The Effect of Elevated Vacuum Suspension Systems on Unilateral Transtibial Wound Healing

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Clinical Question: Does the use of elevated vacuum suspension (EVS) have a direct and beneficial impact on residual limb wound healing among unilateral transtibial (TT) prosthesis users?

Background: The recent introduction and incorporated clinical use of the elevated vacuum system as a viable suspension method for lower limb prosthetic users has been presented as having multiple purported benefits with favorable outcomes for lower limb amputees[1-8]. Although not dissimilar in concept from suction suspension, EVS instead incorporates active vacuum levels using a draw pump to create a consistent negative pressure environment between the socket and the liner[1-5, 8]. The use of sub-atmospheric pressure systems to adhere the limb to the prosthesis within this closed system introduces differing force systems both within and external to the residual limb when compared to traditional suspension methods. As a result of this, theoretical benefits from EVS include maximizing perfusion within the limb[1, 2, 8], and eliminating movement between the socket and liner[1, 4, 5], which reduces pistoning[3, 4, 8], improves prosthetic control[1], and enhances user proprioception[5]. Other texts and qualitative studies suggest that EVS influences the risk of skin issues developing[1, 8] and improves wound healing[4, 5, 6, 7], while users have also reported enhanced socket comfort[1, 2, 8] and a better sense of balance[1, 8]. Current standard procedure is to discontinue prosthetic use once an open wound develops for fear of worsening it during weight-bearing activities, but it inhibits rehabilitative efforts and diminishes the patient's quality of life. Maintaining the health of the residual limb is therefore a principal concern among lower limb amputees.

A 2011 outcomes survey collated by Ferraro compared 13 patient responses comparing EVS to pin suspension, with significantly higher ABC scores for EVS users and better reported outcomes regarding pistoning, blister formation, and reduced skin breakdowns in favor of EVS[8]. However, a systematic review by Kahle, et al., in 2014 designated only two peer-reviewed articles that addressed the impact of EVS usage on wound healing, with uncertain supportive results, within the existing body of evidence, finding a large majority of studies to be anecdotal[11]. Therefore, the goal of this critically appraised topic is to assess existing studies on whether EVS systems have a direct and clinically significant impact in assisting with wound healing compared to non-EVS systems. If so, the body of evidence that informs clinical decisions can support the use of EVS as an option in patients with chronic ulceration, multiple skin issues, and reoccurring wounds, rather than prosthetic disuse in favor of wound management.

Search Strategy:
Databases Searched: PubMed, Journal of Prosthetics and Orthotics (www.oandp.org), CINAHL
Search Terms: (wound OR wound care OR wound management OR wound healing OR ulcer) AND (vacuum OR vacuum-assisted OR elevated vacuum OR vacuum suspension OR active suction OR sub-atmospheric) AND (amputee OR transtibial OR prosthetics OR prosthesis) *Exact key terms and operators used in engine search.
Inclusion Criteria: Transtibial amputees, 2000 to present day, national or international studies, written or translated English

Synthesis of Results: Three studies[9, 10, 12] and one systematic review[11] looked at the effectiveness of EVS as an intervention in wound healing amongst a total of 36 participants, of which 32 were retained for final analysis. The study designs were diverse, with two randomized designs (one controlled[9], and the other crossover[12]), a case series involving six subjects[10], and a systematic review[11] regarding this appraisal's topic. The two randomized studies[9, 12] compared vacuum-assisted systems and alternative suspension methods, with similar follow-up timelines at 36[9] and 32 weeks[12]. Key results from two studies showed that all residual limb wounds healed over the period of study[9, 10] and that the use of an EVS prosthesis did not inhibit the eventual healing of open wounds[9], although some subjects from both studies report incidences of reopened wounds or developed new ones during the course of the study[9, 10]. The review by Kahle, et al., found that the 2012 Traballesi study also contained a high risk of bias, that was not elaborated on, despite it meeting the qualifications of a peer-reviewed study employing objective measures. The study by Rink, et al., supports many of the purported benefits of EVS, in that physiological qualities that contribute to skin issues and wound development, such as reactive hyperemia, skin barrier function, and perfusion, showed improved results in an EVS system compared to standard pin or suction prostheses[12]. Limitations across the three studies included small sample sizes[9, 10, 12], and the inability to reinforce compliance and correct usage of EVS[9, 12], while individual limitations included a high attrition rate[9], and lack of a control group for comparison[10].

