The Effectiveness of Prosthetic Technologies and Strategies at Managing Residual Limb Volume Changes

Ana Groff, Caroline Embry, W. Lee Childers PhD, CP
Georgia Institute of Technology; School of Biological Sciences
Creation date: December 2017; Reassessment date: December 2022

Clinical Question: Are available prosthetic technologies or strategies effective at managing residual limb volume changes for people with transtibial amputations?

Background: An intimate fit between the socket and residual limb is essential for stable ambulation and prevention of pain and injury. Fluctuations in residual limb volume (RLV) will alter prosthetic fit and are a major challenge faced by prosthetic limb users diurnally and long-term. Socket volume reductions as small as 1.0% have been shown to induce clinically detectable alterations in socket fit and correspond to approximately 1-ply sock changes on an average-sized residual limb.[6] Decreases in RLV can lead to excess pistoning and gait instability, while gains can lead to soft tissue injury and discomfort.[3]

Measurement of RLV change have used a variety of measures ranging from circumferential tape measurements to laser scanning techniques.[4] These external measures are limited to changes in residuum size/shape but not actual tissue fluid difference creating these changes. Bioimpedance on limb tissues reflect tissue fluid changes, is a sensitive analysis of residual limb volume change as determined by extracellular fluid volume,[5] has been used to measure limb volume changes over long time courses, and will be the focus of this review.

There are several methods for people with amputations to accommodate for daily changes in their RLV. The most common extrinsic method is the addition or removal of prosthetic socks, the thickness of which will take up the volume lost by the residual limb. This simple and affordable method is limited by the inconvenience of having to doff and don the prosthesis, requirement of adequate sensation for the person to feel and recognize a change in their limb volume, and possibility of further reducing RLV and compromising socket fit.[5] An intrinsic method is the use of elevated vacuum-assist (EVS) devices that draw fluid into the residual limb during low weight-bearing conditions to slow daily volume loss.[4] Its limitations include the difficulty of maintaining vacuum seal and possibility of skin injury due to negative pressure exposure. Other extrinsic methods include emerging adjustable socket technologies. A liquid-filled bladder (extending from a technology described in 2003[1], could be used to reduce socket volume to enhance mechanical coupling to limb during activities and then deflate during rest to facilitate fluid volume recovery into the residuum.[6,7] A simple strategy to limit RLV losses may also be to remove the socket for short periods of time throughout the day. It is not clear which of these prosthetic technological aids or strategies will provide the best method of managing residual limb volume. The purpose of this critically appraised topic was to determine the relative performance of the new liquid bladders, sock addition/removal, doffing prosthesis/liner, or EVS on the management of RLV.

Search Strategy:
Databases Searched: PubMed, CINHAL, Google Scholar
Search Terms: "transtibial amputation" AND "volume change" AND "bioimpedance analysis"
Inclusion/Exclusion Criteria: English, bioimpedance analysis, residual limb volume changes outcome

Synthesis of Results: Five studies were identified (see Evidence Table).[2-6] Generally, the number of subjects ranged from 7 to 28 and these subjects had a unilateral transtibial amputation for greater than 15 years. RLV changes were measured with bioimpedance while using prosthetic socks, doffing socket/liner for a recovery period, EVS suspension systems, and liquid-filled bladders with protocols pre-post testing sitting, standing, and walking. High variability was found within studies with mean RLV changes from -0.9% to 3.2% and absolute ranges up to 4.8%. All technologies and strategies examined in these studies proved effective when examining average RLV change; however, the method of doffing socket and liner showed the greatest effect. This strategy showed the greatest RLV change and the least variability among subjects for both daily short-term and long-term responses. Other technologies and strategies did not show consistent results across subjects. Some subjects with dysvascular conditions tended to display results contradicting expecatations.[5,7] However, most studies did not have enough subjects to provide sub-group analyses to analyze correlation of other health conditions to RLV changes.

Clinical Message: While sock addition/removal, EVS, and liquid bladders all demonstrate the ability to manage RLV, the strategy of doffing the prosthesis and liner for a recovery period is the most effective intervention. High intersubject variability regarding other technologies demonstrate the patient specific nature of RLV management and limitations of generalized recommendation. Larger studies with a direct comparison across technologies and sufficient number of subjects to determine what patient specific factors best predict when and how to use a particular technology will be necessary before a clinical guideline can be established.

