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Vacuum level effects on gait characteristics for unilateral transtibial amputees with elevated vacuum suspension

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ABSTRACT

Background: The elevated vacuum suspension system has demonstrated unique health benefits for amputees, but the effect of vacuum pressure values on gait characteristics is still unclear. The purpose of this study was to investigate the effects of elevated vacuum levels on temporal parameters, kinematics and kinetics for unilateral transtibial amputees.

Methods: Three-dimensional gait analysis was conducted in 9 unilateral transtibial amputees walking at a controlled speed with five vacuum levels ranging from 0 to 20 in Hg, and also in 9 able-bodied subjects walking at self-preferred speed. Repeated ANOVA and Dunnett's *t*-test were performed to determine the effect of vacuum level and limb for within subject and between groups.

Findings: The effect of vacuum level significantly affected peak hip external rotation and external knee adduction moment. Maximum braking and propulsive ground reaction forces generally increased for the residual limb and decreased for the intact limb with increasing vacuum. Additionally, the intact limb experienced an increased loading due to gait asymmetry for several variables.

Interpretation: There was no systematic vacuum level effect on gait. Higher vacuum levels, such as 15 and 20 in Hg, were more comfortable and provided some relief to the intact limb, but may also increase the risk of osteoarthritis of the residual limb due to the increased peak external hip and knee adduction moments. Very low vacuum should be avoided because of the negative effects on gait symmetry. A moderate vacuum level at 15 in Hg is suggested for unilateral transtibial amputees with elevated vacuum suspension.

1. Introduction

There are an estimated 1.5 million people with amputations living in the United States (McGimpsey & Bradford, 2008). Of these, approximately 400,000 have unilateral lower-limb amputations who are at a substantially higher risk to develop osteoarthritis (OA) in the hip and knee of the intact limb than in the able-bodied population (Struyf et al., 2009; Lemaire & Fisher, 1994; Gailey et al., 2008). Previous studies have shown that improper prosthetic fit and alignment were associated with secondary physical conditions, including knee OA in the intact limb, osteoporosis in the amputated limb and back pain (Struyf et al., 2009; Gailey et al., 2008; Sagawa et al., 2011). Additionally, gait asymmetries are common in persons with unilateral amputations, which is often demonstrated by a relatively longer stance time, a greater peak adduction moment for the hip and knee, and a larger first peak of vertical ground reaction force (GRF) on the intact limb (Gailey et al., 2008; Sagawa et al., 2011; Royer & Wasilewski, 2006; Bateni & Olney, 2002). A well-fitting prosthesis provides more comfortable control of the residual limb. This suggested a benefit from improved prosthesis design that includes socket comfort and could also reduce the loading burden of the intact limb and the risk of degenerative joint OA (Royer & Wasilewski, 2006; Nolan & Lees, 2000).

The elevated vacuum suspension system (EVSS) has been cited as providing a better fitting socket and a superior prosthetic linkage compared to other suspension systems (Board et al., 2001; Klute et al., 2011; Goswami et al., 2003; Street, 2006). This system creates a strong coupling between the residual limb and prosthesis by drawing out air between the socket and liner. Previous studies have reported that the EVSS could effectively reduce vertical pistoning in the socket (Board et al., 2001; Klute et al., 2011), increase the rotational stability of residual limb (Papaioannou et al., 2009) and prevent volume loss and even promote slight volume gain of the residual limb (Goswami et al., 2003; Street, 2006). In addition to a stable socket volume, the EVSS showed a lower positive pressure impulse during stance and greater negative

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pressure impulse during swing duration compared with the pin suspension and suction suspension system (Beil & Street, 2004; Beil et al., 2002). This is important to amputees since positive pressure rather than negative pressure causes skin irritation and breakdown. Additionally, gait symmetry was found to improve at high vacuum conditions in contrast to no vacuum for step length and stance duration (Board et al., 2001). All of these effects of EVSS positively affect limb function and benefit the wearer with improved mobility and quality of life.

Although the number of amputees using the EVSS is growing quickly, a paucity of research has focused on the effect of different vacuum pressure settings including what should be considered a sufficient or preferred vacuum level. Questions about performance changes with vacuum level differences remain unanswered. One previous study investigated the effect of two intermediate vacuum levels (10 and 15 in Hg) and a suction condition on the residual limb volume with a single K2 transtibial amputee (Gerschutz et al., 2010). A significantly lower volume fluctuation with vacuum than suction condition was found and the two tested vacuum levels had similar absolute percent changes in volume. Another study evaluated the amputees' outcome from 8 to 20 in Hg using amputee feedback and vacuum pressure data (Gerschutz et al., 2011). The results suggested that most amputees preferred vacuum setting greater than 14 in Hg and vacuum pressure fluctuations decreased with an increase vacuum setting.

So far, the effects of EVSS on gait parameters at different vacuum levels have not been well quantified. What has been published only discusses two temporal gait parameters at one elevated vacuum (Board et al., 2001). Therefore, the purpose of this research was to address this gap and reveal the effect of vacuum levels on gait characteristics for unilateral transtibial amputees (TTA), including temporal parameters, kinematics and kinetics. The knowledge gained may benefit amputees, clinicians and prosthetic designers to better understand the effect of vacuum level on amputee gait.

