The Influence of Vacuum-assisted Suspension on Clinical Outcomes in Lower Limb Amputees
Final Report

Summary of Work

When receiving a new prosthesis, one of the biggest concerns for the user is comfort and fit. Dissatisfaction with prosthetic comfort is quite common and is one of the leading factors limiting prosthetic use and the amount of time spent in weight-bearing activity. Proper suspension is a key component of socket comfort and fit.

Vacuum assisted socket suspension (VASS) uses negative pressure to tightly anchor the socket to the limb by removing all air from the closed space between the limb and socket. This results in a constant level of high vacuum that has been shown to reduce peak intrasocket socket pressure and pistoning of the residual limb, and thus improve fit. However the effects of VASS on function and mobility remain largely unknown. Moreover, the effects of acute loss of vacuum in current VASS users is unknown, despite the fact that many users periodically experience problems with their vacuum system - e.g., leaks or malfunctioning pump. The improved fit and reduction in pistoning reported with VASS should logically limit dissipation of energy during gait and in turn reduce the energetic costs of walking, which is significant given the already elevated energetic costs associated with prosthetic use. By reducing peak intrasocket pressure, VASS may also improve socket comfort. Accordingly, VASS users may experience immediate reductions in comfort, and in turn function following acute loss of vacuum. The presumably tighter linkage between the user and the prosthesis that VASS offers may facilitate faster self-selected and maximum walking speed, and better performance on demanding locomotor tasks. This may partly explain prior preliminary work of others indicating that VASS reduces falls.

Our work sought to: 1) quantify the effects of VASS on energetic costs of gait and performance-based outcomes by evaluating changes in these measures immediately after altering suspension; 2) compare self-reported outcome measures between a group of VASS and non-VASS users; and 3) compare prospectively-reported, community-based falls and stumbles over the course of one year between a group of VASS and non-VASS users.

Eighteen current VASS users and 18 non-VASS users, all of whom were active, community-ambulators participated in one of more aspects of this work, which included: 1) completion of laboratory tasks for VASS users; 2) completion of electronic versions of surveys to assess self-reported outcomes; 3) completion of electronic surveys to quantify the effects of VASS on fall risk. The laboratory tasks involved quantitative gait analysis, performance of ten meter walk (10mW) and timed up and go (TUG) tests, and six minutes of walking during which we calculated self-selected speed (SSS) and energetic costs of walking as well as socket comfort (using the socket fit comfort score) after the walk. These tasks were performed under three suspension conditions: *i*) VASS - existing suspension; *ii*) suction - achieved by inactivating the vacuum but maintaining a one-way valve to prevent air from entering the socket; *iii*) sleeve – attained by inactivating the vacuum and blocking the one-way valve which were randomly ordered. Electronic surveys to assess to assess prosthetic use and locomotor function included the Locomotor Capabilities Index (LCI5), the Houghton Scale, the Activities Specific Balance Confidence Scale (ABC) and the Well-Being, Frustration, Perceived Response and Social

Burden Scales of the sections of the Prosthetic Evaluation Questionnaire. To quantify the effects of suspension on fall risk participants completed surveys sent by email every two weeks for one year, asking if the participant fell (i.e., “unintentionally came to rest on a lower surface”) or stumbled (i.e., lost balance but did not fall) in the prior two weeks, and if so what the circumstance were of the fall/stumble. Participants were withdrawn from this aspect of the study for failure to respond to three consecutive mailings.

There was no effect of suspension on energetic cost of transport (p=0.47) or SSS (p=0.40). However participants performed TUG in shorter time using VASS and suction (p=0.02 VASS vs. sleeve; p=0.049 suction vs. sleeve; p=0.54 VASS vs. suction) and performed the 10mW with greater speed while using VASS compared to both suction (p=0.027) and sleeve (p=0.011). The use of VASS resulted in a significant, within-subject increase of 1.5 and 3 points in socket comfort compared to suction (p=0.001) and sleeve (p=0.001), respectively. None of the self-reported outcomes measures differed between VASS and non-VASS users. However, the relative risk of falling (i.e., experiencing one or more falls over the period of time during which participants were in the prospective portion of the study) was reduced by 50% (95% confidence intervals (CI) on relative risk (RR): 0.28-0.88) in persons with transtibial amputation who used VASS. In addition the risk of recurrent falls (i.e., experiencing two or more falls over the period of time during which participants were in the prospective portion of the study) was reduced by nearly 90% in persons with transtibial amputation who used VASS (RR=0.02-0.79). While the risk of falls or recurrent falls was not affected by VASS in persons with transtibial amputation, the relative rate of falls per person-year (which accounts for differences in follow-up time) was reduced by nearly 80% in these individuals (95% CI on the rate ratio: 0.07-0.47).

