AWARD NUMBER:
MR140156, Contract: W81XWH-15-1-0575

TITLE:
Physiologically Relevant Prosthetic Limb Movement Feedback for Upper and Lower Extremity Amputees

PRINCIPAL INVESTIGATOR:
Paul Marasco, PhD

CONTRACTING ORGANIZATION:
The Cleveland Clinic Foundation
9500 Euclid Ave.
Cleveland OH 44195-0001

REPORT DATE:
Dec 2019

TYPE OF REPORT:
Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
DEC 2019	Final	15 Sept 2015 - 14 Dec 2019

4. TITLE AND SUBTITLE

Physiologically Relevant Prosthetic Limb Movement Feedback for Upper and Lower Extremity Amputees

5a. CONTRACT NUMBER
W81XWH-15-1-0575

5b. GRANT NUMBER
MR140156

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Paul Marasco*, Jacqueline Hebert, Alex Makhlin, Courtney Shell, Ahmed Shehata

E-Mail: marascp2@ccf.org

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

The Cleveland Clinic Foundation
9500 Euclid Ave.
Cleveland OH 44195-0001

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The illusionary sensation of movement directly influences motor control through internal models. As a component of perceptual mapping of the limb muscles we are using a modified matching protocol to examine how the brain perceives vibration-induced illusionary input. This will help us to understand which muscles need to be vibrated to most effectively influence motor control. Mapping the upper and lower limbs of able-bodied participants created a library of possible perceptions and suggests that participant expectations about illusionary input affect perceptions. Mapping in amputee participants has shown that vibration-induced illusionary input to residual muscles can generate movement percepts. Differential performance of with illusory input during functional tasks was observed, indicating that this feedback is incorporated into movement planning. We have developed novel socket designs capable of integrating vibration tactors while accommodating or improving upon existing function. We explored different wired and wireless solutions to control the integrated vibration tactors in response to prosthesis movement. Upper limb participants who previously underwent targeted reinnervation surgery successfully completed functional testing wearing sockets with an integrated vibration tactor.

15. SUBJECT TERMS

Movement, Sensorimotor Control, Prosthetic, Amputee, Kinesthesia, Perceptual Illusion

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	47	19b. TELEPHONE NUMBER *(include area code)*

Table of Contents

Page

1. Introduction.....1

2. Keywords 1

3. Accomplishments 1

4. Impact 22

5. Changes/Problems.....23

6. Products 23

7. Participants & Other Collaborating Organizations 24

8. Special Reporting Requirements.....28

9. Appendices.....29

1. **INTRODUCTION:**

The intrinsic feeling of limb movement (kinesthesia) is important to the use of our arms and legs, yet this sense is completely absent in amputees, who must monitor all use of their prosthesis visually. This represents a functional departure from biological limbs, where movement- and position-state feedback play vital roles in the seamless execution of everyday activities. We have worked to stimulate the appropriate sensory receptors in the residual muscles of the forearm (hand/wrist movement), upper arm (elbow movement), upper leg (knee movement), and lower leg (ankle movement) to provide a physiologically relevant sense of limb movement mapped to the appropriate joints/functions of a prosthetic limb for the general amputee population. We have developed a small wearable robotic tactor interface to activate the kinesthetic receptors that remain in the residual limb. The robot has the power to push into deeper tissue to reach and vibrate the receptors with up to 90 Hz and at least 1 mm displacement. We have used perceptual mapping to determine the functional organization of the kinesthetic receptors and establish effective modes of communication. We used the tactor interface to project perceptions of limb movement to a prosthesis and measure function. We did this with matching and reaching tasks. In order to develop devices that have clinical applicability, prosthetic socket designs have been explored to accommodate the implementation restraints of the kinesthetic tactors.

2. **KEYWORDS:**

Movement, Sensorimotor Control, Prosthetic, Amputee, Kinesthesia, Perceptual Illusion.

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

Specific Aim 1: Systematically investigate the perceptions of limb movement accessible in the general amputee population.			
Major Task 1: Perceptual Mapping	**Mos.**	**% Completion**	**Date Completed**
Subtask 1: IRB	1-6	100%	31-05-16
Subtask 2: Percept Mapping	6-12	100%	31-08-19
Subtask 3: Data Analysis/Manuscript Prep	13-24	50%	
Milestone(s) Achieved: IRB Approval at all necessary sites as well as Complete Perceptual Mapping.	24	83%	
Specific Aim 2: Tactor Integration and Testing			
Major Task 1: Tactor Device Development			
Subtask 1: Development of Experimental Tactor System	1-12	100%	01-05-19
Milestone(s) Achieved: Completion of Tactor System	12	100%	01-05-19
Major Task 2: Integrate kinesthetic percepts with prosthetic limbs and perform functional testing			
Subtask 1: Tactor Integration	13-15	100%	01-04-19
Subtask 2: Matching and UE OFT and Visual Loading	16-30	90%	
Subtask 3: Data Analysis/Manuscript Prep	25-36	50%	
Milestone(s) Achieved: Completion Matching	36	80%	

Specific Aim 3: Develop practical implementations of kinesthetic sensory feedback through novel socket solutions to integrate the robotic tactors in a clinically feasible manner			
Major Task 1: Novel and Clinically feasible Socket Design			
Subtask 1: Socket Design/Iteration	7-12	75%	
Subtask 2: Implementation Gait Analysis	13-30	75%	
Subtask 3: Data Analysis/Manuscript Prep	25-36	100%	01-08-19
Milestone(s) Achieved: Implementation of Socket Design	36	90%	

- **What was accomplished under these goals?**

Specific Aim 1) Perceptual mapping

***Major activities*:**

Major Task 1: Perceptual Mapping

Subtask 1: IRB

Specific objectives:

Completion of required Human Subjects Research oversight requirements.

Significant results or key outcomes, including major findings, developments, or conclusions:

Local IRB approval was obtained in year 1 of the project and annual continuing review approval was obtained in each of the subsequent years.

Other achievements:

N/A

Stated goals not met:

None. Activity Complete

Subtask 2: Percept mapping

Specific objectives:

Percept mapping in able-bodied participants' upper and lower limbs.

Significant results or key outcomes, including major findings, developments, or conclusions:

In our original able-bodied mapping protocol, we began by vibrating the biceps and asked the participants to report any sensations besides simple vibration. After five minutes, we told them that some participants report movement around the elbow and ask them to report any similar sensations. After an additional five minutes, we informed participants that some people feel their elbow extending or flexing. Without instructing participants what types of movement sensation to expect (priming), percepts reported varied among participants and between days for the same participant (Table 1). This is contrary to results reported in literature, in which participants were instructed to report sensations of specific movements. We suspected that instructing participants which movements to expect influenced the perceived movements that they reported.

As a first step to investigating the inconsistency in reported percepts, two previously-mapped participants returned for elbow movement percept identification under a previously-published alternative protocol that included priming by instructing them to report sensations of elbow extension when the biceps were vibrated. When mapped previously without priming, the participants inconsistently reported sensations when receiving vibration. When primed to expect sensations of elbow extension using this previously-published protocol, both participants reported sensations of elbow extension when the biceps were vibrated.

Since priming may have an influence on perceived motion, we modified our original protocol to explore the influence of priming on perceived movement sensations. Participants were still instructed at the beginning of the mapping session to report sensations besides simple vibration while the biceps muscle was vibrated then, after five minutes, informed that some participants had reported sensations of movement around the elbow. Five minutes after the second set of instructions, participants were randomly assigned to be primed with either muscle-action-matching information or opposite-muscle-action information. If primed with muscle-action-matching information, participants were told that some participants reported sensations of elbow flexion; if primed with opposite-muscle-action information, participants were told that some participants reported sensations of elbow extension. To date, twelve naïve able-bodied participants have been mapped under the modified version of our protocol. Three participants never reported sensations of movement, one participant immediately reported sensations of movement without priming, and the final eight participants completed the priming protocol. When primed to report muscle-action-matching movements (Table 2), one participant consistently reported muscle-action-matching movements, another two participants consistently reported opposite-muscle-action movements, and the fourth participant reported a mix of both types of movements. When primed to report opposite-muscle-action movements (Table 3), participants reported a majority of opposite-muscle-action movements. Three participants reported only opposite-muscle-action movements, while one participant reported two instances of muscle-action-matching movements but for the majority of the muscles tested, reported opposite-muscle-action movements. In two instances, movements not associated with the vibrated muscle (e.g., elbow flexion when the flexor carpi radialis was vibrated) were also reported. These results suggest that although vibration-induced perceptions of motion tend to move opposite the action of the vibrated muscle, priming participants to report movements opposite the action of the vibrated muscle decreases variability in reported percepts between participants.

Table 1. Movements perceived when the participant was not primed to report specific movement directions. Cells are shaded to indicate that the perceived movement matched the muscle action (green), the perceived movement was opposite the muscle action (orange), or that the muscle was not tested for that participant or no movement sensation was reported (grey). * indicates that perceived movements were different when tested on different days.

