

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 ($P=.0056$; $38,000\pm 9,000$ steps per 2wk vs $73,000\pm 18,000$ 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 ± 3 mm vs 6 ± 4 mm, 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 approxi-

mately 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.

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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)

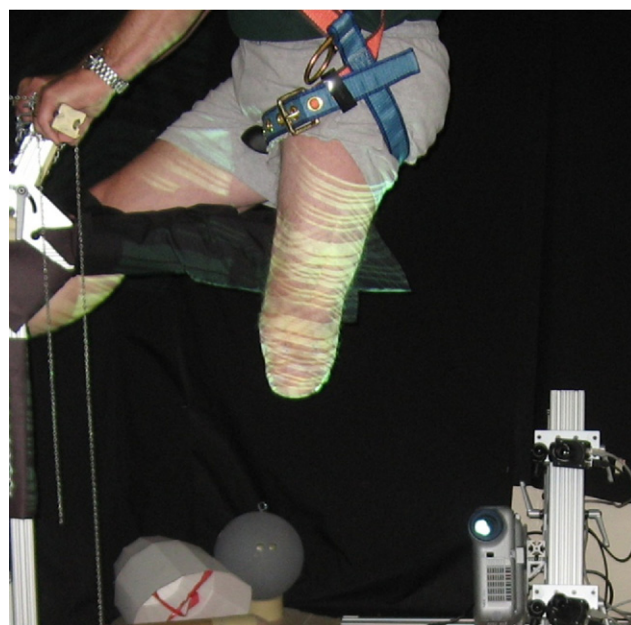


Fig 1. Lower limb scanner used to measure residual limb volumes. One projector-camera pair of the 6 used to project structured light onto the residual limb is shown above.

over the 8-L working volume. The limb volume was calculated by transecting the mesh through the 6 equidistant marks on the lower leg. Once the subject was in place in the scanner, doffing the prosthesis took approximately 15 seconds. Experimental conditions were statistically compared using the limb volume calculated from the first complete scan. To assess measurement repeatability, 4 additional complete scans were captured immediately after the first scan. Thus, the initial scans consisted of 5 complete scans obtained in the first 1.085 seconds. Thereafter, a complete scan was captured once every minute for the next 7 minutes. The first complete scan and the subsequent 7 scans were used to examine how the limb volume changed over time by using the following exponential function:

$$V(t) = V(\infty) - \Delta V e^{-kt}$$

where t is time in minutes, $V(t)$ is the limb volume at time t , $V(\infty)$, is the steady-state limb volume without a prosthesis that would be exponentially approached at infinite time, and ΔV is the difference between $V(\infty)$ and limb volume at the moment of doffing ($V(0)$). Goodness of fit was measured with Pearson's r . These curve fits were used to estimate the time required to reach 50% and 95% of the total volume change after doffing.

Limb pistoning. The change in the resultant distance between the prosthetic-side knee joint marker triad and the residual limb thigh triad was measured using a 12-camera motion analysis system^h while subjects weighted and unweighted their prosthesis standing in place.

Prosthesis Evaluation Questionnaire. Qualitative differences between the study limbs were assessed using the PEQ.^{16,17} This standardized, self-report instrument is specific to persons with lower limb amputations and is used to evaluate the prosthesis and life with the prosthesis by using a health-related quality-of-life framework.² Three scales measuring residual limb health (6 questions), ambulation (8 questions), and frustration (2 questions) were scored. Residual limb health questions examined sweat, smell, volume changes, rashes, ingrown hairs, and blisters. Ambulation questions queried ability to walk in general, in close spaces, on stairs and ramps, in urban environments, and on slippery surfaces. Frustration was assessed by frequency of occurrence and rating. All scales were scored so that 100 indicated the best outcome (ie, most healthful, easiest to walk on, least frustrating).

Data Analysis

The effect of the study limb on activity level, limb volume, and limb movement relative to the socket was analyzed using repeated-measures 1-way analyses of variance. Analyses were carried out using R 2.9.0 software.¹ Statistical significance was set at $P < .05$. No statistical analyses were performed on the PEQ self-report data because of the small sample size and greater expected variances.

