Clinical Policy Bulletin: Prosthetic Limb Vacuum Systems

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Policy

Aetna considers the eVAC, the Harmony Vacuum Management System (Vacuum Assisted Socket System (VASS)), and the LimbLogic VS Prosthetic Vacuum Suspension System, specialized vacuum pump residual limb volume management and moisture evacuation systems medically necessary for use with lower limb prostheses to increase suspension and proprioception and improve gait.

See also CPB 0578 - Lower Limb Prostheses.

Background

The Vacuum Assisted Socket System (VASS), developed by Total Environmental Control (TEC), is a specialized device used with artificial limbs to manage residual limb volume fluctuation in amputees. The system consists of a TEC liner, suspension sleeve and air evacuation pump. The device creates an elevated vacuum between the liner and the socket wall. The elevated vacuum promotes natural fluid exchange that regulates volume fluctuation in the residual limb, reduces forces to the residual limb, and increases suspension and proprioception. The manufacturer claims that the enhanced linkage from the vacuum between the liner and the socket wall decreases weight and promotes an improved gait.

Murphy (2014) stated that elevated vacuum systems are a form of suspension that is becoming more often used and seen in the younger population of wearers requiring a continued level of suspension throughout a variety of activities. An elevated vacuum system uses a draw pump to draw air out of the socket pulling air from between the residuum and the inner socket to maintain the tissue against the walls of the socket at a desired level of a vacuum within the confines of the socket, thus preventing movement in all
directions. The suspension is not for those with inconsistent volume loss requiring frequent sock ply management.

According to the manufacturer, studies conducted at St. Cloud (MN) State University indicate a daily volume loss of 6 to 12% in the residual limb (wearing liner, sealing sleeve and expulsion valve). The same sample group (with VASS Technology) lost less than 1% of residual limb volume. Current published peer-reviewed evidence for the VASS consists of two small un-blinded studies. One study involving 9 amputees compared peak pressures between skin and liner during stance and swing phases during a 20-min walk with a standard prosthetic socket and a vacuum-assisted socket (Bell et al, 2002). Another study examined stump volume in 10 amputees before and after a 30-min walk (Board et al, 2001). Neither of these studies examined the effect of VASS on clinical outcomes (reductions in disability or improvement of function).

In a randomized cross-over study, Klute et al (2011) examined the effect of a VASS system as compared with pin suspension on lower extremity amputees. Unilateral, trans-tibial amputees (n = 20 enrolled, n = 5 completed). Interventions were (i) total surface-bearing socket with a VASS, and (ii) modified patellar tendon-bearing socket with a pin lock suspension system. Main outcome measures included activity level, residual limb volume before and after a 30-min treadmill walk, residual limb pistoning, and Prosthesis Evaluation Questionnaire. Activity levels were significantly lower while wearing the VASS system than the pin suspension (p = 0.0056; 38,000 +/- 9,000 steps per 2 wk versus 73,000 +/- 18,000 steps per 2 wk, respectively). Residual limb pistoning was significantly less while wearing the VASS system than the pin suspension (p = 0.0021; 1 +/- 3 mm versus 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. The authors concluded that 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, non-vacuum systems. Participants took approximately 50% as many steps while wearing the VASS which, when coupled with their subjective responses, suggests a preference for the pin suspension system.

Sanders et al (2011) employed bioimpedance analysis to measure the residual limb fluid volume of 7 transtibial amputee subjects using elevated vacuum sockets and non-elevated vacuum sockets. Fluid volume changes were assessed during sessions with the subjects sitting, standing, and walking. In general, fluid volume losses during 3- or 5-min walks and losses over the course of the 30-min test session were less for elevated vacuum than for suction. Numerous variables, including the time of day that data were collected, soft tissue consistency, socket-to-limb size and shape differences, and subject health, may have affected the results and had an equivalent or greater effect on limb fluid volume compared with elevated vacuum. Researchers should well consider these variables in the study design of future investigations on the effects of elevated vacuum on residual limb volume.