The Effectiveness of Prosthetic Technologies and Strategies at Managing Residual Limb Volume Changes

Ana Groff, Caroline Embry, W. Lee Childers PhD, CP
Georgia Institute of Technology; School of Biological Sciences
December 2017

Evidence Table

Article	Sanders, 2013	Sanders, 2012	Sanders, 2011	Sanders, 2016	Sanders, 2016
Population	N = 19, transtibial amputation ≥ 18 mo, 7 with PAD, 11 HTN, 4 DM, and 2 CHF, prosthesis used ≥ 5 h/dy	N = 28, transtibial amputation (18 trauma, 7 PAD); able to ambulate on level walkway ≥ 10 min	N = 7 (6 trauma, 1 dysvascular), unilateral transtibial amputation ≥ 1 yr, walk without AD ≥ 5 min	N = 16, transtibial amputation, able to ambulate on treadmill ≥ 5 min and stand continuously ≥ 2 min	N = 8, transtibial amputation ≥ 1 yr, 1 PAD & 1 CHF patient, wore prosthesis ≥ 8 h/dy, walk without AD ≥ 5 mins
Study Design	Non-blinded pre-test post test design	Non-blinded pre-test post test design	Series of one-shot design case studies	Non-blinded pre-test post test design	Non-blinded pre-test post test design
Intervention	Commercial fluid polyurethane bladder fixed to inner A/P prosthetic socket	1-ply Soft Sock (polyester)	EVS, manual vacuum, and lock and pin suspension socket prostheses	Socket and liner	Custom platinum cure silicone fluid socket bladder-liners
Comparison	Bladder fluid injection vs removal	Addition and removal of sock ply	EVS vs suction vs lock and pin suspension sockets don/doffing use	Doffing of prosthesis and liner vs doffing prosthesis only vs donned prosthesis and liner	Fluid filled vs empty bladder liners
Methodology	Subjects sat, stood, and then walked on treadmill at self-selected pace for 90s with bladder liquid added (in 5-7 mL increments) and then same amount removed for 6 cycles	RLV measured at outset of testing after walking 3 min at preferred walking speed, after walk following addition of 1-ply sock, and after walk following removal of sock.	Subjects sat 2 min, stood 3-5 min, walked on treadmill 3-5 min 2x, & then sat 10 mins with 1) an EEVS, 2) manual EVS or suction socket while walking, 3) an EVS from 25-60 kPa, & 4) lock and pin suspension.	Subjects went through 3 cycles of 90s sit, 90s stand, 5 min walk, brief stand before 30 min rest during which subject 1) left prosthesis and liner donned, 2) doffed prosthesis only, or 3) doffed prosthesis and liner, then repeated cycle three times	Subjects underwent 6 cycles of sitting then standing for 90 s, and then walking for 5 min with liquid added (2.5-7.0 mL increments) in bladder-liners. Between 3-4 cycles, sat 10 min with liquid left in bladders or removed.
Outcomes	Changes to in-socket residual limb volume post fluid injection and removal via bioimpedance analysis	RLVC post sock addition and removal measured via bioimpedance analysis; AR ratios	Changes in in-socket residual limb volume post 10 min sitting in 1-4 conditions via bioimpedance analysis	RLVC for each condition for 30-min rest period, short- and long-term responses via bioimpedance analysis	RLVC for in-socket post fluid injection and removal via bioimpedance analysis
Key Findings	Bladder liquid addition resulted in RLV loss for 15 of 19 subjects (mean -0.6% ± 0.4) (range -2.5 to 1.1%) and RLV gain for 4 of 19 (all with PAD). Bladder liquid removal resulted with high variability of RLVC (mean 0.1± 0.4%) (range -2.0 to 1.5%).	Sock addition resulted in RLV loss for 22 of 28 subjects (mean -0.9±1.3%) (ranging from -4.0 to 0.8%) and RLV gain for 6 of 28. Sock removal resulted in RLV gain for 18 of 28 subjects (mean 0.5±0.8%) (ranging from -1.2 to 2.8%) and RLV loss for 8 of 28. Subjects who reduced in RLV throughout study or had high AR ratios tended to be obese, smokers, or have PAD.	EVS demonstrated greater increase in limb fluid volumes (ranging from –1.6 to 1.2 %) when compared to suction or lock-and-pin suspension but was not consistent across measures.	For prosthesis and liner doffed, both short-term and long-term response showed majority (13-14 of 16) subjects having RLV gain. Mean was 2.7±2.7% (anterior) and 3.2±2.6% (posterior) for short term response and 1.9±2.3% (anterior) and 2.1±2.1% (posterior) for long-term. For prosthesis only doffed, results were mixed. For neither doffed, all subjects displayed RLV loss.	Subjects demonstrate daily variability (1.2%/h anterior and 1.1%/h posterior for limb regions) in rates of RLVC despite consistent protocol. Removing liquid in liner had low RLV gain (0.2 ± 0.7% posterior) over short and long term retention.
Study Limitations	Clinical judgement of socket fit 2 mL difference of liquid injection vs objective measure. Inconsistent # and location of bladders (3-4), no trial for fluid subsequent removals from largest to smallest to account for gradual volume loss.	Electrode configuration did not allow for measurement of distal limb swelling. ASGP measurements taken on only 19 of 28 participants.	No controlled EVS type - both electronic and manual. Inconsistent time of day measurements for different suspension systems No recovery time in between session Brief subject accommodation to EVS prosthesis	Subgroup analysis (analyzing factors such as comorbidities or type of suspension) was not performed due to small sample size. Short test sessions (<2 hrs) did not allow quantification of long term retention of residual limb fluid volume.	Separate testing days for optimal bladder fit did not account for individual physiological limb volume differences Delay (25 s) to remove liquid and associated delay in bioimpedance measurement bias towards reduced fluid volume changes recorded. No carryover to long-term application