RESULTS

Twenty individuals gave informed consent to participate in this institutional review board-approved protocol. Three withdrew before beginning the study protocol. One individual had contralateral knee surgery, 1 became a bilateral amputee, and 1 was withdrawn for compliance concerns raised by the participant's physician.

Twelve subjects terminated the protocol before completion (9 traumatic, 3 dysvascular). Eleven wore pin suspensions at the time of recruitment, and 1 wore a vacuum-assisted suspen-

sion from a different manufacturer. Nine early terminators had been successfully fit with the VASS and required 2.3 ± 1.4 check sockets (mean \pm SD) during a 3.2 ± 2.5 -week period. Seven early terminators had been successfully fit with the PIN and required 1.6 ± 0.5 check sockets during a 1.6 ± 0.5 -week period. Explanations given for terminating included problems or issues with the VASS ($n=4$), illness or limb health issues ($n=4$), excessive protocol time commitment ($n=3$), or did not like the study limb prosthetic foot ($n=1$).

Five subjects completed the protocol (4 traumatic, 1 dysvascular; mean age \pm SD, 56 ± 9 y; mean time \pm SD postamputation, 13 ± 15 y; mean body mass \pm SD, 84 ± 11 kg; mean height \pm SD, $1.78 \pm .11$ m). All 5 wore pin suspensions at the time of recruitment. VASS fitting required 3.4 ± 0.5 check sockets during a 3.4 ± 0.5 -week period. PIN fitting required 1.4 ± 0.5 check sockets during a 1.2 ± 0.4 -week period. The 5 who completed the protocol were the 3rd, 4th, 8th, 16th, and 18th subjects recruited. Their overground self-selected walking speed was 1.3 ± 0.2 m/s, while their treadmill self-selected walking speed was $.8 \pm 0.3$ m/s.

Outcomes

The activity level was significantly less ($P=.0056$) when subjects wore the VASS ($38,000 \pm 9,000$ steps per 2wk) when compared with the PIN ($73,000 \pm 18,000$ steps per 2wk).

The limb volume, independent of exercise, was not statistically different ($P > .05$) for the VASS ($.72 \pm .13$ L) compared with the PIN ($.68 \pm .14$ L). The 30-minute treadmill walk had no effect on limb volume ($P > .05$); pretreadmill volume was $.70 \pm .14$ L compared with a posttreadmill volume of $.69 \pm .13$ L. Measurement variability, defined as the limb volume SD as a percentage of the mean (obtained over a 1.085-s period), ranged from $\pm 0.1\%$ to $\pm 1.5\%$.

Doffing the prosthesis resulting in a rapid change in limb volume for the PIN postexercise, VASS preexercise, and VASS postexercise conditions; all exhibited rapid increases in limb volume immediately after doffing the prosthesis that plateaued in less than 10 minutes (fig 2). Modeling the volume change with an exponential function was warranted ($r > .97$) for these 3 experimental conditions. The modeling results (table 1) suggest that the residual limb will eventually experience a 4.5% increase in volume after doffing the PIN postexercise, a 4.1% increase after doffing the VASS preexercise, and a 6.3% increase after doffing the VASS postexercise. Half of the change in volume occurred in less than 2 minutes, and 95% of it occurred in less than 8 minutes. An exponential function curve for PIN preexercise could not be fit for real values of $V(0)$ with a goodness of fit greater than .42; therefore, no model results are presented for this condition.

Limb pistoning was less ($P=.0021$) for the VASS (1 ± 3 mm) compared with the PIN (6 ± 4 mm).

Subjects opined that their residual limb was healthier while wearing the PIN (90 ± 5) compared with the VASS (77 ± 20), it was easier to ambulate while wearing the PIN (95 ± 6) compared with the VASS (67 ± 22), and it was less frustrating while wearing the PIN (91 ± 11) compared with the VASS (43 ± 29).

DISCUSSION

Retaining subjects was a significant challenge. Those who completed the protocol were evenly distributed during the recruitment period, suggesting that prosthetist experience in fitting the prostheses was not a factor. However, fitting the VASS was more complicated than fitting the PIN because more check sockets and additional time were required to obtain an adequate fit.