The results from this series of case studies did not consistently demonstrate that elevated vacuum maintained or increased limb fluid volume nor do they consistently demonstrate that elevated vacuum had no effect. Instead, elevated vacuum maintained or increased limb fluid volume on 6 of the 7 subjects and affected some measures of limb fluid volume change but not others. Results from these cases suggested that in future research efforts evaluating elevated vacuum, researchers need to consider a number of study design variables that may influence limb volume change measurements. These variables need to be considered when test results between 2 different conditions (e.g., elevated vacuum
versus suction) are compared. Variables include:

- Limb soft tissue mechanical consistency
- Size of residual limb relative to size of socket
- Socket shape
- Subject health
- Time after donning that measurements are taken (if out-of-socket measurement technique used)
- Time into session that measurements are made and ordering of interventions within a session
- Time of day of test
- Use of elevated vacuum as the regular prosthesis (i.e., subject accommodation)
- Weight differences between prostheses tested

The authors concluded that this series of case studies on 7 subjects showed that some subjects demonstrated less decrease (or more increase) in limb fluid volume using sockets with elevated vacuum compared with suction sockets or lock-and-pin suspension sockets, while others did not. Some measures of limb fluid volume changed consistently, while others did not. A number of variables may affect limb fluid volume change. When designing future research studies, investigators need to consider these variables in study design, particularly when comparing elevated vacuum to another socket design.

In a randomized controlled study, Traballesi et al (2012) examined the effects of a vacuum-assisted socket system (VASS) in a sample of trans-tibial amputees with wounds or ulcers on the stump and evaluated prosthesis use as a primary outcome. Secondary outcome measures were mobility with the prosthesis, pain associated with prosthesis use, and wound/ulcer healing. A total of 20 dysvascular trans-tibial amputees suffering from ulcers due to prosthesis use or delayed wound healing post-amputation were enrolled. Participants were separated into 2 groups: (i) the experimental group was trained to use a VASS prosthesis in the presence of open ulcers/wounds on the stump; and (ii) the control group was trained to use a standard suction socket system prosthesis following ulcers/wounds healing. At the end of the 12-week rehabilitation program, all VASS users were able to walk independently with their prosthesis as reflected by a median Locomotor Capability Index (LCI) value of 42, whereas only 5 participants in the control group were able to walk independently with a median LCI value of 21. At the 2-month follow-up, the participants used their VASS prostheses for 62 hours a week (median; range of 0 to 91), which was significantly longer than the control group using the standard prosthesis for 5 hours per week (range of 0 to 56, p = 0.003). At the 6-month follow-up, the difference between VASS-users (80, range of 0 to 112 hours a weeks) and control-users (59, range of 0 to 91) was no longer significant (p = 0.191). Despite more intense use of the prosthesis, pain and wound healing did not significantly differ between the 2 groups. The authors concluded that these findings showed that the VASS prosthesis allowed early fitting with prompt ambulation recovery without inhibiting wound healing or increasing pain.

Residual limb wounds are typically treated by suspension of prosthetic use until healing occurs, increasing the risk of long-term prosthesis nonuse. Sockets with vacuum-assisted suspension may reduce intra-socket motion and be less disruptive to wound healing. Hoskins, et al. (2014) conducted a case series to measure residual limb wound size over time in persons with transtibial amputation while using prostheses with vacuum-assisted suspension. Six subjects with residual limb wounds were fit with vacuum-assisted suspension sockets. Wound surface area was calculated using ImageJ software at the time of fit and each subsequent visit until closure. Average wound surface area at initial measurement was 2.17 ± 0.65 cm²(2). All subjects were instructed to continue their normal activity level while wounds healed, with a mean of 177.6 ± 113 days to wound closure. The
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Investigators concluded that results suggest that well-fitting sockets with vacuum-assisted suspension in compliant individuals did not preclude wound healing. The investigators stated that further research is required to substantiate these case-based observations.

Komolafe et al (2013) noted that despite increasingly widespread adoption of vacuum-assisted suspension systems in prosthetic clinical practices, there remain gaps in the body of scientific knowledge guiding clinicians’ choices of existing products. In this study, these researchers identified important pump-performance metrics and developed techniques to objectively characterize the evacuation performance of prosthetic vacuum pumps. The sensitivity of the proposed techniques was assessed by characterizing the evacuation performance of 2 electrical (Harmony e-Pulse [Ottobock; Duderstadt, Germany] and LimbLogic VS [Ohio Willow Wood; Mt. Sterling, OH, USA]) and 3 mechanical (Harmony P2, Harmony HD, and Harmony P3 [Ottobock]) prosthetic pumps in bench-top testing. Five fixed volume chambers ranging from 33 cm(3) (2 in(3)) to 197 cm(3) (12 in(3)) were used to represent different air volume spaces between a prosthetic socket and a liner-clad residual limb. All measurements were obtained at a vacuum gauge pressure of 57.6 kPa (17 in Hg). The proposed techniques demonstrated sensitivity to the different electrical and mechanical pumps and, to a lesser degree, to the different setting adjustments of each pump. The authors concluded that the sensitivity was less pronounced for the mechanical pumps, and future improvements for testing of mechanical vacuum pumps were proposed. The authors noted that overall this study offered techniques that are feasible as standards for assessing the evacuation performance of prosthetic vacuum pump devices.