PAD: peripheral arterial disease; HTN: hypertension; DM: diabetes mellitus; CHF: congestive heart failure, RLVC: residual limb volume change, AD: assistive device, AR ratios: add/remove ratios

The Effectiveness of Prosthetic Technologies and Strategies at Managing Residual Limb Volume Changes

Ana Groff, Caroline Embry, W. Lee Childers PhD, CP
Georgia Institute of Technology; School of Biological Sciences
December 2017

References:

1. Greenwald RM, Oran RC, Board WJ. Volume Management: Smart Variable Geometry Socket (SVGS) Technology for Lower Limb Prosthetics. *J Prosthet Orthot*, 2013;15(3):107-112.
2. Sanders JE, Hartley TL, Phillips RH, et al. Does temporary socket removal affect residual limb fluid volume of trans-tibial amputees? *Prosthetics and Orthotics International*. 2016;40(3):320-328.
3. Sanders JE, Cagle JC, Allyn KJ, Harrison DS, Ciol MA. How do walking, standing, and resting influence transtibial amputee residual limb fluid volume? *Journal of Rehabilitation Research and Development*. 2014;51(2):201-212.
4. Sanders JE, Harrison DS, Myers TR, Allyn KJ. Effects of elevated vacuum on in-socket residual limb fluid volume: Case study results using bioimpedance analysis. *The Journal of Rehabilitation Research and Development*. 2011;48(10):1231-1248.
5. Sanders JE, Harrison DS, Allyn KJ, Myers TR, Ciol MA, Tsai E. How do sock ply changes affect residual-limb fluid volume in people with transtibial amputation? *The Journal of Rehabilitation Research and Development*. 2012;49(2):241-256.
6. Sanders JE, Redd CB, Cagle JC, et al. Preliminary evaluation of a novel bladder-liner for facilitating residual limb fluid volume recovery without doffing. *Journal of Rehabilitation Research and Development*. 2016;53(6):1107-1120.
7. Sanders JE, Cagle JC, Harrison DS, Myers TR, Allyn KJ. How does adding and removing liquid from socket bladders affect residual-limb fluid volume? *Journal of Rehabilitation Research and Development*. 2013;50(6):845-860.