Clinical Message: While results from the Rink[12], Hoskins[10], and Traballesi[9] studies support EVS as a suitable system for preventing ulcer formation and allow patients with existing ulcers to continue ambulating, more research is required to determine if there is a direct correlation between EVS systems and whether they are directly beneficial in wound healing. Ideally, future studies should incorporate larger study samples and objective outcome measures for assessing the direct correlation between EVS and wound healing.

Evidence Table

Clinical question: Does the use of elevated vacuum suspension (EVS) have a direct and beneficial impact on residual limb wound healing among unilateral transtibial (TT) prosthesis users?

	Traballesi, et al. (2012)[9]	Hoskins, et al. (2014)[10]	Kahle, et al. (2014)[11]	Rink, et al. (2016)[12]
Population	20 dysvascular transtibial participants initially recruited. 4 individuals dropped-out. 10 randomized into control group (CG) and 10 randomized into the intervention group (VAG). 3 dropped out of CG and 1 from VAG.	6 unilateral transtibial participants with existing open wounds on residual limb. Average wound size: 2.17 ± 0.65 cm^2	35 potential articles retrieved; 8 pertinent articles selected; 2 on the topic of wound healing. Article topics included: • Limb physiology (volume, pressure, residual limb movement) • Wound healing • Function (ABC, Step activity, Gait symmetry)	10 participants with unilateral lower limb amputations recruited (5 transtibial, 5 transfemoral). Half of the group on suction, and the other half on pin suspension, prior to study.
Study Design	Randomized controlled study	Case series	Systematic review	Randomized crossover study
Inclusion / Exclusion Criteria	Inclusion criteria: • 18 to 80 y/o • K2, K3 level • Wound dehiscence from post-op or ulcer from mechanical stress • Stable clinical condition • Intact mental status Exclusion criteria: • Severe comorbidities • Phantom limb pain	Inclusion criteria: • Unilateral transtibial amputation • Open wound present on the residual limb	Inclusion criteria: • Subjects use vacuum-assisted or sub-atmospheric technology • Peer-reviewed journal publication • Includes transtibial and/or transfemoral amputated subjects Exclusion criteria: • Individual cases or case series • Related to suction • Not relating to prosthetics • Editorial or non-peer-reviewed • Conference proceedings • Published before 1990 • Non-English • Non-human subjects used	Inclusion criteria: • 18 to 65 y/o • Unilateral transtibial or transfemoral • Unimpaired contralateral side • Can ambulate in prosthesis Exclusion criteria: • Smoker • Renal failure • Used EVS system prior to study
Intervention	Vacuum-assisted suspension (VAS) system using the Ottobock VASS TEC Harmony.	Vacuum-assisted suspension system using SealMate Liners and Prosthetic Design Elevated Vacuum Locking System.	Non-applicable.	Elevated vacuum suspension system using the Willow Wood LimbLogic Vacuum System.
Comparison	Total surface bearing suction socket with one-way expulsion.	No control group.	Non-applicable.	Non-EVS system; standard of care using subject's current prosthesis (pin or suction).
Methodology	After subjects were randomized into control and intervention groups, they were enrolled in a 12-week rehab program with required physical therapy for 60 minutes/day at 5 days/week. Monitoring of open wounds occurred during W1-4, W6, W8, and W12 of the rehab program. Data accrual for the Locomotor Capability Index, wound progression, and pain levelswere scheduled at W20, W28, and W36 (two, four, and six months after completion of rehab). Total observation timeline of this studyoccurred over 36 weeks.	Custom socket and VAS prosthesis provided on Day 1 for all subjects. Wound surface area was assessed at first onset and at each follow-up appointment until wound closure. Follow-up occurred every 1-2 weeks after first onset and until wound closure. Two raters independently measured all wound surface areas using the NIH ImageJ software. A mean value of the area was determined using both raters' inputs (variability between the raters was ± 0.2%).	Four databases (PubMed, CINAHL, Cochrane, Web of Science) searched using selected keywords relating to VAS. Bibliographic citation software was used to gather references and remove duplicates. Two investigators independently reviewed all articles according to the inclusion and exclusion criteria, and were deemed pertinent, non-pertinent, or uncertain. Uncertain articles were reviewed and determined by a third reviewer.	Half of the subjects were randomized into non-EVS standard of care (Group A) and the other half into the intervention group with EVS test socket (Group B). Skin health and perfusion measurements were taken at baseline (Wk 0), at 16-weeks of use (Wk 16), and at the end of the study (Wk 32). Groups A and B were switched into the intervention and control groups, respectively, at week 16. Measurements taken compared in-socket andout-of-socket as well as the subject at rest, static weightbearing, and treadmill walking.