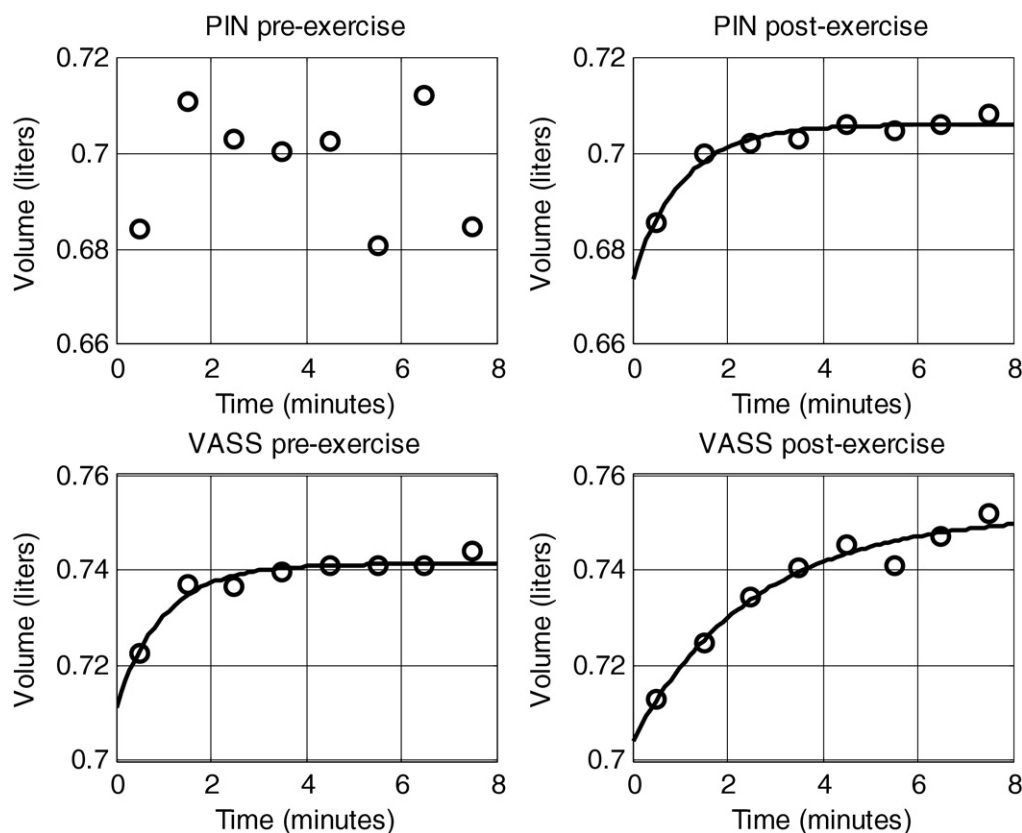


Fig 2. Residual limb volume and recovery after doffing. Modeling the change in residual limb volume with an exponential function was warranted ($r > .98$) for 3 of the 4 experimental conditions.

The activity level of individuals while wearing the PIN was nearly twice that with the VASS. On a per day basis, neither the PIN (5214 steps/d) nor the VASS (2714 steps/d) dropped below the 1450 steps/d threshold for remaining a community ambulator,¹⁸ indicating that either prescription would enable individuals to live independently.

The VASS was able to maintain a constant limb volume after a 30-minute treadmill walk. With the use of a similar prosthesis, with the exception of a tethered pump to apply a high vacuum, a 30-minute treadmill walk resulted in a limb volume increase⁸ (3.7%), while an 18-minute treadmill walk resulted in a slight limb volume decrease⁹ (-2.0%). The pump used in this study is operated by body weight forces, which may result in variable vacuum levels; however, the limb volume after the 30-minute treadmill walk (.70±.12L) was the same as before (.70±.12L). The PIN was also able to maintain a constant limb volume; the limb volume after (.68±.13L) the treadmill walk was only slightly decreased (-0.6%) from before (.69±.14L).

For 3 conditions (PIN postexercise, VASS preexercise, VASS postexercise), the rapid change in limb volume could be accurately represented with an empirical exponential function.