Color legend

Matched muscle action	Opposite muscle action	Movement not reported for that muscle or muscle not tested

Muscle	Perceived Motion	Total	C02	C04	C07	C08	C09	C12	C17
Biceps	Elbow flexion	3	✓		✓*	✓			
	Elbow extension	4			✓*		✓	✓	✓
	Extend elbow and shoulder	1		✓					
Triceps	Elbow extension	2			✓*		✓		
	Lift/extend elbow and shoulder	1		✓					
	Elbow flexion	4	✓		✓*	✓		✓	
	Elbow flexion with shoulder abduction + internal rotation	1							✓
Extensor Digitorum	Wrist ulnar deviation	1						✓	
	Wrist flexion	1							✓
Extensor Carpi Ulnaris	Wrist flexion	2			✓			✓	
Flexor Carpi Radialis	Wrist ulnar deviation	1					✓		
	Wrist extension	4			✓	✓		✓	✓
Flexor Carpi Ulnaris	Wrist extension	2						✓	✓
Rectus Femoris	Knee extension	1				✓			
	Knee flexion	4			✓		✓	✓	✓
	Dorsiflexion	1		✓					
Vastus Lateralis	Knee extension	1	✓						
	Knee flexion	1						✓	
	Knee flexion and external rotation	1		✓					
Biceps Femoris	Knee flexion	1				✓			
	Knee extension	3					✓	✓	✓
	Ankle inversion	1			✓				
Medial Hamstring	Knee extension	4	✓		✓	✓		✓	
Tibialis Anterior	Dorsiflexion	3	✓	✓		✓			
	Plantarflexion	3			✓			✓	✓
Lateral Gastrocnemius	Plantarflexion	1	✓						
	Dorsiflexion	1						✓	
	Eversion	1				✓			
Medial Gastrocnemius	Plantarflexion	1				✓			
	Dorsiflexion	4		✓	✓			✓	✓

Table 2. Movements perceived when the participant was primed to report movements that matched the muscle action (i.e., when vibrating the biceps, report sensations of elbow flexion). Cells are shaded to indicate that the perceived movement matched the muscle action (green), the perceived movement was opposite the muscle action (orange), or that the muscle was not tested for that participant or no movement sensation was reported (grey).

Color legend

Matched muscle action	Opposite muscle action	Movement not reported for that muscle or muscle not tested

Muscle	Movement perceived	Total	C13	C19	C20	C24
Biceps	Elbow flexion	1		✓		
	Elbow extension	1	✓			
	Shoulder extension	1				✓
Triceps	Elbow extension	1		✓		
	Elbow flexion	2	✓			✓
Extensor Digitorum	Wrist extension	1			✓	
	Wrist flexion	2	✓	✓		
Extensor Carpi Ulnaris	Wrist flexion	1		✓		
Flexor Carpi Radialis	Wrist flexion	1			✓	
	Wrist extension	3	✓	✓		✓
Flexor Carpi Ulnaris	Wrist extension	3	✓	✓		✓
Vastus Lateralis	Knee flexion and hip medial rotation	1				✓
Rectus Femoris	Knee extension	2		✓	✓	
	Knee flexion	1	✓			✓
Biceps Femoris	Knee flexion	2		✓	✓	
	Knee extension	2	✓			✓
Tibialis Anterior	Plantarflexion	2	✓			✓
Lateral Gastrocnemius	Dorsiflexion	1	✓			
Medial Gastrocnemius	Plantarflexion	1			✓	
	Dorsiflexion	2	✓	✓		

Table 3. Movements perceived when the participant was primed to report movements that were opposite of the muscle action (i.e., when vibrating the biceps, report sensations of elbow extension). Cells are shaded to indicate that the perceived movement matched the muscle action (green), the perceived movement was opposite the muscle action (orange), or that the muscle was not tested for that participant or no movement sensation was reported (grey).

Color legend

Matched muscle action	Opposite muscle action	Movement not reported for that muscle or muscle not tested

Muscle	Movement perceived	Total	C14	C16	C21	C22
Biceps	Elbow extension	2		✓	✓	
	Shoulder extension	1	✓			
Triceps	Elbow extension	1				✓
	Elbow flexion	2		✓	✓	
	Slight elbow flexion with shoulder flexion	1	✓			
Extensor Digitorum	Wrist ulnar deviation	1	✓			
	Wrist flexion	2		✓	✓	
Extensor Carpi Ulnaris	Wrist flexion	1		✓		
Flexor Carpi Radialis	Wrist extension	3		✓	✓	✓
	Elbow flexion	1	✓			
Flexor Carpi Ulnaris	Wrist extension	2			✓	✓
Rectus Femoris	Knee flexion	3	✓	✓	✓	
Vastus Lateralis	Knee extension	1				✓
	Knee flexion	2	✓	✓		
Biceps Femoris	Knee extension	4	✓	✓	✓	✓
Medial Hamstring	Knee extension	3		✓	✓	✓
Tibialis Anterior	Plantarflexion	4	✓	✓	✓	✓
Lateral Gastrocnemius	Knee extension	1	✓			
Medial Gastrocnemius	Knee extension	1			✓	

Other achievements:

N/A

Stated goals not met:

N/A

Specific objectives:

Percept mapping in amputee participants' lower limbs

Significant results or key outcomes, including major findings, developments, or conclusions:

We have also performed percept mapping in ten lower limb amputee participants to date. Participants with a variety of amputation levels and causes have been recruited (Table 4).

Table 4. Summary of amputation level and causes of amputation for lower-limb amputee participants.

Participant	Amputation	Cause
P1	Left Transfemoral	Vascular

P2	Right Transfemoral	Trauma
P3	Right Transfemoral	Vascular
P4	Right Transtibial	Trauma
P5	Left Transtibial	Vascular
P6	Left Transtibial	Vascular
P7	Left Transtibial	Trauma
P8	Right knee disarticulation	Trauma
P9	Left knee disarticulation; Right leg transtibial	Trauma
P10	Left Transtibial	Trauma

Mapping experiments were performed using a hand-held vibratory system (VB200, Vibrasense, Besancon, France) attached to a flat faced probe tip (2.7 cm diameter). Participants were seated in a chair or laid on a bed, depending on the muscle group being stimulated. Consideration was given to limb positioning such that relaxation of the tested muscle group was promoted, as muscle contraction has been shown to influence the perceived movement. Participants' residual limbs were systematically stimulated. Participants were asked to report any sensations "beyond simple vibration." These descriptions of sensation were documented and the participant was asked to mimic the experienced movement using their intact limb, with respect to perceived direction, range, and speed of movement.

While blind to the researcher's intent, two participants (P1 and P4) spontaneously reported movement percepts about their phantom knee (P1) or ankle (P4) in the direction opposite of the vibrated muscle's action. P10 reported sensations of big toe movement and also a sense of the desire to move in the big toe (i.e., that the big toe was going to curl or lift but had not done so yet). Toe curling was associated with vibration of the tibialis anterior while the desire to lift or curl the big toe was associated with vibration of the remaining gastrocnemius muscle. With continued stimulation of illusion sites, participants P1 and P4 would intermittently report a stationary phantom limb materializing in the same orientation as their intact limb. Participants P2 and P3 experienced a movement sensation more representative of the patellar reflex, i.e., a singular outward jerk of the knee. Participants P2 and P3 did not experience the patellar reflex consistently as this sensation ceased after 1-2 instances. The remaining participants did not experience any movement sensations even with additional seeding information (Table 5). However, excluding participants P5 and P7, vibratory stimulation materialized a phantom limb for participants unable to experience any movement percepts (P6, 8-9). This phantom limb was positioned similarly to the participant's intact limb; it was absent prior to stimulation and retreated following the termination of stimulation. The phantom limb was reported to be most prominent while the vibratory actuator was applying a constant force. Vibration also induced tingling, pressures, temperature variations, and pain on the phantom limb.

Table 5. Time intervals and information provided to participants to experience movement sensations.

Testing Time (Minutes)	Information Provided	Participants Experiencing Movement Sensations
0-10	None (participants uninformed)	P1-P4, P10
10-15	"Some participants report feeling movement in their knee/ankle"	None
15-30	"Some participants report that their knee/ankle is flexing/dorsiflexing"	None

Percept Mapping in Participants that Experienced the Illusion of Movement

Participant P1: Transfemoral

Shortly after the administration of vibration, participant P1 described "a sinking feeling", stating that the vibration was "trying to push [their] leg back" (i.e., bend the knee) and that they had "to oppose it". The participant also articulated the sensation felt as if "the top of [their] thigh [was] not working" and that this forced "the shin [to move] in order [to] compensate". The participant explained that the "pull sensation... [felt] so strong" and that they had "to compensate by pushing" (i.e., kicking out). When they did this, the pushing sensation transformed into a "kicking sensation". This sensation was experienced in multiple sites on the anterior segment of the residual limb (Figure 1). After informing the participant to relax and embrace the sensations felt, they continually reported movement perceptions of knee flexion in multiple sites on their residual limb. In the posterior portion of the residual limb, the participant experienced similar sensations such as their "[phantom] leg [appearing]" similar to their intact leg, including "everything from knee to toes", a "pull slightly inwards", and their leg "pushing down". The movement percept pertaining to knee extension was experienced through the stimulation of a location mirroring Site 1 on the posterior segment of the participant's residual limb.

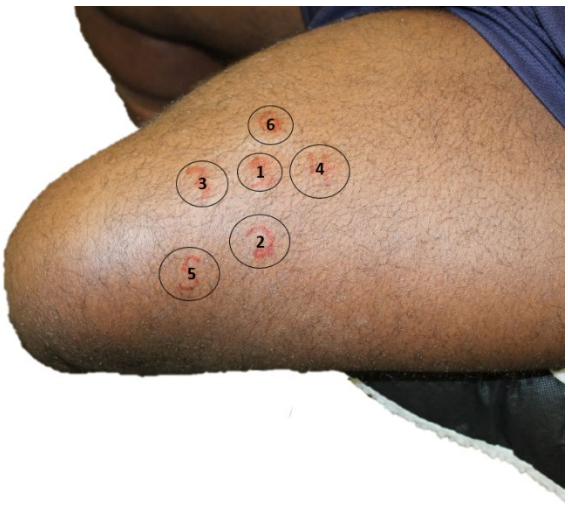

Figure 1. The anterior, lateral view of the residual limb of P1: the numbers (written in red ink) are used as handles to represent the center of areas when stimulated resulted in perception of knee flexion. Site 1 represents the location with the most consistent movement percept.