	Traballesi, et al. (2012)[9]	Hoskins, et al. (2014)[10]	Kahle, et al. (2014)[11]	Rink, et al. (2016)[12]
Outcome Measure(s)	-Subjects asked about prosthetic wear for how many hours per week; a self-report measure that was asked during follow up appointments (W20, W28, W36) -Locomotor Capability Index (LCI); user survey used to score prosthetic mobility and usage -Visual Analogue Scale; self-report measure used to assess pain perception by the subject -Wound/ulcer dimensions (area, perimeter) taken using the J-Micro Vision v1 1.2.7	-Wound surface area (cm^2)	-Physiotherapy Evidence Database (PEDro); a rating system for methodological quality of studies -Scottish Intercollegiate Guidelines Network (SIGN); checklists that assess risk of bias and extract relevant data from studies -Center for Evidence Based Medicine (CERM); assignment of a level or grade of evidence	-Transepidermal water loss (TEWL); a measure for skin barrier function -Transcutaneous oxygen measurement (TCOM); a measure of levels of oxygen saturation within residual limb -Laser Doppler flowmetry (LDF); a measure of perfusion within the residual limb -Hyperspectral imaging; a measure for determining reactive hyperemia
Key Findings	-Time frame from when users took first steps: • VAG took 16.4 ± 8.6 days • CG took 58.6 ± 24.7 days • p = 0.012 • All VAG users able to walk at W12 • Five CG users were able to walk at W12 • p = 0.001 -LCI score after the 12-week rehab program: • VAG median score: 42 / 42 • CG median score: 21 / 42 • p = 0.002 -Prosthetic usage after 2-month follow up: • VAG: 62 hours/week (median: 66, range: 0-91) • CG: 12 hours/week (median: 5, range: 0-56) • p = 0.003 -Prosthetic usage after 4-month follow up: • VAG: 65 hours/week • CG: 59 hours/week • p = 0.275 -Prosthetic usage after 6-month follow up: • VAG: 80 hours/week • CG: 59 hours/week • p = 0.184 -No significant difference in pain perception between VAG and CG -High variability in wound dimensions: • No significant statistical difference in wound dimensions between VAG and CG as study progressed • Wound healing occurred in 90% of VAG users within 20 weeks of use	-Average wound surface area: 2.17 ± 0.65 cm^2 -Average wound healing time: 177 ± 113 days -All subjects obtained eventual wound closure while wearing a VAS system prosthesis. -Three subjects developed new wounds while in VAS, suggesting that an ill-fitting prosthesis can still contribute to wound formation and development. -Wound healing occurrence could be due to the encouragement of subjects to ambulate rather than the VAS design itself.	-Two articles on wound healing reviewed: • Johannesson (2008) • Traballesi (2012) -Johannesson: • VAS soft removable dressing vs. conventional hard plaster as post-op treatment for TTAs • PEDro Score: 7 / 10 • Moderate risk of bias • Level 2 study • No statistically significant difference in results between the two types of dressings regarding wound healing. -Traballesi: • VAS system vs. standard TSB socket with suction for TTAs with an open ulcer • PEDro Score: 7 / 10 • High risk of bias • Level 2 study • VAS users showed an improvement in LCI scores and time to taking first steps in a prosthesis compared to control. • Suggests that VAS allows for early fitting without inhibiting wound healing or causing pain. -No peer-reviewed evidence-based study currently exists to support that VAS systems assist in wound healing.	-Control sockets and EVS sockets both lowered residual limb skin perfusion at rest. • No statistically significant difference between out-of-socket and in-socket perfusion measurements across suspension methods and across the timeline. -EVS preserved skin barrier function. • W16: TEWL values increased for control users from baseline to 16 weeks of use. • TEWL values for EVS users decreased by 19.5% compared to control and decreased by 20% for high stress areas compared to control. -EVS TcPO2 measurements between out-of-socket and at activity levels were not significantly lower after 16 weeks of use. • TCOM levels decreased by 44.3% at baseline and 53.7% at 16 weeks of use for control. • TCOM levels decreased by 43.1% for EVS group at baseline but no difference after 16 weeks. -Reactive hyperemia measurements significantly less in EVS compared to pair-matched standard sockets. • Reactive hyperemia measurements decreased by 34.7% for EVS users compared to control.

