ORIGINAL ARTICLE

Vacuum-Assisted Socket Suspension Compared With Pin Suspension for Lower Extremity Amputees: Effect on Fit, Activity, and Limb Volume

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ABSTRACT. Klute GK, Berge JS, Biggs W, Pongnumkul S, Popovic Z, Curless B. Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect on fit, activity, and limb volume. Arch Phys Med Rehabil 2011;92:1570-5.

Objective: To investigate the effect of a vacuum-assisted socket suspension system as compared with pin suspension on lower extremity amputees.

Design: Randomized crossover with 3-week acclimation.

Setting: Household, community, and laboratory environments.

Participants: Unilateral, transtibial amputees (N=20 enrolled, N=5 completed).

Interventions: (1) Total surface–bearing socket with a vacuum-assisted suspension system (VASS), and (2) modified patellar tendon–bearing socket with a pin lock suspension system.

Main Outcome Measures: Activity level, residual limb volume before and after a 30-minute treadmill walk, residual limb pistoning, and Prosthesis Evaluation Questionnaire.

Results: Activity levels were significantly lower while wearing the vacuum-assisted socket suspension system than the pin suspension (P=.0056; 38,000±9,000 steps per 2wk vs 73,000±18,000 steps per 2wk, respectively). Residual limb pistoning was significantly less while wearing the vacuum-assisted socket suspension system than the pin suspension (P=.0021; 1±3mm vs 6±4mm, respectively). Treadmill walking had no effect on residual limb volume. In general, participants ranked their residual limb health higher, were less frustrated, and claimed it was easier to ambulate while wearing a pin suspension compared with the VASS.

Conclusions: The VASS resulted in a better fitting socket as measured by limb movement relative to the prosthetic socket (pistoning), although the clinical relevance of the small but statistically significant difference is difficult to discern. Treadmill walking had no effect, suggesting that a skilled prosthetist can control for daily limb volume fluctuations by using conventional, nonvacuum systems. Participants took approximately half as many steps while wearing the VASS which, when coupled with their subjective responses, suggests a preference for the pin suspension system.

Key Words: Amputees; Lower extremity; Gait; Activities of daily living.

THE FIT BETWEEN A RESIDUAL lower limb and a prosthesis is a key determinant for successful ambulation.[1] A well-fit prosthesis provides a comfortable and functional limb, allowing pursuit of many vocational and recreational interests. Unfortunately, many amputees complain of an ill-fitting prosthesis.[1-4] Poor socket manufacturing[5,6] may play a role, but more than likely the problem is related to within-day residual limb volume losses caused by compressive forces acting on the limb during weight-bearing activities.[7] Failure to accommodate limb volume loss by donning additional socks can result in limb pistoning (axial movement of the limb relative to the socket), skin irritation or breakdown, discomfort, and/or a reduction in activity.

Application of a vacuum to the space between the prosthetic liner and socket may draw fluids into the residual limb during non–weight-bearing activities, resulting in a more consistent fit and obviating the need for donning additional socks.[8,9] When tethered to an external pump at a constant high vacuum, subjects actually gained limb volume after walking on a treadmill.[8] Intentionally oversizing the sockets resulted in even greater limb volumes.[9] These results suggest that a consistent fit could be maintained by vacuum systems through the course of everyday activities instead of the deterioration sometimes witnessed by individuals wearing nonvacuum systems.

The purpose of this study was to compare the fit and function of 2 different, but widely prescribed, socket and suspension systems: a total surface-bearing socket with a vacuum-assisted suspension system (VASS), and a modified patellar tendon-bearing socket with a pin lock suspension system. Hypotheses for activity level, limb volume before and after a 30-minute treadmill walk, and limb pistoning were tested in a randomized crossover experiment with unilateral transtibial amputees. A subjective comparison was also performed using a questionnaire.

METHODS

Participants

Unilateral, transtibial amputees between 18 and 70 years of age who were able to walk on a treadmill for 30 minutes were

List of Abbreviations

PEQ	Prosthesis Evaluation Questionnaire
PIN	pin suspension system
VASS	vacuum-assisted suspension system

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eligible to participate in this study. Amputees of diabetic or dysvascular etiology must have worn a prosthesis for at least 1 year; all others must have been 6 months postamputation and have worn a prosthesis for at least 4 months. Individuals were excluded if they had a disorder, pain, or injury that interfered with their gait.

Prosthetic Interventions

Two study limbs were built and aligned for each subject by a certified and licensed prosthetist with 15 years of clinical experience, before beginning the experimental protocol. The VASS included a custom urethane TEC liner[a] or a polyurethane Profile Liner,[a] a Harmony sleeve,[a] a Harmony vacuum pump,[a] a total surface-bearing socket, an aluminum pylon, and a Seattle Lightfoot2[b] prosthetic foot. The prosthetist had been trained by the manufacturer to fit the VASS system. Two manufacturer representatives witnessed a fitting at the study beginning; neither recommended any significant changes to our fitting practice. Plaster casts of the residual limb, formed using a 3-stage vacuum casting technique (−68kPa), were undersized by 10% of their circumference to size the liner and 4% to fabricate the socket. Most of the castings and subsequent fittings occurred on the same day, and all were within 7 days of each other. The pin suspension system (PIN) included an Alpha Spirit, uniform, 6-mm-thick liner with an integrated locking pin,[c] a modified patellar tendon-bearing socket, an aluminum pylon, and a Seattle Lightfoot2 prosthetic foot. Passive plaster casts of the residual limb were formed over the gel liner and a nylon sock, and modified to preferentially distribute weight through the patellar tendon, medial tibial flare, lateral fibular flare, and both the pretibial and posterior musculature. When necessary or desired, all subjects had available Knit-Rite Soft-Socks[d] to wear. The number of check sockets and the time to achieve a successful fit were recorded to document the fitting process.

