered to participate in the study and were randomly grouped into an experimental (EXP, n=10) and a control (CON, n=10) cohort (Table 1). The sample size was calculated according to rehabilitation program effects on functional mobility in previous study by Gailey et al. (2020) with an  $\alpha$ level of 0.05, and an actual power (1- $\beta$ ) of 0.80. The calculations (G × Power, Version 3.1.9.2, University of Kiel, Germany) revealed that the sample size of n= 10 would be sufficient for each group to find significant effects of the exercise-based amputee rehabilitation program. Subjects were recruited from a major regional prosthetics center, the local prosthetic clinics and amputee support groups. Participants were eligible if they met inclusion and exclusion criteria. According to inclusion criteria men aged 40-55 years underwent to traumatic transtibial amputation at least 6 years before enrollment, who fitted with their current prosthesis for at least 5 years and suffer from chronic upper and lower body musculoskeletal pain were included in the study. According to exclusion criteria those with pain symptoms or functional limitations that preclude their participation in a rehabilitation exercise program, with impaired hearing and vision, medical conditions that could affect their ability or balance, and reduced sensation of the non-affected limb were not included in the study groups. After being informed about the study procedures, benefits, and possible risks, the subjects signed an informed consent form following the guidelines of the Institutional Review Board at the University.

**Table 1.** Descriptive data of the experimental(EXP, n=10), and control (CON, n=10) groups

	EXP	CON
Age (y)	48.3±3.2	47.6±4.3
Height (cm)	176.8±3.1	176.1±7.1
Body mass (kg)	$82.5 \pm 10.8$	$85.9{\pm}10.8$
Body mass index (kg/m <sup>2</sup> )	26.3±3.2	$27.6 \pm 4.1$

#### Study design

In a randomized-controlled longitudinal design, subjects were divided into 2 groups, including an experimental group that went through an 8-week rehabilitation exercise-based program, on 3 days per week schedule, and a control group that did not undergo any exercise training program. The overall study lasted 11 weeks with the 1st week dedicated to subjects' familiarization with the program, the 2nd week dedicated to pre-tests, the 3rd to 10th week dedicated to training program and the 11th week dedicated to post-tests. One leg standing (OLS) and Y-balance tests as well as quality of life were measured pre- and post-training. Two measurements, with 96 h interval, were used to determine the reliability of tests and the interclass correlation coefficient (ICC) of the balance tests was  $r \ge 0.95$ .

#### Testing procedures

The subjects participated in a familiarization session for 90 min before testing to reduce any differences in learning effects. The standardized postural performance and anthropometric measures were completed in 2 sessions with at least 24 h interval. In the first testing session, body mass and height were assessed. In the second session, quality of life questionnaire was filled and OLS and Y-balance tests were administered with 30 min interval. All tests were administered at the same location, in the same order, at the same time of day (i.e., 2:00–5:00 p.m.) and by the same investigator.

#### Anthropometric measures

Height was measured to the nearest 0.1 cm with the use of a wall-mounted stadiometer (Seca 222, Terre Haute, IN, USA). Body mass was measured to the nearest 0.1 kg using a medial scale (Tanita, BC-418MA, Tokyo, Japan).

#### Postural control performance

One leg standing (OLS) test was administered at first to determine static balance (Ahmed et al., 2010). The OLS test is one of the balance tests used to diagnose musculoskeletal amputation disability symptom complex. For this test, subjects performed standard warm-up including 10 min light running and stretching movements, and then performed five times OLS for familiarization. The subjects' OLS test time was determined by asking the subject to put their hands on their waist and raise on one leg; then, using a stopwatch (Sper Scientific Direct, Evans Rd, Scottsdale, AZ) the amount of time was measured, until the raised leg touched the floor. This test was repeated if the subject (1) did not touch the hip with the untested leg, (2) did not touch the waist with the arms, or (3) performed lateral movements in standing leg (Ahmed et al., 2010).

The postural control test was assessed at 30 min post OLS test, by the Y-balance test (Asadi et al., 2015). To assess PC ability, it appears that Y-balance test is one of the valid tests. In this test, the subjects performed a warm-up including ten minutes stretching and ballistic movements in the lower extremity, and then performed five trials of the Ybalance test for familiarization. In the postural control performance test 3 directions (i.e., anterior [A], posteromedial [PM], and poster lateral [PL]) were used. The subject maintained a single-leg stance while reaching with the contralateral leg (reach leg) as far as possible along the appropriate vector. The subject lightly touched the furthest point possible on the line with the most distal part of the reaching foot. The subject was instructed to touch the furthest point on the line with the reaching foot as lightly as possible to ensure stability was maintained through adequate neuromuscular control of the stance leg. The subject then, returned to a bilateral stance while maintaining equilibrium. The tester measured manually the distance from the center of the grid to the touch point with a tape measure in centimeters. Measurements were taken after each reach by the same tester. The subjects performed 3 reaches with 15 sec interval and the average of 3 trials was recorded for further analysis. Trials were discarded and repeated if the subject (1) did not touch the line with the reaching foot while maintaining weight bearing on the stance leg, (2) lifted the stance foot from the center grid, (3)lost balance at any point in the trial, or (4) did not maintain start and return positions for one full second. Each participant's legs were measured from the anterior superior iliac spine to the distal tip of the medial malleolus using a standard tape measure with participants lying supine. Leg length was used to normalize excursion distances by dividing the distance reached by leg length then multiplying by 100 (Gribble, & Hertel, 2003).

