The effect of elevated vacuum suspension systems on residual limb volume is unclear from current literature

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Clinical Question: Do elevated vacuum suspension (EVS) systems mitigate volume fluctuations in the residual limb better than traditional suspension systems in patients with unilateral transtibial amputation?

Background: Optimal prosthetic socket fit is essential for stable ambulation. The fit between the prosthesis and residual limb can be disrupted by residual limb volume fluctuation because fluid loss or gain throughout the day will shrink or swell the residuum whereas the prosthetic socket does not change.[1] Swelling of the residuum may prevent the user from being able to don and thus use their prosthesis. Shrinking of the residuum (if gone uncorrected through the use of prosthetic socks) will cause the residuum to lose total contact and create imbalance and instability during ambulation for the prosthetic user.[2] Poor volume management leading to less residual limb volume relative to the socket can also result in increased movement (pistoning) of the residual limb within the socket, skin irritation with eventual breakdown, areas of high pressure and shear stress, loss of total contact, possible suspension failure, all leading to a reduction in activity and prosthesis use.[3,4] Situations where residual limb volume increases relative to the socket may also lead to poor outcomes in that the resulting high pressures inside the socket can lead to restriction of blood flow which limits nutrient delivery and causes a buildup of cell waste in the tissues.[5] EVS suspension systems may provide a solution for prosthetic users to mitigate the daily residual limb volume compared to traditional suspension systems.[3-7]

Elevated vacuum systems have a vacuum pump to reduce pressures in the space between the prosthetic liner and socket to well below atmospheric pressure.[3] The nature of this design will maintain limb total contact and minimize pistoning between the limb and the socket. EVS system may also maintain limb volume throughout the day because in order for limb volume to decrease, pressures inside residuum limb tissues must be lower that pressures between the limb and socket, something that is physiologically difficult to achieve. However; it is not clear if EVS actually provides a better method to manage residual limb volume compared to traditional prosthetic suspension systems. Therefore, a literature review is necessary to define what, if any, influence EVS has on the management of residual limb volume.

Search Strategy:
Databases Searched: Google Scholar, PubMed, oandp.org
Search Terms: (Transtibial OR “trans-tibial” OR “Below-Knee” OR “below knee” OR “BK”) AND (“VASS” OR “Vacuum” OR “Harmony”) AND “volume”
Inclusion/Exclusion Criteria: 2000- present, English

Synthesis of Results: Five studies were identified (see Evidence Table). Generally, the subjects had a uni-lateral transtibial amputation due to trauma [3-5,7] and the number of subjects ranged from 1 to 11.[3-7] There is evidence comparing the effect of EVS on socket size,[7] suction suspension,[3-5] and pin suspension.[4-5] The protocol generally involved limb volume measurements pre and post walking.[3-7] Limb volume measurement method ranged from immediately casting in alginate,[3,7] to CAD-type scanning,[4,6] to bio-impedence.[5] Key findings for these studies are inconsistent. Some studies showed EVS minimized limb volume changes,[3] while others demonstrated pin suspension offered better performance,[4] or were inconclusive.[5] The low number of subjects utilized combined with inconsistent results demonstrate the potential for EVS to minimize volume fluctuation but prohibit a conclusion as to the true effect of EVS on residual limb volume management.

Clinical Message: Overall, the results indicate that EVS is a potentially viable intervention for patients with fluctuating residual limb volume but requires additional research. Future studies should utilize larger subject samples and more consistent volume measurement method across studies before results may be generalized.

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Evidence Table

	Population	Study Design	Intervention	Comparison	Methodology	Outcomes	Key Findings	Study Limitations
Board et al., 2001	10 subjects, transtibial amputation due to trauma with ability to walk safely for 30 mins	Quasi-experimental matched pretest-postest	EVS via a mechanical pump at -78kPa	TSB interface using one-way valve vs. TSB interface using EVS	Subject walked on a treadmill at 1.34-1.52 m/s for 30 minutes. Limb volume measured pre and post exercise.	Limb volume via alginate casting	Limb volume decreased 6.5% (52 mL) with suction suspension compared to 3.7% (30 mL) with EVS	Alginate casting is prone to errors related to technique inconsistencies. Study funded by EVS manufacturer.
Goswami et al., 2003	11 subjects, transtibial amputation due to trauma or congenital, limb maturity of at least 3 years	One shot pre-test post-test design	EVS at -78kPa with socket volume undersized (-104cc), neutral (-46cc), and oversized (+28cc)	Limb volume across socket sizes	Subject walked on a treadmill at 1.25 m/s for 18 minutes. Limb volume measured pre and post exercise	Limb volume via alginate casting	Subjects lost average of 12 mL (2%) , gained47 mL (7%), and gained 28 mL (4%) in the undersized, neutral, and oversized sockets (respectfully).	Alginate casting is prone to errors related to technique inconsistencies. Study funded by EVS manufacturer.
Gerschutz et al., 2010	Single subject, 9 years post transtibial due to diabetes, K2 ambulator	Case study pre-test post-test design	Limb Logic EVS at 34 KPa and 51 KPa	TSB interface using one-way valve vs. TSB interface with EVS	Subject walked 250 steps. Limb volume measured pre and post exercise	Limb volume via Omega Tracer scanning system	Trials with suction showed a mean volume change of 4.9%. at 34 KPa and 0.8% change at 51 KPa.	Single subject inhibits generalizability. Study funded by EVS manufacturer.
Klute et al., 2011	20 subjects were recruited. 5 completed protocol.	Randomized crossover	EVS with TSB interface vs. modified PTB socket with a pin lock suspension system	Limb volume across suspension types	3 week acclimation to test socket. Subject walked on a treadmill for 30 min at self-selected pace Limb volume measured pre and post exercise.	Limb volume via 6 camera scanning system	Limb volumes were not significantly different. Subjects preferred pin suspension and took twice as many steps per day.	Low subject retention. All subjects were prior users of pin suspension.
Sanders 2011	7 subjects, uni-lateral transtibial amputation. 6 due to trauma and 1 dysvascular	Series of one-shot design case studies.	All 7 case studies used EVS. 3 compared EVS to suction. 3 compared EVS to pin. 1 only used EVS	Limb volume changes to suspension type and task (standing, sitting, & walking)	Subjects stood for 5 min, walked on a treadmill for 3 or 5 min, sat for 2 min, stood for 5 min, walked for 3 or five minutes.	In-socket limb volume via bio-impendence	EVS did not consistently increase or maintain limb volume. EVS minimized volume changes during swing phase.	Inconsistent protocol application. Inconsistent socket shape across suspension, Little time for accommodation

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7. Goswami J, Lynn R, Street G, Harlander M. Walking in a vacuum-assisted socket shifts the stump fluid balance. *Prosthetics and orthotics international*. 2003; *27*(2): 107-113.

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