Participant P4: Transtibial

Participant P4 experienced movement perceptions of ankle dorsiflexion shortly after the administration of vibration. At Site 7 (Figure 2), the participant reported that vibratory stimulation caused “the ankle joint [to become] really tight”, which eventually caused the “foot [to start] torquing inward” (inversion) until “it got so tight the ankle couldn’t move it anymore”. Stimulation of Site 8 (Figure 2) caused “intense vibration all along [the] top of [the] foot” such that “it [wanted] to lift outward, pointing up” (dorsiflexion). Vibrations at Site 9 (Figure 2) “torqued [the foot] up”, and the participant “really felt it in [their] ankle” as the percept was “torqueing tight”.

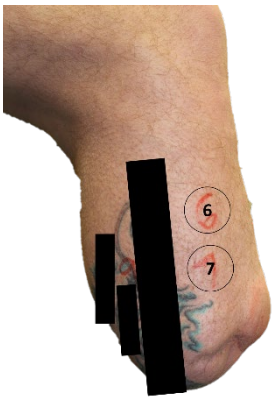

Figure 2. The lateral view of the residual limb of participant P4: the numbers are used as handles to represent the center of areas when stimulated resulted in movement percepts. Sites 6/7, encoded areas (written in red ink), and 8 are located anterior and posterior of the participants fibula, respectively; Site 9 is located on the participants gastrocnemius. Sites 7 and 8/9 represent locations where the participant experienced movement percepts of ankle dorsiflexion coupled with inversion and eversion, respectively. Site 8 represents the location with the strongest movement percept. Site 6 corresponded to sensation on the heel.

Participant P4 also reported that vibrations invoked a feeling on the foot as if “someone cupped [their] ankle and started squeezing”. The participant elaborated that they “could feel it on the outside of the heel on the back of the foot, not towards the toes” and that “it cupped the heel and around the inside of the heel and up in the arch”. This sensation was experienced by stimulation of sites 4 and 5 (Figure 3) as well as 6 (Figure 2).

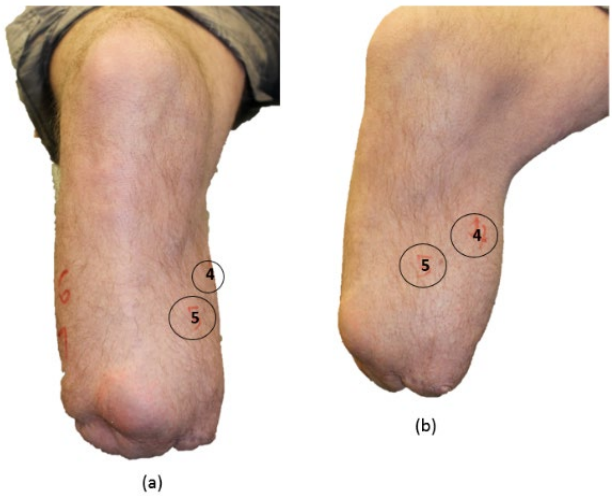

Figure 3. The anterior (a) and medial (b) views of the residual limb of participant P4: Stimulation of Sites 4 and 5 generated a sensation as if “someone cupped [the] ankle and started squeezing”.

Participant P10: Transtibial

A number of sites were found where illusion-inducing vibration applied to the remaining tibialis anterior and gastrocnemius elicited percepts of movement in participant P10. Vibration of the tibialis anterior elicited sensations of the big toe curling and vibration of the gastrocnemius elicited a sense of the desire to move in the big toe (i.e., that the big toe was going to curl or lift but had not done so yet).

Remaining Participants and Other Sensations

Participant P2: Transfemoral

Vibration induced a multitude of sensations on participant P2's phantom limb, including tingling sensations, pressure points, vibration, tension, and the patellar (knee) reflex. The tingling sensations can be grouped into a static or dynamic sensation experienced in the participant's phantom limb. The static tingling was experienced by stimulating Sites 2, 4 and 7 (Figure 4). This static tingling was felt "across [the] toes" and more specifically at the "underside of three middle toes". The static tingling sensation was also experienced at the "end of knee and a little bit on the top of the calf". Tingling sensations which traversed various segments of the phantom limb were identified by stimulating Sites 3 and 6 (Figure 4). This dynamic tingling was often described as a "waving back and forth" that was "more pronounced" than the static sensation and concentrated on the phantom foot. Vibration on these sites also induced various pressure points on the phantom limb, such as: "a barely discernable … touch feeling on [the] tips of [the] toes", "a touch sensation on [the] shin", or "deep pressure on the foot" and "calf". Vibrations on Site 3 ultimately produced a sensation similar to "a really strong shock from static electricity" applied to the phantom knee; this site was avoided in further testing to minimize discomfort to the participant. Vibrations on Site 5 (Figure 4) produced a similar vibration "through [the] inner side of calf bone". Vibration at Site 1 (Figure 4) produced a sensation in the phantom knee like that experienced in "the doctor's office [when] they check your knee reflex". This sensation was not consistent and eventually evolved to a "tingly pressure under the knee and up under kneecap".

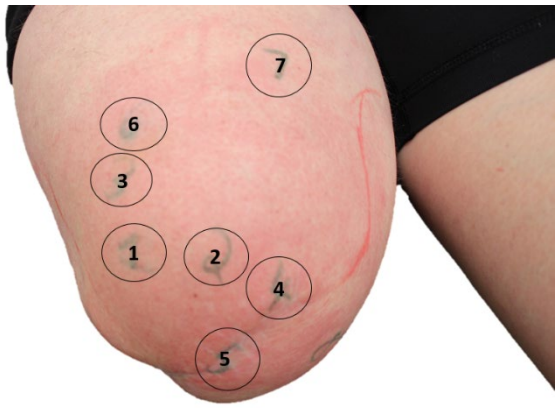

Figure 4. The anterior view of participant P2's residual limb (right leg): the numbers are used as handles to represent the center of areas when stimulated produced unique sensations. Vibration at Site 1 produced a sensation in the phantom knee similar to the patellar reflex. Through continual stimulation, the sensation ceased and was replaced by a tingling sensation. Stimulation of Sites 3 and 6 resulted in a tingling sensation on that phantom foot which was described as a "waving back and forth". Vibrations on Site 3 were ultimately stopped as they resulted in painful sensations for the participant. Stimulating Sites 2, 4, and 7 produced a static tingling sensation concentrated on the phantom foot. Vibration on site 5 produced a similar vibration on the phantom calf bone.

Participant P3: Transfemoral

Stimulating Site 3 (Figure 5) resulted in participant P3 also experiencing the patellar reflex sensation about their phantom knee. Similar to participant P2, the reflexive sensation eventually transformed into a tingling sensation. The participant articulated that, "if I had a knee it would want to kick out a little". This sensation was only experienced once. Through continued stimulation, the reflexive sensation ceased, and the participant began to "[feel] a tingling along [their] phantom limb". This sensation was "strongest after [vibration]" ceased. The remaining sites produced tingling sensations on various segments on the phantom limb.

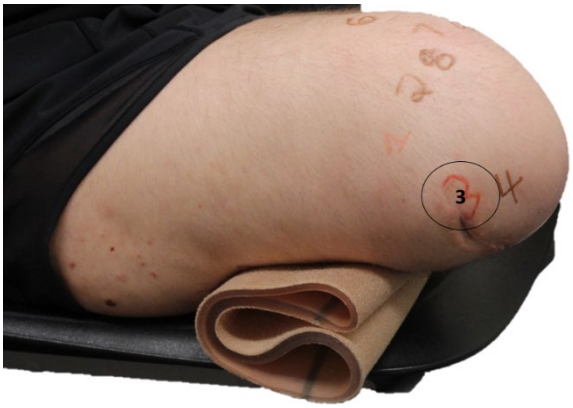

Figure 5. The lateral view of participant P3's residual limb (right leg): the numbers are used as handles to represent the center of areas when stimulated produced unique sensations. Vibration at Site 3 produced a sensation in the phantom knee similar to the patellar reflex. Through continual stimulation, the sensation ceased and was replaced by a tingling sensation. The remaining Sites produced tingling sensations on various segments of the phantom limb.

Participant P5: Transtibial

Participants P5 and P7 reported no phantom sensations. However, P5 reported that stimulation of the medial portion of their residual limb, on their distal thigh, produced a temperature change in the anterior lateral portion of the limb. Referring to the affected site, the participant described that "it felt like it was [cooler]… when you were vibrating".

Participant P6: Transtibial

Stimulation of various segments of participant P6's residual limb resulted in a consistent "tingling" sensation "at the stump". The exception being stimulation of the lateral segment of the residual limb, proximal to the knee, which evoked "a slight electrical shock". To mitigate discomfort, this site was avoided in further testing.

Participant P9: Bilateral

Vibrating various segments in the transtibial residual limb of participant P9 produced a variety of sensations in their phantom limbs, especially the foot. The participant felt tingling sensation in very specific locations of the phantom limb. This included the "shin", "front of calf", " ball of foot", "left side of ball of foot", "ring toe", and "arch of foot". The tingling sensations experienced at the ball of the foot eventually developed into an "intense feeling, almost pain", much like the electrical shock experienced by other participants; this site was avoided in further testing.

Table 6. Summary of other sensations not related to the kinesthetic illusion.

Participant	Sensations Experienced	Vibration Induced Phantom Limb
P2	Patellar reflex, Tingling, Pressure, Vibration, Shock	Yes
P3	Patellar reflex, Tingling	Yes
P5	Change in temperature	No
P6	Tingling, Shock	Yes
P7	None	No
P8	None	Yes
P9	Tingling, Shock	Yes

Other achievements:

N/A

Stated goals not met:

We are in the process of completing additional data analyses and preparing manuscripts to report our findings.

Subtask 3: Data Analysis/Manuscript Preparation

Specific objectives:

Analyze data from percept mapping experiments and prepare manuscript(s).