	Traballesi, et al. (2012)[9]	Hoskins, et al. (2014)[10]	Kahle, et al. (2014)[11]	Rink, et al. (2016)[12]
Key Limitations	-Difficulty in standardizing correct donning procedure for VASS, especially for older subjects. -Vacuum level generated through mechanical pump, which is dependent on the activity level of the subject. -Small sample size of subjects with high attrition rate. -CG users were kept to standard protocol (use of prosthesis once wounds have healed), whereas VAG users were fitted earlier despite open wounds.	-No comparison or control group. -Depth and severity of wounds not accounted for in analysis. -Subjects were of differing etiology, comorbidities, and times since amputation. -Unreinforced subject compliance using vacuum system and varied wound care management practices. -Subjects were recruited from a single practice.	-Very small sample of articles assessed. -Limited amount of peer-reviewed evidence-based articles on VAS compared to anecdotal studies. -Prosthetist skill sets are not equal or measurable across studies. -Users have bias towards certain sockets, materials, and componentry. -Discomfort, unfamiliarity, loss of confidence can lead to subject attrition (attrition rate 29% among this review's body of evidence).	-LDF data excluded from analysis during treadmill walking due to motion artifact affecting data collection. -LDF calibration technique inhibits inter-LDF data comparison amongst differing studies incorporating LDF as a measure. -Relying on subject feedback and the inability to monitor vacuum levels and daily vacuum use by subjects while not at the laboratory. -Small sample size.
Conclusion	The VAS system did not inhibit wound healing for VAG users, suggesting that wound formation is not a contraindication for early prosthetic fitting, weightbearing, and ambulation.	The use of VAS in well-fitting sockets and in compliant individuals did not prevent wound healing from happening, suggesting that it is possible for patients with open wounds to use a prosthesis without limiting or halting ambulatory activities.	Current existing articles using evidence-based objective outcomes are limited in supporting clinical applications of VAS for wound healing. While articles outside this review's criteria support VAS as favorable in wound healing, there is still no standard of care when open wounds develop. More research is required to determine if VAS is directly correlated with wound healing.	Outcome results suggest that EVS systems can improve perfusion levels, preserve skin barrier function, and provide a stable environment for adaptive vascular remodeling in the residual limb compared to control users on alternative suspensions. These results support that EVS has a positive impact on the physiology of the amputated limb, with the potential to prevent ulcer formation.

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