Based on this work, we conclude that, in absence of active vacuum, current users of VASS experience an immediate reduction in comfort which may limit their ability to attain faster walking speeds. However the absence of active vacuum does not have an immediate negative affect on the cost of transport and there was no effect on outcome-measures. Therefore, acute loss of vacuum may not negatively impact patients’ ability to perform daily tasks before vising his/her prosthetist. At the same time, providing VASS could benefit prosthetics users that feel limited by the ability to achieve faster speeds. While we expected to observe an effect of VASS on self-reported outcomes, the non-significant findings may indicate that the measures used to quantify the effects of suspension on prosthetic use, locomotor capabilities and prosthesis-related quality of life were ill-suited for the high functioning population evaluated. Finally, the work of this study provides initial preliminary evidence that prescription of VASS may reduce the risk of falls, and particularly recurrent falls, which is not trivial as the latter are associated with significantly worse outcomes for prosthetic users. However, given the small, heterogeneous population considered, larger studies are warranted in to support these results.

Summary of Accomplishments

The work supported through this grant resulted in the training of a student and clinician in the conduct of biomechanics- and outcomes-based prosthetics research as well as at least one peer-reviewed publication and several research presentations. The work has also supported several grant applications and lead to multiple successful collaborative opportunities with local researchers conducting prosthetics research. These accomplishments are detailed below.

- Dr. Rosenblatt trained a University of Illinois at Chicago (UIC) undergraduate student - Ms. Tess Ehrhardt - to assist in the collection, post-processing and analysis of biomechanical data from a motion capture system, including calculation of symmetry indices under the three socket suspension conditions. Ms. Ehrhardt included findings from the work in her undergraduate Honors College thesis and presented these findings at the 2015 UIC Student Research Symposium. She was listed as a contributing author on all manuscripts associated with this work. Ms. Ehrhardt is currently enrolled in a MPO program at the University of Washington.

- Preliminary findings of the work were presented by co-investigator Ms. Rachel Fergus in a talk entitled "Energetic Cost of Gait and Functional Mobility: A Comparison of Vacuum, Suction, and Sleeve Suspensions" at the 2015 Annual Meeting of the Academy of American Orthotists and Prosthetists (www.oandp.org/publications/jop/2015/2015-23.pdf). At that time Ms. Fergus was a prosthetic resident at Scheck and Siress and following this presentation she was invited to present in the resident research section of the AAOP Midwest Chapter meeting. The work on the current project contributed toward her resident research requirement.

- Acceptance of a manuscript entitled "The effects of vacuum assisted socket suspension on energetic costs of walking, functional mobility, and prosthesis-related quality of life" for publication in the Journal of Prosthetics and Orthotics. At the time of submission of this report, the aforementioned manuscript is not yet published/indexed. The PI expects a second manuscript entitled "The effect of vacuum assisted socket suspension on prospective, community-based falls by lower limb prosthesis users" to be accepted for publication within 1-2 months following completion of this final report (manuscript is currently in revision).

- Data from the accepted manuscript mentioned above was used to support several, currently in-review grants, submitted to the Department of Defense in response to their Prosthetics Outcomes Research Program and well as to several other related research programs. One of the co-investigators listed on these applications includes an assistant professor at a nearby university with expertise in outcomes-based research for prosthetic users. The PI has been eager to develop collaborations with this individual and acknowledges that the work funded by AOPA has helped facilitate this relationship, which is expected to foster many new initiatives to benefit prosthetic users in the future.

- The PIs effort on this work fostered an interest in developing novel technologies to improve residual limb health and increase socket comfort for lower limb prosthetic users. Pursuant to this interest the PI organized a multidisciplinary team including a UIC Professor in Mechanical Engineering and an Associate Professor at Northwestern University Department of Physical Medicine and Rehabilitation department. Leveraging work from this project, and the expertise of the other team members, the group received federal funds to design and develop an intelligent prosthetic liner that can automatically adjust intrasocket pressure in response to real-time measures and adapt the automation process based on learned user preferences.