Significant results or key outcomes, including major findings, developments, or conclusions:

Results of completed data analysis described above for subtask 2.

Other achievements:

N/A

Stated goals not met:

We are in the process of completing additional data analyses and preparing manuscripts to report our findings.

Specific Aim 2) Tactor Integration and Testing

***Major activities*:**

Major Task 1: Wearable Untethered Tactor Device Development

Specific objectives:

Design, Device Manufacture, and Delivery

Significant results or key outcomes, including major findings, developments, or conclusions:

Design and final layout for the wearable, untether tactor for generation of the kinesthetic illusion is complete. Four of the devices have been manufactured and delivered (Figure 6).

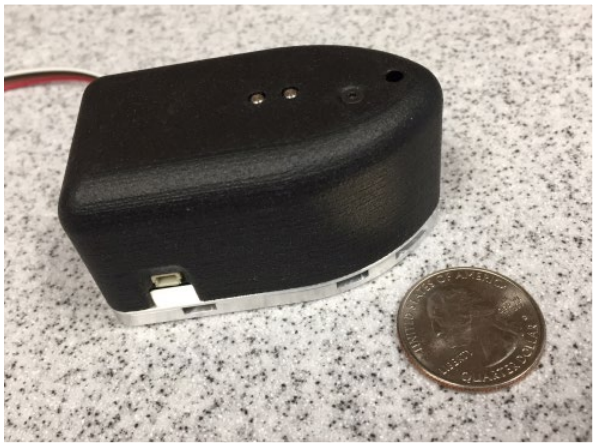

Figure 6. Wearable untethered tactor developed by HDT.

Other achievements:

N/A

Stated goals not met:

N/A

***Major activities*:**

Major Task 2: Integrate kinesthetic percepts with prosthetic limbs and perform functional testing

Subtask 1: Integration with Prosthetic Limbs for Functional Testing

Specific objectives:

Tactor Integration with Socket

Significant results or key outcomes, including major findings, developments, or conclusions:

Untethered tactors have been tested in experiments to generate the illusion in three upper limb amputee participants who have undergone targeted reinnervation. The device was successfully attached to the socket and programmed to provide the illusion of hand close movements timed to coincide with closing of the prosthetic hand (Figure 7). The participants successfully completed multiple functional tests using the tactor for kinesthetic feedback. A string potentiometer attached to the prosthetic hand was used to detect movement of the hand. When the signal from the potentiometer exceeded an experimentally tuned threshold (Figures 8 and 9), the tactor was activated to provide the sensation of hand movement to the participant via the untethered tactor.

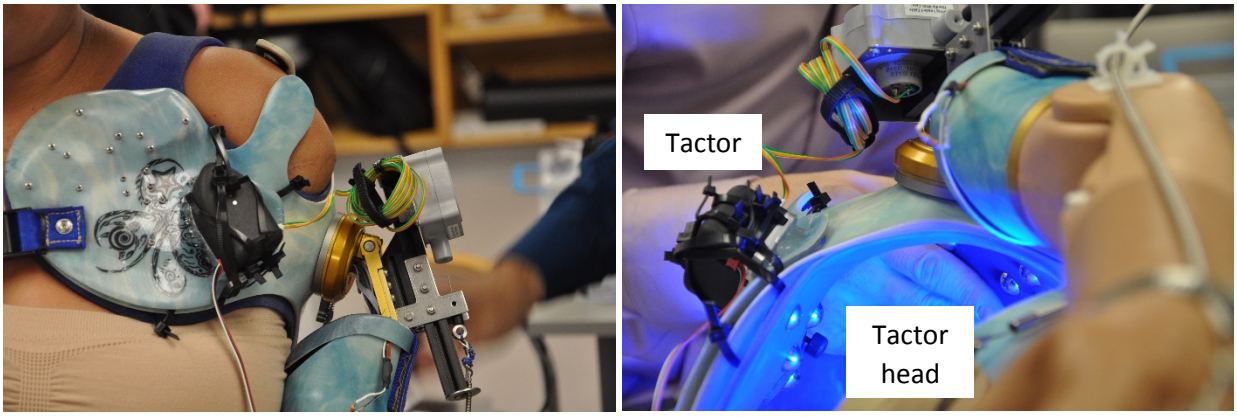

Figure 7. Kinesthetic tactor attached to a socket for a participant with a shoulder disarticulation who has undergone targeted reinnervation. The tactor is mounted on the outside of the socket and the tactor head extends through to connect with the muscle underneath the socket.

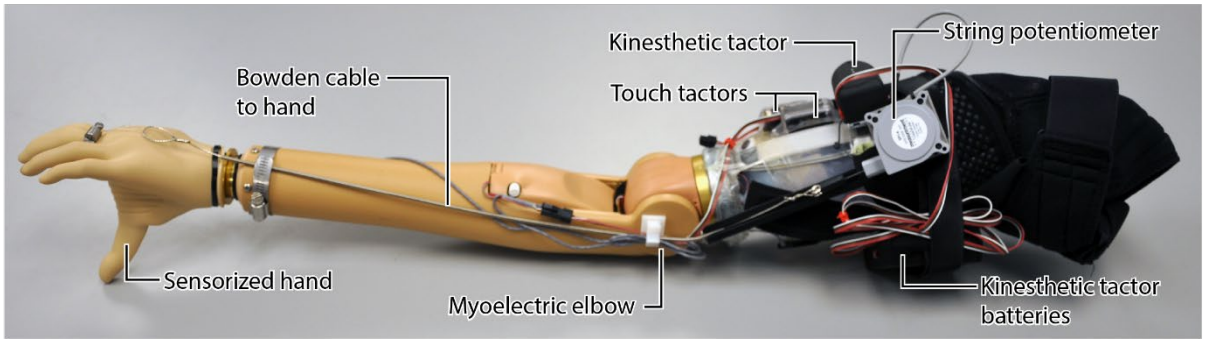

Figure 8. A lateral view of a transhumeral prosthesis equipped with the kinesthetic tactor and equipment for initiating tactor vibration when the prosthetic hand closes.

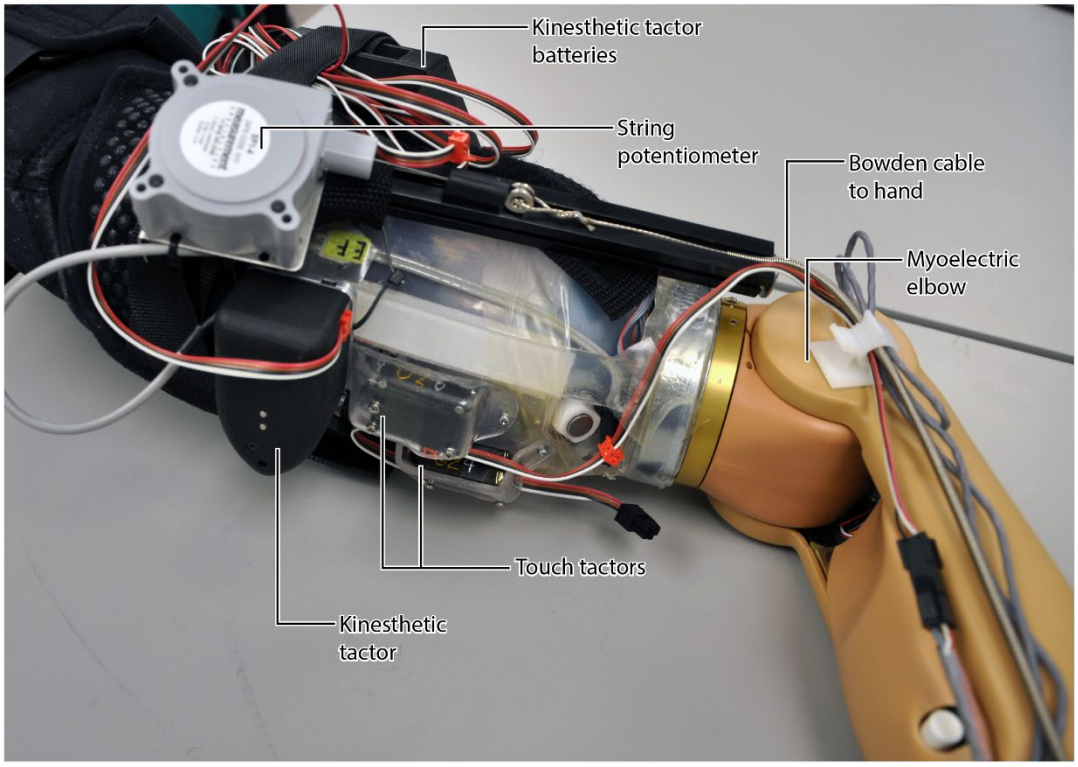

Figure 9. Close-up view of a transhumeral prosthesis equipped with the kinesthetic tactor and equipment for initiating tactor vibration when the prosthetic hand closes.

We have also developed a method to administer the movement illusion by driving the tactor in response to movement detected by a wireless inertial measurement unit-based system. A wired and wireless solution was developed with a corresponding threshold-based controller. The capacity of the system to administer the movement illusion was determined through a case study with a lower-limb prosthesis user capable of experiencing the movement illusion. Participant P1 was selected as they experienced strong and consistent movement percepts. For reference, the benchtop test was run exactly one week after initial percept mapping. The benchtop system was comprised of two wireless inertial measurement unit-based systems attached proximal and distal to a single joint of a robotic arm. The automated robotic arm was used for repeatability and consistency across trials, as opposed to relying on investigators to manually move a prosthetic limb; moving the prosthesis for the same duration and rate across trials would be difficult to achieve manually. However, the participant was informed that motion of their prosthesis was responsible for driving the vibratory tactor and was shown the wireless inertial measurement unit-based systems attached proximal and distal to the knee joint of their prosthesis whenever vision was not occluded; the participant was unaware that the robotic arm was used instead (Figure 10).

