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Transtibial amputee gait during slope walking with the unity suspension system

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ABSTRACT

Background: People with lower limb amputation may experience walking limitations on slopes because of missg musculoskeletal and neuromuscular systems. Elevated vacuum suspension could benefit transtibial amputee gait for slope walking, but research is lacking to inform clinical practice.

Methods: Twelve people with unilateral transtibial amputation were fitted with the Unity elevated vacuum suspension system (Össur) and Pro-Flex XC foot. 3D motion analysis was performed for 7° incline, 7° decline, and level walking within a CAREN-Extended system virtual Park environment. Randomized and blinded walking trials were completed with the vacuum active or inactive.

Results: Statistically significant differences ($p < 0.05$) were found between vacuum conditions when walking uphill or downhill for temporal spatial, kinematic, and kinetic gait parameters; however, effect sizes were small ($r \leq 0.35$). Prosthetic step length decreased for both vacuum conditions on downhill compared to uphill walking. Symmetry index was < 10% for step length, step time, and stance time for both vacuum condition during downhill walking, indicating acceptable symmetry. During incline walking, step length was only symmetrical with active vacuum. Knee range of motion was not restricted, for both conditions.

Conclusion: Active vacuum improved gait symmetry for incline walking, but the other differences between vacuum conditions were small and may not be clinically significant. Therefore, the Unity system approach for elevated vacuum suspension had a positive, but small, effect on walking and should maintain appropriate walking even with vacuum failure, until limb volume changes adversely affect socket fit (i.e., elevated vacuum helps control limb volume fluctuations over time).

1. Introduction

Prosthetic socket suspension systems affect gait, balance, satisfaction, and quality of life, and therefore, is an important step in prosthetic rehabilitation [1–5]. Previous studies indicated that vacuum assisted suspension system (VASS) can improve gait symmetry, proprioception, and satisfaction compared to other suspension systems due to an enhanced connection between residual limb and socket [2,3,6–12]. VASS use a mechanical or electric pump to actively remove air between the liner and socket, while suction systems use a passive one way valve to expel the air.

Board et al. was the first to examine elevated vacuum effects on residual limb motion inside the socket, limb volume, and gait symmetry during level walking [2]. They demonstrated that step length and stance time were more symmetric when walking with an active vacuum suspension system compared to inactive vacuum (suction). More recently, Ferreira & Neves (2015) reported that gait symmetry improved when walking with an elevated vacuum system, compared to the Kondylen Bettung Munster suspension system [13]. However, Ferreira & Neves [13] and Xu et al. [14] did not find significant differences for temporal-spatial and kinematic gait parameters when using VASS.

Elevated vacuum systems are also associated with increased maintenance requirements since the sleeve, liner, and valve often need to be replaced [3]. Some VASS systems limit knee range of motion since a knee sleeve is required for a proper seal between the socket and liner [3,15]. To address these limitations, the Unity elevated vacuum suspension system (Össur) was developed. This vacuum system consists of a mechanical vacuum pump and a hypobaric sealing membrane around a silicon liner [16]. As a result, this design does not require an external knee sleeve. We previously examined the Unity system for individuals

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Table 1
Participant characteristics. Stump size (circumference) was measured at 4 cm proximal to the stump's distal end. Stump length was measured from the patella's inferior edge to the stump's distal end.

Sex	Age (year)	Amputation (years)	Amputation cause	Height (cm)	Weight (kg)	Activity level	Stump length (cm)	Stump size (cm)	Old suspension
Male	85	2	Infection	175	97	K3	15.0	31.0	Pin/lock
Male	29	5	Trauma	173	72	K3	16.0	26.0	Suction
Male	53	12	Trauma	186	85	K4	18.0	27.0	Suction
Male	52	13	Diabetic	180	86	K4	13.5	25.5	Pin/lock
Male	70	9	Diabetic	179	77	K3	13.0	25.0	Pin/lock
Female	44	22	Trauma	164	81	K3	13.0	28.0	Pin/lock
Male	48	3	Trauma	185	93	K3	18.0	29.5	Pin/lock
Male	61	2	Trauma	175	94	K3	18.0	32.0	Suction
Male	76	74	Trauma	178	81	K3	12.5	23.7	Pin/lock
Male	63	6	Trauma	175	83	K3	15.0	25.0	Pin/lock
Male	59	4	Diabetic	185	134	K3	20.0	35.0	Pin/lock
Male	46	5	Trauma	184	104	K3	23.0	28.0	Pin/lock
Average	57.2	13.1		178.3	90.6		16.2	28.1	
SD	15.3	20.0		6.4	16.4		3.2	3.38	

