Auto Control of Volume Management for Limb Loss

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Study Protocol

The objective of this research is to develop and test an automatically-adjusting prosthetic socket system for prosthesis users. The system integrates with a range of adjustable socket technologies, including those that are commercially available. The system we will develop allows small size adjustments for both tightening and loosening the socket. Adjustable panels may be attached to the prosthetic liner using a mechanical method such as Velcro, adhesive, or a thin strap or clasp to allow the liner to be pulled out with the panels when the socket is loosened. The user does not need to remove the prosthesis or bend down to make adjustments. The system will later be enhanced to automatically change the fit of an adjustable socket without distracting the user. It helps to maintain consistent limb fluid volume when the service member or Veteran is actively using the prosthesis. It does this using information from sensors within the socket and small motors that control adjustable panels in the socket wall.

The developed technology will apply two concepts learned from our recent researched funded by the DOD. One concept is to slowly enlarge the socket the right amount during dynamic activity. The other concept is to loosen the socket during resting to allow healthy fluid return to the limb.

A multi-aim, longitudinal study will be carried out to test this new prosthetic technology. All aims of the study will involve similar procedures meant to investigate the use of our adjustable socket (the interface between the prosthesis and residual limb), with iterative improvements made in each aim.

SPECIFIC AIMS:

Aim 2: Assess the performance of an adjustable socket in our laboratory.

Aim 3: Assess how prosthetic users use a wireless, adjustable socket to manage change in limb volume.

Aim 4: Assess the performance of an automatic, adjustable socket in our laboratory.

Aim 6A: Assess the performance of an adjustable socket in our laboratory that is able to quickly enlarge and quickly return to normal size to enable full or partial doffing while seated.

Aim 6B: Assess how prosthetic users respond to an adjustable socket that is able to quickly enlarge and quickly return to normal size automatically to enable full or partial doffing while seated.

Aim 8: Assess how prosthetic users respond to an adjustable socket, which is attached to their liner, that is able to enlarge while seated and return to normal size before ambulation.

Aim 9: Assess how prosthetic users respond to an adjustable socket, which is attached to their liner, that is able to quickly enlarge and quickly return to normal size automatically during ambulation.

Aim 10: Involves in-field testing of the adjustable prosthetic system developed in the prior aims. Subjects will use the test socket in 3 different configurations throughout the course of this study: (A) automatic control mode, (B) manual control mode, and (C) adjustment disabled mode. (A) In the automatic control mode, sensors that are built into the socket will be used to monitor the movement and position of the limb within the socket and use this information to automatically adjust the socket panels in an effort to improve the fit. Adjustments may occur while they are sitting, standing, and walking. The system will be integrated into an app on a smartphone. We will provide the phone. (B) In the manual control mode subjects will be able to make adjustments to the panels using the smartphone app. Changes will not be made automatically. (C) In the disabled mode, the ability to adjust panels will be turned off.

A description of the study procedures that will be used is given here; the attached table outlines what specific procedures will be done at the study visits for each aim:

	Aim 2, Aim 8, Aim 9	Aim 3	Aim 4	Aim 6A	Aim 6B
Visit 1—may not be needed if the participant has already had a socket made and has answered health questions	3 hours -Walk on treadmill -Questions related to prosthesis and limb health -Scan socket to make an adjustable test socket -vascular tests	3 hours -Walk on treadmill -Questions related to prosthesis and limb health -Scan socket to make an adjustable test socket -vascular tests	3 hours -Walk on treadmill -Questions related to prosthesis and limb health -Scan socket to make an adjustable test socket -vascular tests	2 hours -Questions related to prosthesis and limb health -Scan socket to make an adjustable test socket -vascular tests	2 hours -Questions related to prosthesis and limb health -Scan socket to make an adjustable test socket -vascular tests
Visit 2—approximately 4 weeks after visit 1, when their adjustable test socket is ready	3 hours -May place electrodes on skin of residual limb -Test socket fit -May place sensors onto socket and/or liner to measure activity and limb movements in the socket. -Stand then walk on treadmill at varying speeds while adjustable socket is controlled by researchers to reduce limb movement within the socket	5 hours -May place electrodes on skin of residual limb -Test socket fit -May place sensors onto socket and/or liner to measure activity and limb movements in the socket -May wear heart rate monitoring watch -Teach participant how to use the controller to adjust the socket, practice in the lab and then around the building; once comfortable leave the lab for up to 4 hours wearing the socket and conduct normal activities or follow a more structured protocol.	3 hours -May place electrodes on skin of residual limb -Test socket fit -May place sensors onto socket and/or liner to measure activity and limb movements in the socket. -May wear heart rate monitoring watch -Stand then walk on treadmill at varying speeds while adjustable socket is controlled automatically to reduce limb movement within the socket	4 hours -May place electrodes on skin of residual limb -Test socket fit -May place sensors onto socket and/or liner to measure activity and limb movements in the socket. -Perform series of sit-to-stand and stand-to-sit transitions, with periods of walking or resting in between. Researchers will make the socket release to become larger when seated and recover back to normal size when preparing to stand	7 hours -May place electrodes on skin of residual limb -Test socket fit -May place sensors onto socket and/or liner to measure activity and limb movements in the socket. -Teach participant how to use the adjustable socket with release mechanism; they will practice in the lab and around the building while being monitored by a staff member. Once comfortable they will leave the lab for 3-4 hours wearing the socket and conduct normal activities