Kuntze Ferreira and Neves (2015) compared gait deviations between Kondylen Bettung Münster (KBM) and vacuum prosthetic fitting using the Gait Profile Score (GPS), the Movement Analysis Profile (MAP) and temporal-spatial parameters. Seventeen transtibial amputees that received their prosthesis from the Brazilian governmental health system participated in this study. Twelve of them used KBM prosthetic fitting on their prosthesis and five used vacuum prosthetic fitting. Kinematic and temporal-spatial parameters data were captured by a six-camera Motion Analysis system (Santa Rosa, CA). The results showed that the vacuum group walked faster than the KBM group but the differences in temporal-spatial parameters between them were not significant. The GPS for the intact limb (IL) and the overall GPS differentiated between the groups of prosthetic fitting. Hip flexion/extension and knee flexion/extension were higher in KBM group than in the vacuum group, although only knee flexion/extension for the intact limb revealed significant difference between the groups. In KBM group, the major deviations were in hip flexion/extension for both limbs, knee flexion/extension for both limbs and ankle dorsi/plantar flexion for the prosthetic limb. The vacuum group showed deviations especially in ankle dorsi/plantar flexion for both limbs, knee flexion/extension for the prosthetic limb and hip rotation for the prosthetic limb. Besides, the vacuum group was more symmetrical than the KBM group. This study concluded that subjects who used vacuum prosthetic fitting presented smaller gait deviations and a more symmetrical gait than those who used KBM prosthetic fitting.

Samitier, et al. (2014) investigated the effect of vacuum-assisted socket system on transtibial amputees’ performance-based and perceived balance, transfers, and gait. Subjects were initially assessed using their prosthesis with the regular socket and re-evaluated 4 weeks after fitting including the vacuum-assisted socket system. We evaluated the mobility grade using Medicare Functional Classification Level, Berg Balance Scale, Four Square Step Test, Timed Up and Go Test, the 6-Min Walk Test, the Locomotor Capabilities Index, Satisfaction with Prosthesis (SAT-PRO questionnaire), and Houghton Scale. A total of 16 unilateral transtibial dysvascular amputees, mean age 65.12 (standard deviation = 10.15) years were included. Using the vacuum-assisted socket system, the patients significantly improved in balance, gait, and transfers: scores of the Berg Balance
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Scale increased from 45.75 (standard deviation = 6.91) to 49.06 (standard deviation = 5.62) \((p < 0.01)\), Four Square Step Test decreased from 18.18 (standard deviation = 3.84) \(s\) to 14.97 (3.9) \(s\) \((p < 0.01)\), Timed Up and Go Test decreased from 14.3 (standard deviation = 3.29) \(s\) to 11.56 (2.46) \(s\) \((p < 0.01)\). The distance walked in the 6-Min Walk Test increased from 288.53 (standard deviation = 59.57) \(m\) to 321.38 (standard deviation = 72.81) \(m\) \((p < 0.01)\). The investigators concluded that vacuum-assisted socket systems are useful for improving balance, gait, and transfers in over-50-year-old dysvascular transtibial amputees.

CPT Codes / HCPCS Codes / ICD-9 Codes

Other CPT codes related to the CPB:

97760 - 97762  Orthotics management and prosthetic management

HCPCS codes not covered for indications listed in the CPB:

L5781  Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system [includes eVAC and LimbLogic VS Prosthetic Vacuum Suspension System methods]

L5782  Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system, heavy duty [includes eVAC and LimbLogic VS Prosthetic Vacuum Suspension System methods]

Other ICD-9 codes related to the CPB:

755.20 - 755.29  Reduction deformities of upper limb

755.30 - 755.39  Reduction deformities of lower limb

886.0 - 887.7  Traumatic amputation of other finger(s), arm, and hand (complete) (partial)

895.0 - 897.7  Traumatic amputation of toe(s), foot, or leg (complete) (partial)

997.60 - 997.69  Amputation stump complication

V49.60 - V49.67  Upper limb amputation status

V49.70 - V49.77  Lower limb amputation status

The above policy is based on the following references:


3. Board WJ, Street GM, Caspers C. A comparison of trans-tibial amputee suction and
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