2. Methods

2.1. Subjects

Eighteen adult male subjects participated in this study. Nine unilateral TTA currently using the EVSS comprised the sample of interest, with a mean (SD) age of 51.1 (16.1) years, height of 183.3 (6.0) cm, body mass of 94.8 (12.1) kg, and BMI of 28.3 (4.0) kg/m^2. These amputees were recruited from regional prosthetic clinics and were free from musculoskeletal disorders and leg pain, and did not require assistive devices for walking. Of these unilateral TTA, five amputations occurred due to trauma, one was vascular, and three resulted from other causes. All amputees had dynamic response prosthetic feet and mechanical vacuum pumps. Self-assessed K-activity levels were used to describe the activity and capability of the amputee. K1 is classified as the most limited category and K4 the most active (Medicare & Services, 2005). Seven unilateral TTA were K3 and two were K4 in this assessment, implying that all of the TTA in this study were capable of ambulating with variable cadence. The nine adult male control subjects were recruited from University of Utah and had a mean (SD) age of 27.8 (3.7) years, height of 180.1 (5.3) cm, body mass of 82.9 (17.7) kg, and BMI of 25.5 (4.8) kg/m^2. Each control subject was free from limb injuries or other disorders which would affect their gait. Institutional review board approval was obtained and all participants signed an informed consent document before participating in the study.

2.2. Procedures

Prior to the gait analysis, the Trinity Amputation and Prosthesis Experience Scales (TAPES) questionnaire was completed by amputees to assess various aspects of having an artificial limb including psychosocial adjustment issues, activity restriction and prosthesis satisfaction (Gallagher & MacLachlan, 2004). The portion of TAPES regarding activity restriction was also completed by the control group.

For the gait data collection, 14 mm reflective markers were attached bilaterally to the participants using a standard lower extremity and trunk modeling protocol common for clinical gait assessment (Davis et al., 1991). A static trial was performed for each subject to calibrate the marker set for that individual. A knee alignment device was placed on the knee in the static trial to assist in defining the frontal plane of the thigh segment. Subjects wore shoes during trials. For amputees, ankle markers on the prosthetic side were placed over the center of rotation of the prosthetic ankle joint and the markers on the prosthetic shank were placed to approximate the same location as the intact limb. All markers were placed by the same researcher to limit marker placement variability. Amputees wore their own personal socket and prosthesis during both static and dynamic trials. Three-dimensional motion data were captured with a ten-camera motion capture system (Vicon Motion Systems Ltd., Oxford, UK) at 100 Hz and GRFs were measured using four force plates (Advanced Mechanical Technology, Inc. Watertown, USA) at 1000 Hz.

A pressure measurement system (Fig. 1) was developed to measure vacuum pressure inside the socket. The gauge has a scale ranging from 0 to 30 in Hg with increments of 1 in Hg (Item no. VG150-18PBM, Anver Corporation, Hudson, USA). The gauge has an accuracy of 0.75 in Hg, according to the manufacturer. One length of hose (Tygon R-3603, Saint Gobain Performance Plastics, Akron, USA) connects the gauge to a brass tee having three barbs. Stemming from one side of the tee is another length of hose leading to a one-way check valve. One side of the one-way valve was connected to the vacuum socket of the prosthetic limb via a hose which is part of the prosthetic limb. As a result, pressure in the socket was directly measurable. A hand-held vacuum pump (Model MV8500, MityVac Corporation, St. Louis, USA) was connected to the third barb of the brass tee for pulling elevated vacuum levels in the vacuum socket.

Vacuum levels of 0, 5, 10, 15, and 20 in Hg were assigned in random order to unilateral TTA in a static standing position. Five trials with clean force plate strikes were collected for each limb at each vacuum level. Vacuum was monitored for every trial with the gauge attached to the prosthesis. If vacuum changed by more than 2 in Hg from the target value, the pump was reconnected and vacuum was pulled to the target level before continuing with more trials. After each set of trials, amputees were questioned to assess the prosthesis comfort level based on a scale from 1 to 10, with 10 being the highest level of comfort. Walking speed for amputees was controlled to be within the range of 1.20 to 1.40 m/s with a target of 1.30 m/s, which was similar to the adult preferred walking speed published in the literature (Kirtley et al., 1985; Öberg et al., 1993). This process was achieved by the instructions from a custom walking speed timing system described elsewhere (Greenland, 2012). Control subjects walked at their typical walking speed for five successful trials with each limb.

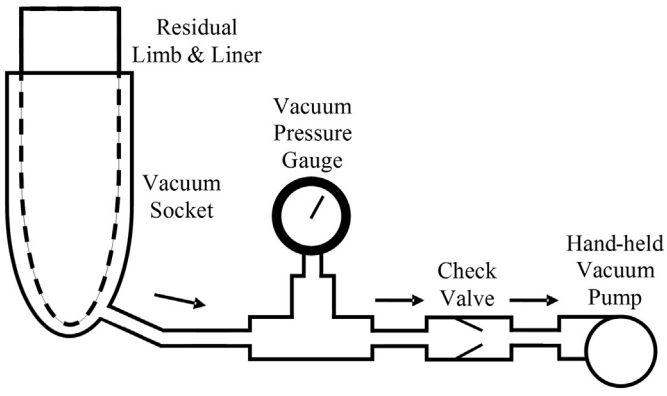

Fig. 1. Diagram of vacuum pressure measurement system.