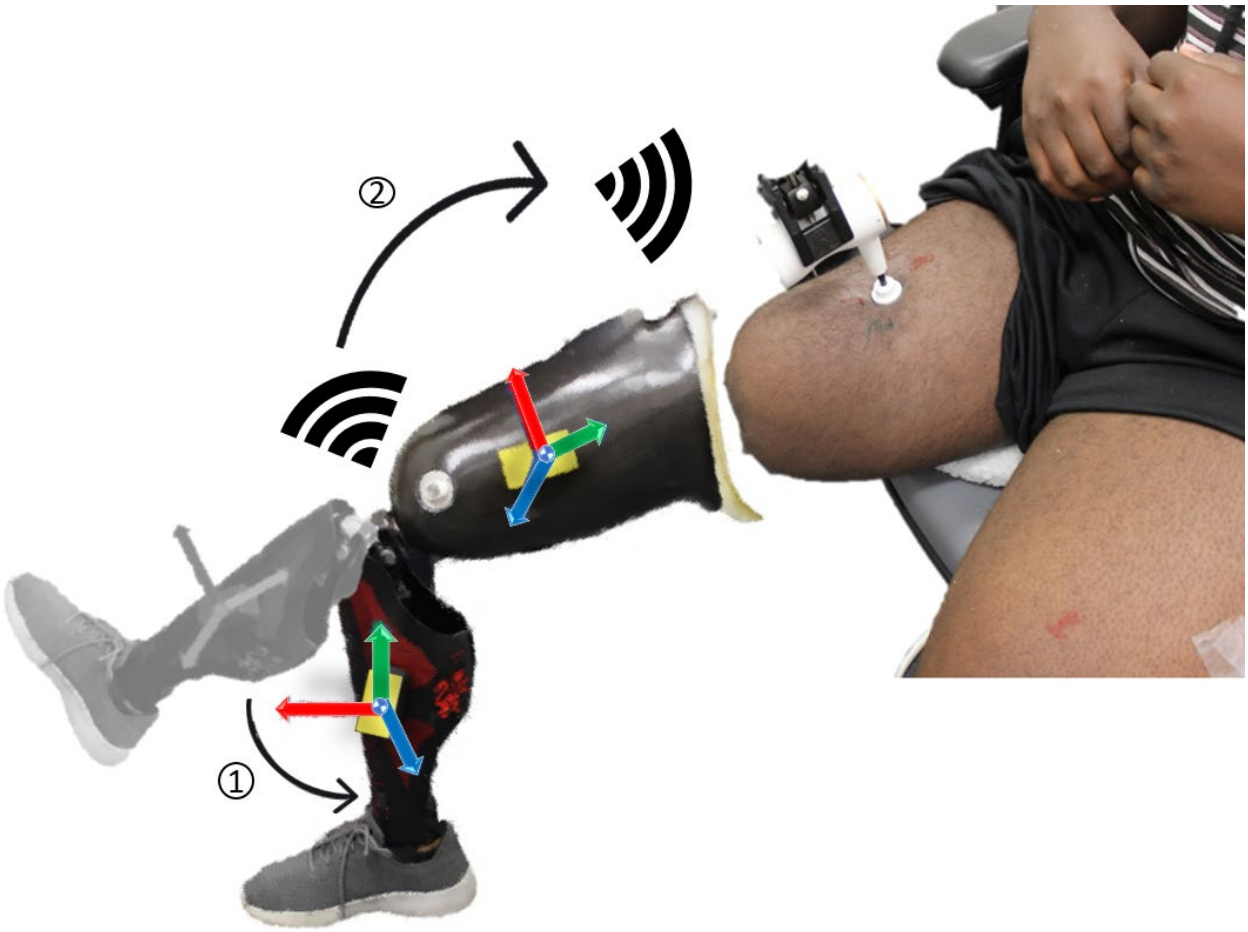

Figure 10. The participant was shown their prosthesis with wireless inertial measurement unit-based systems attached proximal and distal to the knee joint. They were informed that motion of the prosthesis, as detected by the wireless modules, was responsible for triggering the vibratory tactor.

As the automated robotic system moved, the wireless inertial measurement unit-based systems detected its motions and triggered the vibration of the actuator (Figure 11b). The vibratory tactor was fixed to a location on the participant that consistently elicited strong movement percepts (Figure 11a). Although both the wired and wireless systems were able to trigger the vibratory actuator, only the wireless system was used for the duration of the trial as it is more ergonomic. Even though the wireless system operates with a shorter battery life, it allows for greater flexibly of system placement when compared to the wired approach.

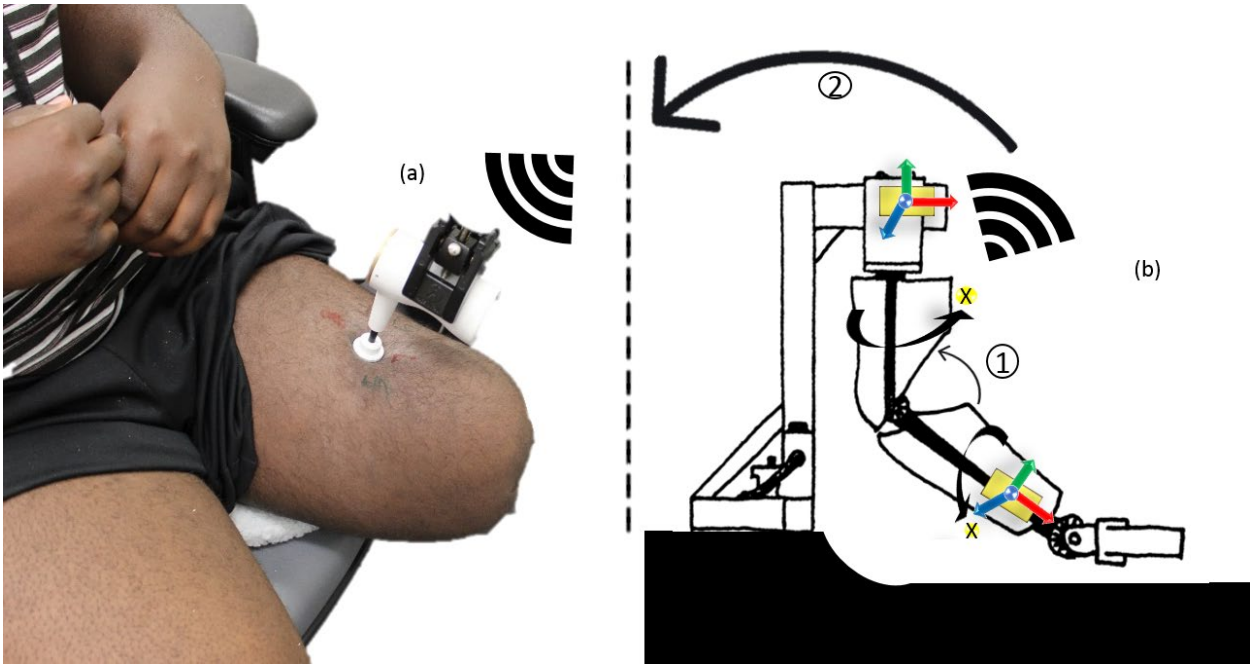

Figure 11. (a) The participant was seated with a vibratory tactor pressed into their residual limb. A clamp was used to fix the vibratory tactor to a site eliciting strong and consistent movement percepts. (b) The vibratory tactor was driven by the single axis motion of a robotic limb detected by the wireless inertial measurement unit-based system. This robotic limb was used for repeatability and consistency across the trials. Note, the image of the robotic arm was adapted from Brenneis DJ, et al. "Initial Investigation of a Self-Adjusting Wrist Control System to Maintain Prosthesis Terminal Device Orientation Relative to the Ground Reference Frame." *2018 7th IEEE International Conference on Biomedical Robotics and Biomechatronics (Biorob)*. IEEE, 2018.

Both the wireless and wired system were capable of driving the vibratory tactor through detection of the single axis motion of the robotic arm. Through the entire trial, the threshold-based controller was able to track the state of the prosthesis and properly activate or deactivate the vibratory actuator. Although the wireless system was more ergonomic than its wired counterpart, wireless communication introduced a greater delay. The accumulated delay at the instance when the tactor was triggered was approximately 48 and 93 ms, for the wired and wireless systems respectively. However due to the internal transients (inherent delay within electronic systems) of the tactor, there was a noticeable and repeatable delay from triggering to actuation (0.5 seconds). The internal transients of the vibratory tactor were estimated by subtracting the total delay of the wireless system (movement of the wireless inertial measurement unit-based systems to actuation) from the cumulative delay within the system at the onset of triggering. The total delay of the wireless system was determined through the use of a high-speed camera (iPhone SE, Apple Inc., USA, CA) analyzed frame by frame (Vegas Pro, MAGIX, UK, Herts). The initial frame was chosen to be the first instance of wireless inertial measurement unit-based system movement, the final frame was determined by identifying the frame in which the vibration motor stabilized to its predetermined stimulation setting (1 mm, peak-to-peak and 90 Hz).

Other achievements:

N/A

Stated goals not met:

We have successfully integrated the tactor into upper limb sockets and developed a method of controlling the tactors for both upper and lower limb applications, but have not yet attached a tactor to a lower limb socket.