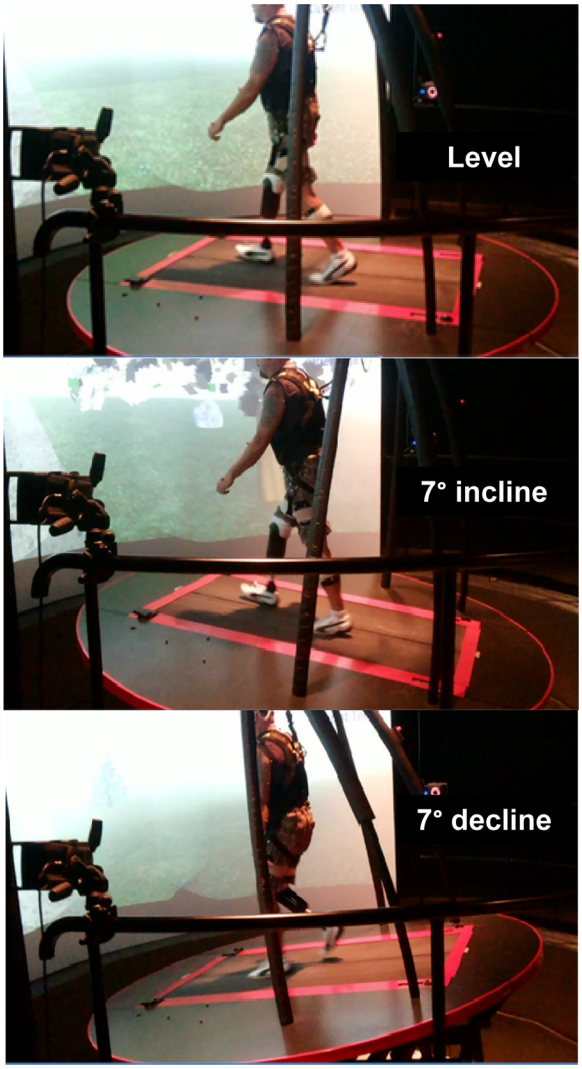

Fig. 1. Participant walking in the CAREN-Extended Park application: level (top), uphill (middle), downhill (bottom).

with a transtibial amputation while walking on a level self-paced treadmill (under review), where active vacuum effects on gait parameters were small compared to an inactive vacuum condition (i.e., suction suspension) and not clinically significant. However, step length symmetry between prosthetic and intact limbs improved with active elevated vacuum during level walking.

Walking up and down sloped surfaces is a necessary daily task since our living environments commonly include non-level surfaces. Walking uphill or downhill is more challenging than level walking due to the greater range of motion and forces required [17,18]. Due to the loss of joint(s), muscles, and nerves, people with lower limb amputation may experience functional limitations during slope walking. To date, gait effects from elevated vacuum suspension during slope walking has not been studied. Therefore, research is needed to better understand walking performance for individuals with a transtibial amputation when walking with the Unity system on sloped surfaces.

The purpose of this research was to compare the effects of the Unity elevated vacuum suspension system on relevant gait parameters for unilateral transtibial amputees during incline and decline walking while the vacuum was active or inactive (i.e., suction socket system). We hypothesized that temporal spatial, kinetic, and kinematic gait parameters would be different with elevated vacuum system compared to inactive vacuum when walking uphill or downhill. A better understanding of VASS gait effects will help with clinical decisions related to prosthetic socket suspension prescription.

2. Methods

Twelve active individuals with unilateral transtibial amputation were recruited from The Ottawa Hospital Rehabilitation Centre (TOHRC) Prosthetics and Orthotics Service (Table 1). Participants were included if they walked without walking aids, reported steady limb volume changes over the previous year, and wore their prosthesis daily. Exclusion criteria were medical conditions or medications that adversely affect locomotion or balance and stump length less than 10 cm [16]. This research was approved by The Ottawa Hospital Research Ethics Board and all participants provided written informed consent. Participant data were based on the International Society for Prosthetics and Orthotics recommendation on defining participants in prosthetics research [19]. Nine participants wore pin/lock suspension systems and three participants wore suction sockets at the start of the study.

2.1. Prosthetic fabrication and training

Prosthetic components were selected for each participant, according to manufacturer guidelines, including an Iceross Seal-In V liner (high or standard profile) and Pro-Flex XC foot with Unity pump. One prosthetist completed casting, modification, socket fabrication, alignment, and training tasks to ensure consistent prosthetic procedures throughout the study. A total surface bearing check socket was fabricated using polyethylene terephthalate glycol-modified (PETG) to verify socket fit. Prosthetic training sessions were provided for all participants until they were comfortable with new system, which included training on donning