	Aim 10
Lab Visit 1—may not be needed if the participant has already had a socket made and has answered health questions	Up to 2 hours -Walk on treadmill -Questions related to prosthesis and limb health -Scan socket to make an adjustable test socket -vascular tests
Lab Visit 2—up to 3 weeks after visit 1, when their adjustable test socket is ready	3 hours -Test socket fit -May place sensors onto socket and/or liner to measure activity and limb movements in the socket -Teach participant how to use the adjustable socket in the 3 different modes that will be tested. Once they are comfortable, they will leave the lab for 4-7 days with socket in the first mode to be tested.
Research engineer visits (2) –at the end of each of the first two socket test modes	1-2 hours each. -Questionnaire and dialog regarding socket test mode that was just completed -Socket will be changed over to next test mode -Refresh participant training on how to use the new test mode -Once comfortable in new test mode, subject will continue using the mode for next 4-7 days.
Lab Visit 3—at the end of the 3rd socket test mode	1-3 hours -Questionnaire and dialog regarding socket test mode that was just completed AND all socket modes tested in the study -Original socket will be returned to initial state and all study instruments will be retained by the lab

Primary quantitative data will be collected via custom study instruments, such as a bioimpedance measurement system to assess limb volume changes and inductive sensors built into the test socket wall to measure limb movement/distance. Qualitative data will be collected from participants directly through self-report of their health history, during study procedures. All data for this research will be collected prospectively.

Statistical Analysis Plan:

Aim 2, Aim 6A, Aim 6B, and Aim 8

The primary outcome measure of change in limb volume was taken at times of socket enlargement and socket reduction. A Shapiro-Wilk test will be used to determine normalcy. Normally distributed data will be compared using paired t-tests. If data is not normally distributed, a Wilcoxon Signed Rank Test will be used to make comparisons. A significance level of 0.05 will be used to determine whether measured differences in limb volume were statistically significant between interventions.

Aim 3

The primary outcome measure of change in limb movement was taken at times of socket enlargement and socket reduction. A Shapiro-Wilk test will be used to determine normalcy. Normally distributed data will be compared using paired t-tests. If data is not normally distributed, a Wilcoxon Signed Rank Test will be used to make comparisons. A significance level of 0.05 will be used to determine whether measured differences in limb movement were statistically significant between socket enlargement and socket reduction.

Aim 4

The primary outcome, integral of absolute error, was measured as participants walked with the adjustable socket's controller maintaining a set socket volume (set point). A Shapiro-Wilk test will be used to determine normalcy. Normally distributed data will be compared using paired t-tests. If data is not normally distributed, a Wilcoxon Signed Rank Test will be used to make comparisons. A significance level of 0.05 will be used to determine whether differences were statistically significant between interventions.

Aim 9

The primary outcome measure of participants who experienced increase in limb fluid volume was assessed after a structured protocol involving socket enlargements and socket reductions. A Shapiro-Wilk test will be used to determine normalcy. Normally distributed data will be compared using paired t-tests. If data is not normally distributed, a Wilcoxon Signed Rank Test will be used to make comparisons. A significance level of 0.05 will be used to determine whether differences were statistically significant between interventions.

Aim 10

The secondary outcome measure of adjustable socket mode preference was taken after testing the socket in all test modes. A Shapiro-Wilk test will be used to determine normalcy. Normally distributed will be compared using paired t-tests. If data is not normally distributed, a Wilcoxon Signed Rank test will be used to make comparisons. A significance level of 0.05 will be used to determine whether socket preference was statistically significant following testing the socket in all modes.