Subtask 2: Matching and UE OFT and Visual Loading

Specific objectives:

Provide illusion-inducing vibration during matching and functional tasks

Significant results or key outcomes, including major findings, developments, or conclusions:

To explore functional performance with illusory movement feedback, we developed a reaching task that able-bodied participants completed while receiving no, sham, or illusion-inducing vibration to the biceps or triceps. Participants were seated at a table and asked to reach targets of different sizes at different distances as quickly and precisely as they could by extending their elbow then touching the target with their knuckle. Participants' view of their arm was occluded by a screen. Blocks of nine trials were completed and which muscle and type of vibration was applied was randomized. Preliminary analyses suggest that illusion-inducing vibration differentially affects performance on the task compared to no vibration and responses during elbow-extension task differ depending on whether the biceps or triceps is provided with vibration. Additional analyses are underway.

We also investigated the inconsistency in reported kinesthetic sensation by exploring the effect of providing participants with additional cutaneous information (skin stretch). To that end, we developed a portable skin stretch device (Figure 12) and an experimental protocol to quantitatively and qualitatively assess the elicited proprioceptive kinesthetic illusion when non-invasively vibrating a muscle belly (Figure 13). Results from tests conducted with a person with transtibial amputation show that stretching skin while vibrating a muscle belly on the residual limb provided a stronger and more consistent kinesthetic illusion (90%) than only vibrating the muscle (50%). In addition, we found that stretching skin enhances the range (1.5 times) and speed (3.5 times) of the illusory movement triggered by muscle vibration (Figure 14).

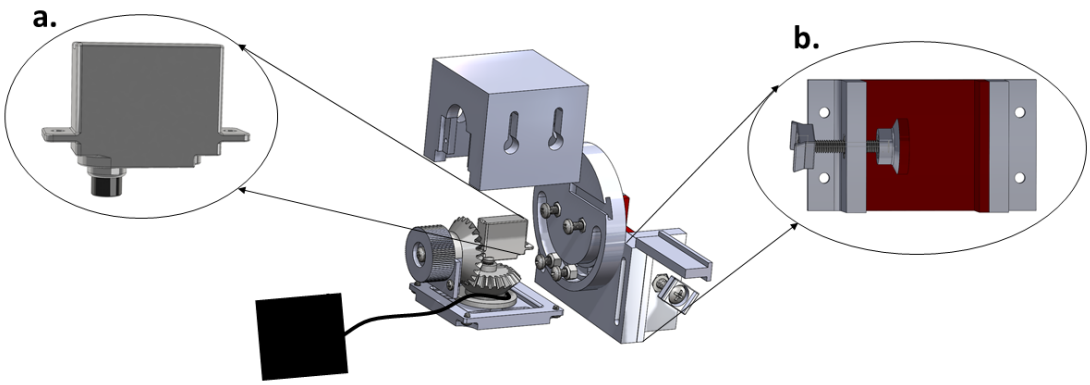

Figure 12. 3D solid model view (exploded) of the skin stretch device. a) Nano servo motor fixed to a bevel gear and a disc used to pull on a thread attached to elastic sports tape. b) 3D printed clamp used to affix the skin stretch device to a chair.

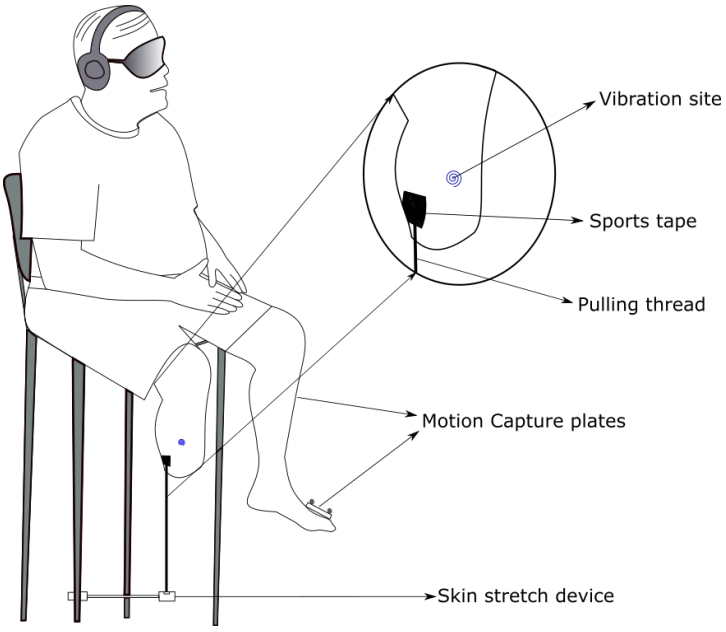

Figure 13. Experimental setup with participant sitting comfortably on a raised chair during a vibration and skin stretch trial.

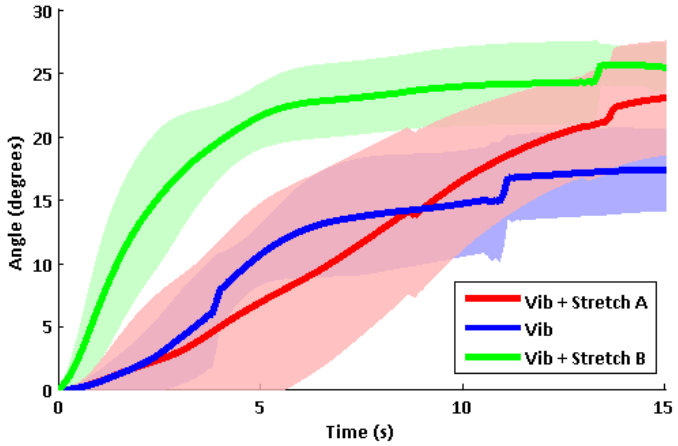

Figure 14. Perceived foot dorsiflexion illusory movement of the missing limb recorded by matching sensation using the intact limb for each testing condition.

Other achievements:
N/A

Stated goals not met:
We are in the process of completing additional data analyses and preparing manuscripts to report our findings.

Subtask 3: Data Analysis/Manuscript Preparation

Specific objectives:
Analyze data from matching and functional task experiments and prepare manuscript(s).

Significant results or key outcomes, including major findings, developments, or conclusions:
Results of completed data analysis described above for subtask 2.

Other achievements:
N/A

Stated goals not met:
We are in the process of completing additional data analyses and preparing manuscripts to report our findings. One manuscript is under review.

Specific Aim 3) Novel and Clinically Feasible Socket Design

***Major activities*:**

Subtask 1: Socket design and implementation

Specific objectives:
Design of a novel and clinically feasible socket to provide tactors access to wearer's skin while remaining comfortable for the amputee to wear

Significant results or key outcomes, including major findings, developments, or conclusions:
Two adaptable socket systems that are adjustable to different users' residual limbs to eliminate the need to create subject-specific sockets have been designed. The first is described in a manuscript has been published in PLOS One,

Katherine R. Schoepp, Jonathon S. Schofield, David Home, Michael R. Dawson, Edmond Lou, McNiel Keri, Paul D. Marasco, Jacqueline S. Hebert. Real time monitoring of transtibial elevated vacuum prostheses: A case series on socket air pressure. PLoS ONE 13(10): e0202716. https://doi.org/10.1371/journal.pone.0202716. This manuscript has been included as an Appendix to the report.

A second modular prosthetic socket was developed which could be easily manufactured using available 3D printers and off-the-shelf components and which was adjustable to accommodate multiple participants with varying levels of transhumeral amputations (Figure 15). This socket was then compared to a conventional suction socket in a case study which evaluated performance based on different mechanical assessments and outcome metrics from ADL tasks. Whereas conventional sockets, custom manufactured by a prosthetist, are typically quite expensive and limited to use by a single person, a socket fulfilling these design criteria would be better suited for light use by multiple participants during validation testing. This work is in preparation for submission.

Following the success of developing low cost transhumeral socket, we translated our knowledge to develop a modular adaptable transradial socket (Figure 17). The developed transradial socket was further modified to support testing with able-bodied participants and is being used in a pilot study to investigate electromyography and force-myography data fusion for prosthesis control (Figure 18).

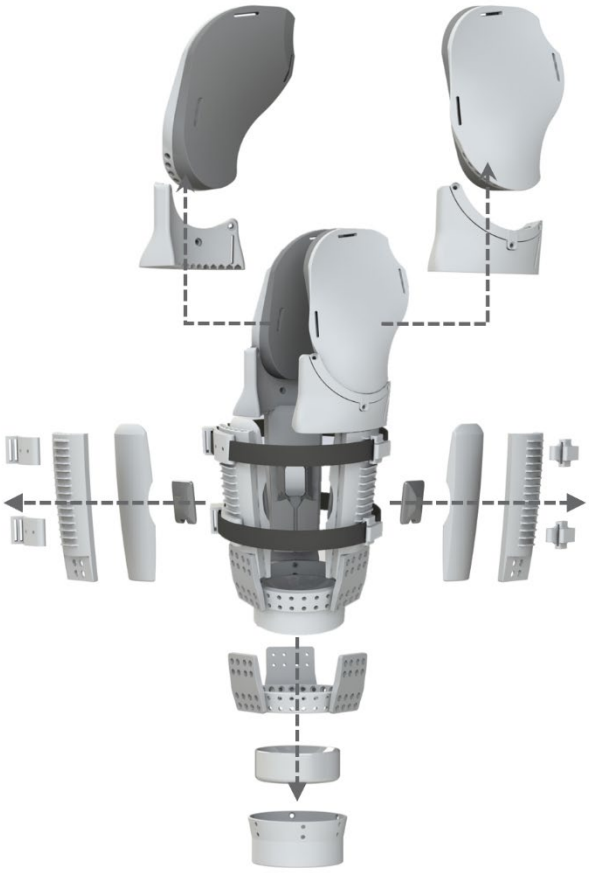

Figure 16. Overview of socket adjustability in 3-D printed adjustable socket. Top to bottom: Shoulder suspension, distal suspension, interior panels, and residual limb support.

Figure 17. Exploded view of the developed modular transradial socket.

