Incorporating Elevated Vacuum Suspension on a Patient's First Prosthesis May Have Significant Benefits But Further Analysis is Needed

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Clinical Question: Does elevated vacuum suspension (EVS) on a patient's initial prosthesis provide significant short- and long-term benefits in regards to managing volume fluctuation and increasing prosthetic use?

Background: The use of a vacuum pump to create a negative pressure environment has been increasingly incorporated in prosthetic socket designs. Though there are conflicting studies,[1,2] EVS has many theoretical advantages over other methods of suspension in lower limb prostheses such as helping to maintain residual limb volume, enhancing proprioception, decreasing the risk of falls, reducing adverse pressures to the limb & subsequently lessening the risk of skin breakdown.[3,4,5,6,7] Prosthetic technology has now advanced to the level where EVS is reliable, measurable[8] and easier for the end user to operate,[4] however questions still arise as to what are the long term effects of using EVS[1,6] and when is it appropriate to fit a patient with a EVS style socket.

Incorporating EVS into a lower-limb amputee's first prosthesis may have significant benefits but there are unknowns that may pose a potential risk. Some of the major advantages include a significant decrease in volume fluctuation eliminating the need for constant sock management, enhanced comfort through a more even distribution of pressure inside the socket which also decreases the chances the user will develop skin deterioration,[1,3,6,7,9] maintenance of optimal socket fit to enhance proprioception and increase confidence during prosthetic gait training, and increased wear times due to mitigation of sock management requirements. With potential benefits of the early application of EVS also come concerns that have not yet been explored in clinical studies. Some such concerns include the following: Can long term application of negative pressure on the limb actually result in adverse effects such as skin breakdown and/or elongation of residuum tissues? If vacuum suspension is used and the socket fit is too large, the risk of these adverse effects increases.

Search Strategy: oandp.org and PubMed
Search Terms: "elevated vacuum suspension", "vacuum suspension in prostheses", "vacuum prosthetics", "negative pressure suspension", "immediate post-op vacuum prosthesis", "vacuum-assisted socket suspension"
Inclusion/Exclusion Criteria: 2000 - present, English

Synthesis of Results: 10 different studies related to EVS and the negative impact of shear forces on the prosthetic limb inside the socket were reviewed. Though the study's funding or the author's affiliation with the manufacturer of a particular vacuum-assisted suspension component must be taken into account, clinical evidence implies several unique advantages to the prosthetic wearer including superior suspension,[4] a decrease in limb pistoning[2,3,6,7] over other suspension techniques resulting in a more uniform application of forces to the limb, enhanced comfort for the end user[7,10] and effective prevention of limb volume loss.[6,7] While several of the studies have shown a volume gain with the use of elevated vacuum[2,6,7] beyond the available socket volume,[6] there was no reported pain, discomfort or signs of skin deterioration. The value of the data from the studies is limited due to small sample sizes, inadequate comparison to their current suspension method, and lack of long-term follow-up with the exception of one single subject case study. Overall, results of these studies suggest that elevated vacuum is a safe and viable option for controlling normal volume loss that occurs from daily prosthetic usage under normal conditions. Further research is needed to ascertain long-term effects, patient candidacy, and when EVS is appropriate for incorporation into the design of a user's prosthesis.

Clinical Message: Results across the identified studies suggest that EVS has a place in prosthetics, but study of the long-term impacts of negative pressure to the vascular system of the lower-limb and appropriate criteria in regards to patient candidacy are still largely unexplored. The benefits of EVS to unilateral, traumatic lower-limb amputees are well established, but future studies should recruit larger samples of patients with amputations due to vascular complications to expand evidence to guide candidacy. Such studies should also monitor participants over a period of 1-2 years to better understand long-term effects of negative pressure on the prosthetic user.