Protocol

Subjects were randomly assigned to study limb and fit with an activity monitor. After a 3-week acclimation, subjects returned to the laboratory where their overground self-selected walking speed was measured while walking down a 20-m hallway 3 repeated times. Subjects were then fit with a safety harness to reduce risk while stepping in and out of the limb scanner. Once seated in the scanner, the subject doffed the study prosthesis, and a permanent ink marker was used to mark 6 equidistant points on the skin around the circumference of the lower leg at the height of the tibial tuberosity, specifically including the skin above the center of the tibial tuberosity itself and above the center of the fibular head. Subjects then donned their study prosthesis, climbed out of the limb scanner, and stood in place for 5 minutes to allow their limb volume to reach a steady-state condition within their socket. Subjects then stepped back into the limb scanner, quickly doffed their study prosthesis, and the preexercise limb scanning sequence began. Once complete, the subject donned the study prosthesis and walked for 30 minutes on a motorized treadmill. The speed was self-selected during the first few minutes and then held constant. Postexercise, subjects quickly doffed their study prosthesis, and the limb scanning sequence was repeated.

Subjects again donned the study prosthesis, and a triad of 14-mm reflective markers was adhered to the proximal lateral aspect of the socket at the knee joint center and another triad to the residual limb thigh. Subjects then stood in place and shifted their weight from side to side to enable measurement of limb pistoning. The time between donning the prosthesis and obtaining these measurements was approximately 20 minutes while the retroreflective markers were placed on the standing subject.

Subjects continued to wear the study prosthesis for 1 additional week after which they returned to the laboratory to provide responses to the Prosthesis Evaluation Questionnaire (PEQ)[2] and to download step activity measurements. Subjects then switched to the other study prosthesis and repeated the protocol.

Outcomes

Activity level. To measure participant activity levels,[10-13] each was fit with an instrument[e] to record the total number of steps occurring in 1-minute intervals during the last 2 weeks while wearing each study limb.

Residual limb volume. To measure limb volume, subjects were asked to sit on a bicycle seat mounted on a custom fixture (fig 1). The residual limb was extended downward and then scanned by an optical measurement system consisting of 6 scanning units. Each scanning unit consisted of a stereo pair of cameras[f] mounted adjacent to a video projector.[g] Five scanning units were positioned equally around and below the subject, and one was positioned directly beneath the subject; all were approximately 1m away from the subject with unobstructed views.

The scanner operates on the principle of stereo matching of structured light. Stereo shape capture generally consists of aiming 2 cameras at a subject, recording 2 images, and then, for each pixel in 1 image, finding the corresponding pixel in the other image. Given a calibrated camera pair, each corresponding pair of pixels maps to vectors that intersect on the surface of the object. The projection of structured light (a pattern of known geometry) onto the contoured limb surface enables detailed shape capture and reconstruction, the accuracy of which is enhanced by using moving patterns with multiple projector-camera pairs.[14,15] Each complete scan, captured in .217 seconds, consisted of 13 image pairs from each of the 6 projector-camera pairs. These were combined to form a mesh that had a positional accuracy of 0.1mm (root mean square)

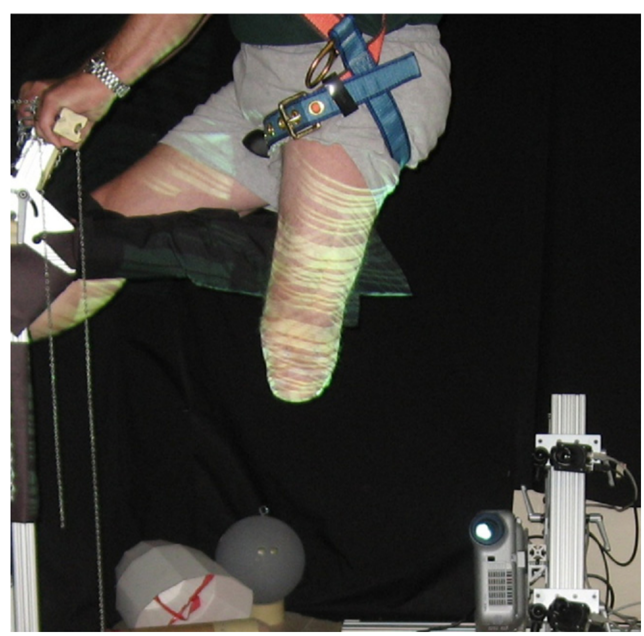

Fig 1. Lower limb scanner used to measure residual limb volumes. One projector-camera pair of the 6 used to project structured light onto the residual limb is shown above.