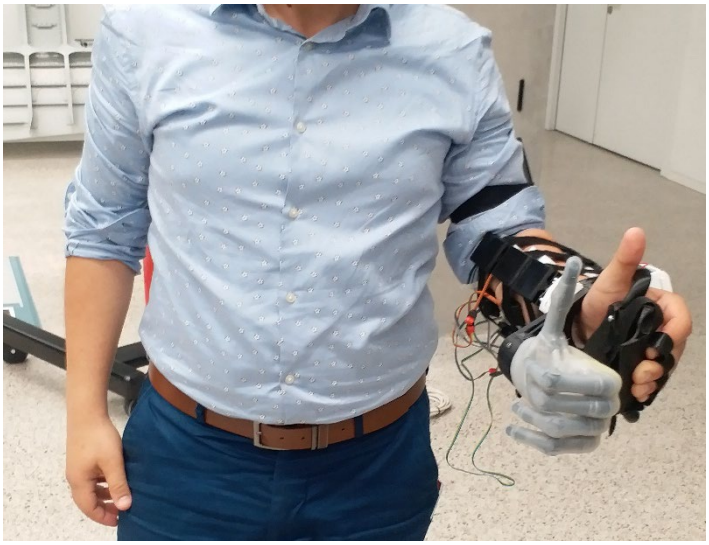

Figure 18. Non-disabled pilot participant wearing the developed modular transradial simulated prosthesis.

Other achievements:

A manuscript has been published in PLOS One, Katherine R. Schoepp, Jonathon S. Schofield, David Home, Michael R. Dawson, Edmond Lou, McNiel Keri, Paul D. Marasco, Jacqueline S. Hebert. Real time monitoring of transtibial elevated vacuum prostheses: A case series on socket air pressure. PLoS ONE 13(10): e0202716. https://doi.org/10.1371/journal.pone.0202716.

Stated goals not met:

N/A

Subtask 2: Implementation Gait Analysis

Specific objectives:

Develop and validate a protocol to analyze the effects of sensory feedback during gait

Significant results or key outcomes, including major findings, developments, or conclusions:

Traditionally, gait assessment relies on motion capture via body-affixed markers, requiring a trained clinician to appropriately attach the markers to anatomic landmarks on the subject. Gait assessment in individuals with amputation, using any of the well-established marker placement sets (e.g., Helen-Hayes Marker Set - HMS), is limited because marker placement on the prosthesis is not clearly defined. We developed a simplified motion capture Cluster Marker Set (CMS) that generates sufficiently accurate gait kinematics while allowing fast and easy marker attachment for gait assessment on the CAREN. The CMS consists of a set of seven plates, each holding four reflective markers, to be attached on each of the segments defining the lower limb (i.e., pelvis, 1; thighs, 2; shanks, 2; feet, 2). The plates have been designed to be easily and rapidly attached to each segment by use of elastic Velcro straps. Traditionally, clustered markers sets need either to be carefully aligned to the corresponding segment main axis, or to be calibrated using additional body landmarks. As part of the CMS, we designed a functional calibration protocol that does not require plates to be placed in a particular orientation nor require specific landmarks for calibration. Calibration for the CMS is performed by running a calibration algorithm with motion data captured from a sequence of pre-set calibration movements (sit-to-stand routines) to be performed once the plates are in place.

Different tests already exist to measure the effect of sensory feedback in balance control during standing. The most commonly used tests are different variations of the sensory organization test (SOT). The SOT allows testing of balance control during standing for different conditions aimed at testing the effect of the visual, vestibular and proprioceptive systems during balance. Balance after lower limb amputation is challenged during standing but the challenge becomes more relevant during walking. We have integrated the SOT into the CAREN and developed a set of SOT-based tests to expand the test to measure balance performance during standing and walking.

The lack of sensory feedback from the amputated limb results in a challenge to the nervous system to regulate balance. This challenge is further increased when balance is challenged by perturbations such as those resulting from tripping or slipping. In particular, responses to perturbations are difficult for lower limb users to modulate because of the lack of information about the onset of the perturbation as well as the perturbation characteristics such as type (e.g., trip vs slip) and magnitude. We have defined a set of reactive tests to be performed to the CAREN that challenge balance by delivering perturbations of different types and magnitudes to measure balance reactive performance.

The aforementioned balance performance tests run on the CAREN as a set of modules.
We have developed different modules that can be stacked together as an assessment package that provides outcome measures related to the different balance performance characteristics that need to be tested to evaluate lower limb prosthesis function. There are 5 balance modules (passive, active, and reactive) and 4 self-paced walking modules including slopes, perturbations, and rocky terrain. Each module consists of a set of standing or walking conditions and perturbations that allow us to tease out different aspects of balance performance such as balance corrective response strategies and reaction times to balance perturbations.

This gait analysis protocol was developed and tested by able-bodied and lower-limb prosthesis users to validate it.

Other achievements:

N/A

Stated goals not met:

The protocol has not yet been tested by amputees wearing sockets with embedded sensory feedback devices.

Subtask 3: Data Analysis/Manuscript Preparation

Specific objectives:

Analyze data from matching and functional task experiments and prepare manuscript(s).

Significant results or key outcomes, including major findings, developments, or conclusions:
Results of completed data analysis described above for subtask 2.

Other achievements:
N/A

Stated goals not met:
We are in the process of completing additional data analyses and preparing manuscripts to report our findings. One manuscript has been published.

- **What opportunities for training and professional development has the project provided?**

Nothing to report (project not intended to provide training or professional development opportunities)

- **How were the results disseminated to communities of interest?**

Results have been disseminated to communities of interest through a poster presentation at the 2017 Myoelectric Controls Symposium, podium presentation at the 2018 Conference on Movement and Cognition, presentation at the 2018 IEEE Life Sciences Conference, presentation at the 2019 IEEE 16th International Conference on Rehabilitation Robotics, presentation at the 2019 International Society for Prosthetics and Orthotics Canada, presentation at the 2019 Prosthetic and Orthotics Research Day, presentation at the 2019 Society of Women Engineers Conference, and a manuscript in PLOS One: Veterans Disability & Rehabilitation Research Channel. Additional manuscripts are under development and review.

- **What do you plan to do during the next reporting period to accomplish the goals?**

N/A

4. **IMPACT:**
   - **What was the impact on the development of the principal discipline(s) of the project?**

There is debate in the movement perception field about the roles of muscle movement sensation and skin sensation at the joints for determining how a limb is felt to be moving. We have evidence from our current work in neural-machine-interface amputees to suggest that the vibration-induced movement illusion interacts directly with the brain mechanism that initiates and controls intended movements. We are using the experiments conducted in this project to help inform the science of sensory feedback for motor control. As part of the percept mapping experiments, we are also including conditions that mask or alter feedback from the skin to characterize the interplay between feedback from the muscles (induced by the vibratory tactor) and feedback from the skin. We plan to extend these techniques to additional patient populations to assist in rehabilitation.

   - **What was the impact on other disciplines?**

Nothing to Report

   - **What was the impact on technology transfer?**

Nothing to Report

   - **What was the impact on society beyond science and technology?**

Nothing to Report

5. **CHANGES/PROBLEMS:**
   - **Changes in approach and reasons for change**

N/A

   - **Actual or anticipated problems or delays and actions or plans to resolve them**

Final data analysis and submission of additional manuscripts will be completed shortly.

- **Changes that had a significant impact on expenditures**

At Cleveland Clinic bringing in the correct post-doctoral fellow with the necessary skills to take a leadership role in conducting experiments took longer than anticipated. We were set back 5-6 months, however all staff were on-site, trained and producing data. HDT is a commercial company. NCE processing delays prevented HDT from delivering the final devices according to the planned timeline, but data collection proceeded with tethered devices where possible and by working ahead on other aspects of the SOW. At University of Alberta their account for year 1 opened in June 2016 (which officially was supposed to start Sept 1, 2015). University of Alberta could not start work until after the grant opened. The project progressed on pace after the delayed start described above.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

None

- **Significant changes in use or care of human subjects**

None

- **Significant changes in use or care of vertebrate animals.**

N/A

- **Significant changes in use of biohazards and/or select agents**

N/A

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**

Shell C.E. and Marasco P.D. “Interrogating the functional interpretation of joint movement illusions using intentional binding”. Poster presentation and proceeding at the 2017 Myoelectric Controls Conference, p106.

Shell C.E., Schofield J.S., and Marasco P.D. “Do skin and muscle contribute to movement perception conflict?” Podium presentation at the 2018 Conference on Movement and Cognition.

Keri M.I., Shehata A.W., Boser Q.A., Vette A.H. and Hebert J.S. “Development and Verification of a Low-Cost Prosthetic Knee Motion Sensor”. 2018 IEEE Life Sciences Conference (LSC).

Austin J., Shehata A.W., Dawson M.R., Carey J.P. and Hebert J.S. “Improving Performance of Pattern Recognition-Based Myoelectric Control Using a Desktop Robotic Arm Training Tool,” 2018 IEEE Life Sciences Conference (LSC) (pp. 231-234).

Schoepp K.R., Schofield J.S., Home D., Dawson M.R., Lou E., Keri M.I., Marasco. P.D. and Hebert J.S. “Real Time Monitoring of Transtibial Elevated Vacuum Prostheses: A Case Series on Socket Air Pressure”. PLoS ONE 2018; 13(10): e0202716.

Shehata A.W., Keri M.I., Gomez M., Marasco P.D., Vette A.H. and Hebert J.S. "Skin Stretch Enhances Illusory Movement in Persons with Lower-Limb Amputation". 2019 IEEE 16th International Conference on Rehabilitation Robotics (ICORR) (pp. 1233-238).

Hallworth B., Austin J., Williams H., Rehani M., Shehata A.W. and Hebert J.S. “Modular Adaptable Transhumeral Prosthetic Socket for Evaluating Myoelectric Control” 2019 International Society for Prosthetics and Orthotics Canada.

