Title: Does Vacuum Assisted Socket System Improve Knee Proprioception and Dynamic Balance in Transtibial Amputees?

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Introduction

Prosthetic socket suspension offers a critical means to intimately integrate the prosthetic device with the human body. The effects of suspensions on residual limb volume, socket interface pressure and skin problem have been investigated. Though several studies highlighted the benefits of using VASS, some pointed out that the benefit was only marginal and/or amputee dependent. The mixture of inconsistency in outcome measures and relatively meager scientific evidence fails to justify its clinical necessity. VASS is hence still treated as experimental and investigational and not covered by insurance. To further extend our current existing knowledge base on the effects of VASS, studies addressing aspects closely related to amputee's functional performance when using VASS are strongly needed. Effects of VASS on residual volume and skin health have been reported in the literature, however, little is known about its effects on proprioception in lower limb amputees. In an earlier attempt, Swiggum compared the effects of VASS on proprioception with suction suspension and did not find any significant differences in 2D target identification and depth detection. We believe the lack of significance in the study could be mainly attributed to relatively small sample size (i.e., N = 6 and 7 in each group) and less rigorous protocol. The proprioception was assessed without weight bearing in the study. Earlier study showed that weight bearing had enhanced perception of proprioception than non-weight bearing. In a complete gait cycle stance (weight bearing) and swing (non-weight bearing) phases are constantly alternating and it will be reasonable to evaluate proprioception in both conditions. Furthermore, degradation in proprioception might worsen dynamic balance in gait and it remains unknown if VASS will benefit dynamic balance.

Methods

The proposed study has been conducted at the prosthetics &orthotics research lab at the University of Texas Southwestern Medical Center. The research lab has 2,000 square feet open space and is equipped with F-scan system, Delsys EMG system, motion sensors, 3D optical motion analysis system and a portable ultrasound machine. The research lab is also equipped with two desktop PCs dedicated to data acquisition and processing. Dr. Gao has independent office space on UTSW campus.

We have recruited and tested sixteen unilateral transtibial amputees (15 male and 1 female; mean (std); age: 63.4 (7.9) yrs; body mass: 85.5 (22.4) kg; body height: 1.77 (0.10) m) due to either trauma or PVD for more than a year. Participants did not have other neuromuscular disorders and can walk independently and comfortably. Around half of the participants were our patient models (for class demo and instruction) and we had fabricated test sockets with a built-in expulsion valve for each of them. With suspension sleeve and/or vacuum pump, we were able to obtain two other types of suspension: suction and VASS. Participants were placed in three groups according to the suspension types used: 1) suction (n = 9); 2) VASS (n = 7); 3) locking pin (n = 10). Each participant read and signed the consent form before attending the test.

Knee position sense

Participants stood upright between a parallel bar. A custom electrical goniometer was attached to the lateral side of the knee and secured with Velcro on both the thigh and the shank. Knee position sense was tested with and without weight bearing. For each condition, the tested side was started from neutral position (i.e. full knee extension). Then the experimenter guided the participant to place the knee at one of the following positions in random order using the real-time signal from the electrical goniometer as feedback: 5 to 25 degrees with an increment of 5 degrees in flexion. For weight bearing task, the tested side remained on the ground while the other side was lifted off the ground. For non-weight bearing the tested side was lifted in the air with hip flexion of about 30 degrees while the other side remained on the floor. For each preset target position, participants were given a minimum of 10 seconds for familiarization. Afterwards, the participant were instructed to return to the starting position, and then tried to match the preset target position and hold for 3 seconds. Ten trials were conducted for each condition and the matching errors (i.e. the difference between the preset target and the attempted angles) were averaged for further analysis.

Dynamic balance

Participants were instructed to walk on a treadmill with a tri-axial accelerometer attached to the lower back at their self-selected speed. The signals were streamed into a desktop PC via Bluetooth at a frequency of 100 Hz. A 3-min walking trial was repeated three times with 1-min break in between. Local dynamic stability (LDS) was estimated using Lyapunov exponents in mediolateral, anteroposterior and vertical directions. The embedding dimension and time delay were assessed by using Global False Nearest Neighbors (GFNN) analysis and Average Mutual Information (AMI) function respectively. Local divergence exponents (λ^*) was computed to quantify how fast the neighboring trajectories of a reconstructed state space diverge.

Gait

An eight-camera optical motion analysis system with AMTI force plate was used to collect kinetics and kinematics of gait. We used modified Helen-Hays marker set (including 19 reflective markers) and applied the markers on anatomical landmarks. The camera system and the force plate were carefully calibrated and synchronized. Signals were collected at 100 Hz. Before the test, participants were asked to walk for around 3-5 min. Adjustment was made if needed. The patients were instructed to walk at self-paced speed and target the force plate with either side. Walking trial was repeated three times with at least 1-min break in between for each side. Gait parameters including spatiotemporal characteristics and kinematics/kinetics of the joints of both sides in the sagittal plane were obtained using Visual3D.

Outcomes

We have recruited and tested participants as planned. The current number in each group (particularly in suction and VASS) is a bit shy and we are doing our best to recruit particularly those who are using VASS. In the meantime, we are processing the data and conducting statistical analysis. We have recently submitted an abstract to 2017 AAOP meeting focusing on gait performance. We expect to generate at least one journal paper and one/two conference papers in the near future.