Fifty percent of the limb volume change can be estimated to occur in less than 2 minutes, and within 95% of the steady-state volume in less than 8 minutes. Doffing a total surface bearing socket, made with a passive casting procedure and global modification, after a 200-m walk also produced a rapid change in limb volume; the time to reach 95% of the steady-state volume was between 2.9 and 7.7 minutes for 4 of 6 subjects (the other 2 had quite variable data).⁷

Several factors can exert a deleterious influence on the accurate measurement of limb volume including the rate at which volume changes may occur after doffing, amputation etiology, and socket fabrication methods. After doffing a prosthesis, rapidly changing limb volumes necessitate the use of a fast instrument. The optical scanner used in this study (<.22s capture time) was significantly faster than the 3 minutes needed for casting methods,^{8,9} but doffing the limb was still required. Bioimpedance estimates of extracellular fluid volume¹⁹ obviate the need for doffing.

Amputation etiology may also influence limb volume outcomes; limbs of traumatic or congenital etiology change volume more slowly and by a smaller amount than limbs of

Table 1: Residual Limb Volume Changes as Predicted by an Exponential Model

Experimental Condition	$V(\infty)$ (L)	ΔV (mL)	Exponential Constant	Pearson's r	$T_{50\%}$ ΔV (min)	$T_{95\%}$ ΔV (min)
PIN preexercise	NA	NA	NA	<.42	NA	NA
PIN postexercise	.71	32	0.95	.98	0.7	3.2
VASS preexercise	.74	30	1.01	.97	0.7	3.0
VASS postexercise	.75	47	0.39	.98	1.8	7.7

Abbreviations: $T_{50\%}$, time to achieve a 50% change in limb volume; $T_{95\%}$, time to achieve a 95% change in limb volume; $V(\infty)$, steady state limb volume without a prosthesis at infinite time; ΔV , the difference between $V(\infty)$ and $V(0)$.

dysvascular etiology.²⁰ None of the subjects who participated in the tethered high-vacuum studies,^{8,9} and only 1 of the 5 who completed this protocol were dysvascular, suggesting that the populations in these studies are comparable.

Importantly, the VASS exhibited statistically less pistoning compared with the PIN. The difference necessary for clinical significance is unknown, but less movement may reduce the incidence of residual limb injuries, lower back pain, or intact limb degenerative knee arthritis.²¹ X-ray measurements using the tethered high-vacuum suspension showed a 4-mm limb movement,⁸ more than the 1mm reported here. The difference may simply be measurement technique.

The questionnaire results suggest a preference for the PIN over the VASS, but the small number of participants who completed the protocol precludes statistical analysis. The residual limb health scale asks the respondents to rate how much they sweat inside the prosthesis, how smelly it is, how often swelling occurred that changed the fit of the prosthesis, and the occurrence of any rashes, ingrown hairs, and blisters or sores. The participants rated that their residual limb was healthier while wearing the PIN. The ambulation scale asked respondents to rate their ability while wearing their prosthesis to walk in general, walk in close spaces, up stairs, down stairs, up a steep hill, down a steep hill, on sidewalks and streets, and on slippery surfaces. The participants rated their abilities higher while wearing the PIN. The frustration scale simply asked respondents to rate how frequently they were frustrated with their prosthesis, and if they were frustrated, to rate the level of the most frustrating event. The participants rated the PIN less frustrating.

The suspension choice is mired with trade-offs. Locking pins can provide close, secure contact during gait, but the peak negative pressure and pressure impulse during the swing phase of gait can be higher than suction suspension, which may result in distal end skin problems.²² Suction suspensions may be straightforward to don, but can also exhibit distal end skin problems.²³ Vacuum suspensions may not only prevent the skin problems, but there is some evidence to suggest they may accelerate healing.^{24,25}

Study Limitations

An important limitation of the study is that the prestudy prosthetic prescription of all individuals who completed the protocol was a PIN suspension. A 3-week period was provided to acclimate participants to the study prostheses, but some subjects might require a longer period. Retaining subjects was also challenging. Further research on suspension systems might use less arduous methods to improve participant enrollment and increase the size of the sample population.

CONCLUSIONS

The VASS resulted in a better fitting socket as measured by limb 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 using conventional, nonvacuum systems. Participants took approximately half as many steps while wearing the VASS, which, when coupled with their subjective responses, suggest a patient preference for the PIN. The need for fewer check sockets and a shorter time to obtain an adequate fit suggest a clinician preference for the pin suspension.

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