Subjects performed both balance performance tests using their healthy leg and did not perform balance tests with their amputated leg or the spotters; however, an experienced strong conditioning coach provided verbal encouragement and also ensured the safety of the procedure.

#### Quality of life assessment

Subjects completed the specific quality of life questionnaire during a structured interview, with a validated version of the questionnaire (WHOQOL-BREF questionnaire, Cronbach's alpha = 0.85). The questionnaire included 26 questions divided into four areas of well-being including physical health, psychological health social and environment communication. Each question explored the intensity of a perceived symptom, quantified with an integer rating scale between 0 (no discomfort) and 5 (great discomfort). The mean score for the total questionnaire was used for the analysis (Caballero et al., 2013).

#### Training program

The training program was undertaken three times a week for 8 weeks (Saturday, Monday, and Wednesday). Subjects in the EXP group performed side-to-side balance, forward and backward balance, single limb balance, sidestepping, braiding, a ball rolling, resisted elastic kicks in four directions (i.e., flexion, extension, abduction, and adduction), toe box jumps, resisted waking, and agility drills. The training protocol required 2 sets of 15 repetitions with 90 sec intervals to allow for rest for each exercise. In each

session the subjects performed 10 min warm-up and 40 min main training with 5 min of cool-down. The subjects in the EXP group were instructed to perform each exercise with maximal effort. During the training, all subjects were under the direct supervision and were instructed on how to perform each exercise. The subjects in the CON group did not perform any exercise, but were present in the training room.

#### Statistical analysis

Mean scores  $\pm$  SD is presented as descriptive data. Normality for all data, before and after the intervention was checked with the Shapiro-Wilk test. A 2 (group) by 2 (time) repeated measures ANOVA was utilized to analyze changes in the dependent variables measured at pre and post 8 weeks of training. Effect sizes were determined by calculating Cohen's d values, classified as trivial (d $\leq$ 0.19), small (d, 0.20–0.49), medium (d, 0.50–0.79), and large effects (d $\geq 0.80$ ) (Cohen, 1988). The level of significance was set at p $\leq 0.05$ .

### Results

There were no significant differences between groups at pre-test (p>0.05). After 8-week training period, the EXP group showed significant improvements in OLS test in all A, PM and PL directions, and also the quality of life (p < 0.01), whereas the CON group did not show any significant changes (p>0.05). Compared to CON group, time interaction was significant in the EXP group, which indicated significant differences between them in OLS (F1.18=10.62, p=0.014, large ES), direction A (F1.18=7.11, p=0.001, large ES), direction PL (F1.18=6.72, p=0.004, large ES), and quality of life (F1.18=5.88, p=0.004, large ES) (Table 2).

Table 2.	Changes in	the variab	les in respo	onses to 8-w	veek training	intervention	(mean±SD)
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	EXP (n=10)	CON (n=10)			Significance
OLS (sec)					
Pre	26.8±9.8		23.4±9.5		G=0.98
Post	41.3±16.9*†		24.3±16.9		T=0.02
Effect Size	1.01 (0.08, 1.94)	Large	-	-	G×T=0.014
A direction (cm)					
Pre	132.4±33.6		$118.8 \pm 24.8$		G=0.55
Post	155.6±33.2*†		$120.8 \pm 24.1$		T=0.001
Effect Size	0.67 (-0.24, 1.57)	Medium	-	-	G×T=0.015
PM direction (cm)					
Pre	110.5±29.8		111.2±30.1		G=0.11
Post	138.3±28.3*†		$115.4 \pm 28.7$		T=0.03
Effect Size	0.92 (-0.01, 1.84)	Large	-	-	G×T=0.001
PL direction (cm)					
Pre	99.0±18.6		95.9±15.9		G=0.32
Post	115.6±21.3*,†		98.5±17.4*		T=0.02
Effect Size	0.80 (-0.12, 1.71)	Large	-	-	$G \times T = 0.004$
Quality of life (points)					
Pre	$61.2 \pm 15.4$		61.3±14.4		G=0.06
Post	80.3±16.7* <sup>,</sup> †		62.1±14.4		T=0.002
Effect Size	-1.14 (0.19, 2.08)	Large	-	-	$G \times T = 0.004$

Note: OLS: one leg standing; \*: denotes significant differences between pre- and post-training values ( $p \le 0.05$ ); †: denotes significant differences between the EXP and CON groups at post-training ( $p \le 0.05$ ). G = group, T = time.