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Evidence Table

	Gerschutz 2010[1]	Klute 2011[2]	Gerschutz 2015[3]	Major 2015[4]	Sanders 2011[5]	Goswami 2003[6]	Board 2001[7]	Haynes 2010[8]	Restrepo 2014[9]	Sutton 2011[10]
Pop-ulation	1 subject, transtibial vascular amputation, K2 activity level	12 unilateral transtibial amputees	5 subjects, transfemoral prosthesis users, K2 – K3 activity level	18 subjects, unilateral transfemoral amputees already utilizing VASS	7 subjects, all unilateral transtibial, 6 amputations as a result of trauma, 1 as a result of vascular causes, all able to ambulate without an assistive device for min of 5 minutes	11 subjects, all healthy unilateral transtibial amputees due to trauma or birth defects, diets and fluid intakes all monitored and controlled	11 unilateral transtibial amputees as a result of trauma	4 subjects, 3 unilateral transtibial amputees, 1 bilateral transtibial	4 subjects, transfemoral prosthesis users, tests conducted on models of limbs and polypropylene sockets	1 subject, highly active 40 year old transtibial amputee wearing a PTB with IWBTC prosthesis
Study Design	Case study / pre-test & post-test	Randomized Cross-Over Clinical Study	Randomized controlled clinical trial	Randomized controlled clinical study	Individual case studies	Controlled Clinical Study	Controlled Clinical Study	Randomized controlled clinical trial	Controlled clinical study	Single Case Study
Inter-vention	EVS measured at -10Hg, -12Hg and -15Hg with TSB socket	Use of a TSB VASS and a PTB pin-lock system	VASS Transfemoral socket with lowered trimlines	2 different EVS used to hold a pressure range during standing and ambulation	Use of a VASS transtibial socket	Use of 3 different TSB VASS sockets	Use of a 4% undersized TSB VASS socket	VASS used with less than 2-ply fit sockets	High stress levels were applied to the simulated models during stance phase	Patient switched to a TSB socket with EVS
Com-parison	Standard suction suspension with TSB socket	Activity level, limb volume pre and post 30 minute treadmill walk, limb pistoning and patient feedback.	Same user and socket with different pressure using VASS and suction only	Ottobock Harmony compared against Ohio Willowwood LimbLogic	3 subjects trialed VASS compared to suction, 3 subjects trialed VAS to a pin-lock system, the	Subjects on treadmill with 3 different sized VASS sockets at constant pressure and limb volume	Limb volume measured prior to and post treadmill walking under vacuum and normal	Seven different pressure settings tested using LimbLogic VS Communicator	The initial model socket was modified based off hirsuteness, sweatiness and texture in an area 2cm below	Patient followed up with at 1 week, 1 month and 1 year to assess EVS compared to his previous

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					remaining subject only used VAS	increase was compared against socket volume	conditions as well as limb pistoning and gait symmetry were recorded during ambulation with and without vacuum		the ischium to optimize the COF	PTB prosthesis.
Metho-dology	Limb scans compared at different intervals following the completion of 250 steps	Subjects randomly assigned a prosthesis and fit with activity monitor then given 3 weeks to become acclimated with prosthesis before returning for 30 minute walk on treadmill in lab	Sensors used to measure distal end displacement of limb inside socket through 7 step gait cycle	Rate of evacuation and number of times activation required to maintain pressure range measured in 18 standing and 9 participants walking on treadmill at self selected walking speed	All subjects stood without assistance for 5 minutes, walked on treadmill for 3-5 minutes, resting seated for 2 minutes, stood without assistance for 5 minutes, walked for 3-5 minutes	Patients walked on treadmill 3 times at same speed in 3 different sized vacuum sockets undersized, neutral and oversized under consistent pressure (only 7 completed all 3 walks)	Limb was cast before and after 30 minutes of treadmill walking to ascertain volume loss/gain while limb displacement and gait symmetry were measured with x-ray and video respectively	Randomized pressure set with subjects standing for one minute, then taking a step with the prosthetic side to induce a pressure moment, process repeated with all subjects through all pressure settings	A 3D scanner and CT scan were used to create a finite element model and a sclerometer was used to determine the COF at 16 points on the limb during simulated donning, relaxation and loading of the limb	Patient fit with EVS and subsequent follow-ups were conducted with a certified prosthetist to report changes. AMP and other tests used to determine change in functional status.
Outcomes	Omega Tracer used to compare limb volume via scans	Activity levels were lower for with VASS sockets versus pin-lock systems, pistoning was	Correlation between pressure in VASS and distal end displacement	Both systems were successful however the evacuation time and rate of reactivation was	Changes in limb volume during different suspension and activity measured with bioimpedan	Limb volumes increased for all subjects during all 3 walks, and all but one of the test subjects	Volume loss was prevented with the use of vacuum and 5 subjects showed significant volume	Vacuum pressure within a TT TSB socket is uniformly distributed with only a slight pressure gradient	An increase in the COF directly correlates to an increase in shear stresses which in turn leads to an	Patient reported enhanced comfort and wear time with the EVS prosthesis, up to 24hrs/day

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		significantly reduced in VASS sockets compared to pin-lock systems, treadmill walking had no effect on limb volume		significantly different between the two systems	ce.	exceeded volume gain expectations based off available socket volumes in neutral and oversized sockets	gain. Subject reported enhanced propriocepti on. Pistoning was reduced and gait symmetry was improved with the use of vacuum.		increase in risk of soft tissue damage.	during planting season
Key Findings	Significant decrease in volume change with VASS as compared to suction.	Participants preferred pin-lock system to VASS reporting better control and less frustration, since volume loss was not recorded on treadmill study suggests a skilled prosthetist can control daily volume fluctuation with conventional systems.	Significant reduction in distal end displacement in VASS compared to suction and linear correlation between change in pressure and distal end displacement	There are several viable options to achieving VAS with the use of an electronic pump, further exploration would be useful to identify ways to minimize reactivation to help improve battery life	VAS was inconsistent at maintaining limb volume but minimized limb volume changes during swing phase	Limb volumes actually increased beyond available socket volumes however no subjects reported any discomfort or skin redness from the gain indicating that the volume gain occurred globally and that the use of vacuum would not cause any harm when	The use of VAS helps to maintain a better socket fit, improves gait symmetry and may reduce skin irritation.	The LimbLogic Communicator serves as an accurate device for measuring socket pressure in a VASS socket	The shear stresses on the limb were reduced by 25% by varying the COF on the highest point of concentration, 2cm below the ischium, by changing the surface texture	Patient reported enhanced propriocepti on and a relief of sound-side knee pain brought on by a gait deviation as a consequence of his long term previous wearing of an inadequate prosthesis, patient scored higher on AMPPro, patient's skin free of contact dermatitis and hair re-

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						used with an over-sized socket				grew on the residual limb
Study Limit-ations	Single study subject, transtibial prosthesis, authors affiliated with manufactur er	Small sample size, all participants traditionally wore a pin system outside of the trial, a 3 week break-in period may not have been sufficient enough to warrant an accurate evaluation of VASS by participants	Short gait cycle, cause of amputation unknown, small sample size, authors affiliated with manufactur er	Attachment for LimbLogic pump not typical and may have contributed to pressure leakage	Lack of uniform socket design increases potential for variables, study protocol inconsistent	Subjects were not known to suffer from volume fluctuation issues prior to study, study funded by manufactur er	All subjects traumatic amputees not known to have current volume fluctuation issues, diet, hydration and activity level not controlled, manufactur er funded study	Small sample size, Study funded by manufactur er, study did not answer the question of what level of vacuum is appropriate only validated the device as a means for recording pressure settings accurately	Small sample size, simulated models used, no use of a VS	Single subject study, comparativ e socket design out-dated and not frequently used in clinical practice