The outcome of this study adds value to previous studies on balance performance adaptations in one leg amputee population through the use of rehabilitation training approaches. Our findings revealed that an 8-week rehabilitation training approach results in a significant improvement in the OLS and Y-balance tests in all directions. Besides, the subjects showed significant improvements in their quality of life following the training period. An improvement in the balance tasks following the rehabilitation training approach is likely the result of improved neuromuscular control (Thrope, & Ebersole, 2008). The individuals in the EXP group in the current study showed improvements in the OLS and Y-balance tests when compared with the CON group.

The OLS and Y-balance tests may have the potential to be a corollary outcome measure that can be utilized to compare the efficacy of programs to improve sensory-motor in the lower body (Arazi, & Asadi, 2011). The possible mechanism(s) that influenced the balance performance could be muscle activation, neuromuscular properties, and proprioception which have a strong relationship with the OLS and Y-balance tests (Marigold, & Patla, 2002).

In line with our findings, eight weeks of lowerbody exercise training induced improvements in dynamic balance performance (Asadi et al., 2015: Arazi, & Asadi, 2011; Miller et al., 2001). The exercises used in the present study were different forms of resistance and stretch-shortening exercise training that involved proprioception and neuromuscular properties. Also, the exercise rehabilitation program induced a spectrum of balance challenges, specific balance or controlling exercise, which may be necessary for the population to increase their joint awareness resulting in PC improvements (Nagy et al., 2004). In addition, Pauley et al. (2014) reported that two days a week training program in hip abductor could be an effective method to improve balance performance in subjects with amputation leg. Performing exercise training in this study could produce stability challenges thought the exercise session in amputee population and involved feedforward adjustments to improve PC and reduce filling in life (Gailey et al., 2020).

In fact, the significant improvement in balance performance is a welcome result of this program in patients with amputation (Charkhkar et al., 2020) and indeed has been identified as a variable that should be closely considered by clinicians as it relates to functional performance (Nagy et al., 2004; charkhkar et al., 2020). Enhancements in balance tasks following rehabilitation program has been shown to be predictive of social activity, it tends not to change over time, in spite of improvement in walking ability (Chaudhry et al., 2011). In this study, the significant improvement in balance performance both static and ballistic tasks may have resulted from the fact that subjects were able to improve their neuromuscular properties in the lower body over time. Furthermore, previous studies suggested that peripheral and central neural adaptations were caused by a rehabilitation training program in the amputee population, resulted in improved joint position sense and detection of joint motion in the lower body (Charkhkaer et al., 2020). The articular mechanoreceptors involved in the population following the amputee repetitive stimulation in the 8 weeks exercise rehabilitation program. In literature, it was reported that desensitizing the GTO heightens the stretch sensitivity of the muscle spindles to length change (Lephart, & Henry, 1996). Heightening the sensitivity of the muscle spindle system may increase their afferent contributions to the central nervous system concerning the joint position. These adaptations may also be responsible for the enhanced balance performance demonstrated by the population (Lephart, & Henry, 1996).

Other possible mechanisms that influenced the effects of the rehabilitation program on balance performance could be the stimulation of Kinesthesia (Wilkerson et al., 2004). Altogether, improvements in kinesthesia may also be related to the desensitization of the GTOs and heightened sensitivity of the muscle spindles (Wilkerson et al., 2004). Although this mechanism could be theoretical, the findings of the study suggest that possible adaptations occurred following the 8 weeks training intervention. In the current study, acute kinesthesia and possible mechanisms by central and peripheral adaptation were not measured, whereas previous investigations argued the importance of these mechanisms (Wilkerson et al., 2004; Ramirez-Campillo et al., 2018). Therefore, future studies can investigate the impact of the mentioned mechanisms on postural control.

Regarding the quality of life, following the 8 weeks of training program used in this study subjects felt improvements. Since functional performance is associated with quality of life in these people (Ramirez-Campillo et al., 2018) and quality of life was improved in the EXP group; changes in functional performance in the balance tasks and reducing in the filling sense may help explain the quality of life improvements. Some studies have demonstrated that the rehabilitation training program is effective to improve the quality of life in the amputee population (Caballero et al., 2013; Ramirez-Campillo et al., 2018), confirming that this program might be applied to counter-performance decrements among one leg amputee men, which might lead not only to reduced morbidity and mortality, but also to better quality of life.

In conclusion, the results of the current study confirmed that people with unilateral transtibial amputation, who received exercise-based amputee rehabilitation program, demonstrated significant improvement in balance performance in both the static and dynamic balance tests and significant improvements in the quality of life.

### **Declaration of competing interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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