Hallworth B., Shehata A.W., Castellini C., Pilarski P., and Hebert J.S. “A Unified Platform for Assessing Novel Human-Machine Interfaces in Prosthetics” 2019 Prosthetic and Orthotics Research Day, Aalborg University, Denmark.

MacDonald A., Shehata A.W., and Hebert J.S. “The Instrumented Cup: Optimizing a Tool for Assessing Upper-Limb Prosthesis Performance” 2019 Society of Women Engineers Conference, California, USA.

Keri M.I., Shehata A.W., Marasco P.D., Hebert J.S. and Vette A.H. "A Cost-Effective, IMU-Based Method for Tracking Movement and Triggering Kinesthetic Feedback in Lower-Limb Prosthesis Users" In Review in Medical Engineering & Physics Journal.

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

Name:	*Paul Marasco*
Project Role:	*PI*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*4*
Contribution to Project:	*Project oversight. Study Design. Data interpretation.*
Funding Support:	*N/A*
Name:	*Courtney Shell*
Project Role:	*Post-doctoral fellow*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*6*
Contribution to Project:	*Study Design. Data Collection*
Funding Support:	*N/A*
Name:	*Jonathon Schofield*
Project Role:	*Post-doctoral fellow*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*4*
Contribution to Project:	*Study design, Data collection*
Funding Support:	*Miscellaneous grants*
Name:	*Jacqueline Hebert*
Project Role:	*Subcontract PI University of Alberta*

Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*1*
Contribution to Project:	*Lead of research design, implementation and conduct of research at site*
Funding Support:	*University salary supported*
Name:	*Mayank Rehani*
Project Role:	*Research coordinator*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*6*
Contribution to Project:	*Subject recruitment, study coordination*
Funding Support:	*Miscellaneous grants*
Name:	*Ahmed Shehata*
Project Role:	*Post-doctoral fellow*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*6*
Contribution to Project:	*Study design, Data collection*
Funding Support:	*N/A*
Name:	*Francesca Ferrari*
Project Role:	*Research assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*6*
Contribution to Project:	*Study design, Data collection*
Funding Support:	*N/A*
Name:	*McNiel Keri*
Project Role:	*Research assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*6*

Contribution to Project:	*Study design, Data collection*
Funding Support:	*N/A*
Name:	*Ben Hallworth*
Project Role:	*Research assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*6*
Contribution to Project:	*Study design, Data collection*
Funding Support:	*N/A*
Name:	*Eric Wells*
Project Role:	*Research assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*3*
Contribution to Project:	*Data collection*
Funding Support:	*N/A*
Name:	*Cierra Stieglmar*
Project Role:	*Research assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*3*
Contribution to Project:	*Data collection and processing*
Funding Support:	*N/A*
Name:	*Dylan Brenneis*
Project Role:	*Research assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*3*
Contribution to Project:	*Hardware development*
Funding Support:	*N/A*
Name:	*Juan Forrero*
Project Role:	*Postdoctoral fellow*

Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*3*
Contribution to Project:	*Development and validation of gait analysis protocol*
Funding Support:	*N/A*
Name:	*Cyrus Diego*
Project Role:	*Research assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*3.6*
Contribution to Project:	*Software design and implementation*
Funding Support:	*N/A*
Name:	*Shealynn Carpenter*
Project Role:	*Research assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*1*
Contribution to Project:	*Hardware development*
Funding Support:	*N/A*
Name:	*Quinn Boser*
Project Role:	*Research assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*3*
Contribution to Project:	*Data processing and analysis*
Funding Support:	*N/A*
Name:	*Alicia MacDonald*
Project Role:	*Research assistant*
Researcher Identifier (e.g. ORCID ID):	*N/A*
Nearest person month worked:	*1*
Contribution to Project:	*Hardware development*

Funding Support:	*N/A*

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

N/A

What other organizations were involved as partners?

- **Organization Name:** University of Alberta
- **Location of Organization:** Canada
- **Partner's contribution to the project:** Subcontract, Kinesthetic Experiments
  - **Collaboration:** Both laboratories work on project goals and share results

- **Organization Name:** HDT Robotics
- **Location of Organization:** USA
- **Partner's contribution to the projec**t: Subcontract, Device Development
  - **Collaboration:** Wearable Kinesthetic Tactor Development

- **Organization Name:** Louis Stokes Cleveland VA Medical Center
- **Location of Organization:** USA
- **Partner's contribution to the projec**t: Subcontract, Access to VA amputee population, project staff.
  - **Collaboration:** Prosthetics/engineering support

8. **SPECIAL REPORTING REQUIREMENTS**

N/A

APPENDIX

Schoepp K.R., Schofield J.S., Home D., Dawson M.R., Lou E., Keri M.I., Marasco. P.D. and Hebert J.S. “Real Time Monitoring of Transtibial Elevated Vacuum Prostheses: A Case Series on Socket Air Pressure”. PLoS ONE 2018; 13(10): e0202716.

PLOS ONE

RESEARCH ARTICLE

Real time monitoring of transtibial elevated vacuum prostheses: A case series on socket air pressure

Katherine R. Schoepp[1], Jonathon S. Schofield[2], David Home[3], Michael R. Dawson[1], Edmond Lou[4], McNiel Keri[1], Paul D. Marasco[2,5], Jacqueline S. Hebert[1]*

1 Department of Medicine, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, Alberta, Canada, **2** Department of Biomedical Engineering, Lerner Research Institute, Cleveland, Ohio, United States of America, **3** Prosthetics and Orthotics Department, Glenrose Rehabilitation Hospital, Edmonton, Alberta, Canada, **4** Department of Electrical & Computer Engineering, Faculty of Engineering, University of Alberta, Edmonton, Alberta, Canada, **5** Advanced Platform Technology Center of Excellence, Louis Stokes Cleveland Department of Veterans Affairs Medical Center, Cleveland, Ohio, United States of America

* jhebert@ualberta.ca

Citation: Schoepp KR, Schofield JS, Home D, Dawson MR, Lou E, Keri M, et al. (2018) Real time monitoring of transtibial elevated vacuum prostheses: A case series on socket air pressure. PLoS ONE 13(10): e0202716. https://doi.org/10.1371/journal.pone.0202716

Editor: Arezoo Eshraghi, Holland Bloorview Kids Rehabilitation Hospital, CANADA

Received: August 1, 2018

Accepted: October 9, 2018

Published: October 22, 2018

Data Availability Statement: All relevant data are within the paper and its Supporting Information files.

Funding: Partial funding for this project was provided through the Congressionally Directed Medical Research Programs (award number W81XWH-15-1-0575); PDM and JSH. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Abstract

Prosthetic elevated vacuum is a suspension method used to reduce daily volume changes of the residual limb. Evaluation of the effectiveness of these systems is limited due to a lack of correlation to actual socket air pressure, particularly during unconstrained movements. This may explain some of the variability in functional outcomes reported in the literature. Our objective was to develop a light-weight portable socket measurement system to quantify internal socket air pressure, temperature, and acceleration; and to present preliminary results from implementation with three transtibial prosthesis users with mechanical elevated vacuum pumps. Participants completed five functional tasks with and without the vacuum pumps actively connected, including the 2-Minute Walk test, 5-Times Sit-to-Stand test, 4-Square Step test, L-Test, and Figure-8 test. Results demonstrated different gait profiles and pressure ranges for each user. Two of the participants demonstrated substantially lower air pressure (higher vacuum) over time while the pump was active compared to inactive. The minimum air pressure measured for all participants was -34.6 ± 7.7 kPa. One participant did not show substantial changes in pressure over time for either pump condition. Functional task performance was not significantly different between pump conditions. Correlation with accelerometer readings indicated peak positive pressures occurred just following initial contact of the foot in early stance, and the most negative pressures (highest vacuum) were observed throughout swing. This study has demonstrated the use of a portable data logging tool that may serve the clinical and research communities to quantify the operation of elevated vacuum systems, and better understand the variability of mechanical pump operation and overall system performance.

Competing interests: The authors have declared that no competing interests exist.

Introduction

In 2005, there were an estimated 1.6 million people living with an amputation in the United States; this number is expected to increase to 3.6 million by 2050 [1]. Despite advances in prosthetic limb development, optimal socket fit remains a challenge [2–4]. Poor suspension may result in slippage between the socket and the residual limb, particularly during the cyclical loading and unloading associated with gait, which can compromise stability [2]. This can promote irritation, discomfort, and tissue damage [5]. One approach to minimizing this slippage is using elevated vacuum suction suspension, where sub-atmospheric pressure (vacuum) is employed to reduce the relative movement of the user's residual limb with their prosthetic socket [6]. In a typical elevated vacuum socket, the residual limb is covered by a gel liner which sits within a rigid prosthetic socket, and a vacuum is applied through a one-way valve to the space between these layers to improve their connection. The connection between the liner and prosthetic socket is maintained using a proximal seal, which is typically either a suspension sleeve or inner sealing gasket (6). Elevated vacuum systems are predominantly used for attaching lower-limb sockets, though recently there has been preliminary work showing promise for use in transradial [7] and partial-foot amputation cases [8].

Several studies have demonstrated benefits in using elevated vacuum in lower-limb prostheses. When compared to passive suction sockets, vacuum pumps have been shown to maintain or increase residual limb volume during gait [9,10]. This may be due to changes in socket-limb interface pressure, where the vacuum reduces positive contact pressures during stance and increases negative air pressures during swing, thereby increasing the fluid drawn into the limb [11]. In support of this theory, bioimpedance analysis demonstrated an increase in extracellular fluid volume when walking using a transtibial prosthesis with elevated vacuum [12]. Residual limb movement relative to the socket (i.e. pistoning) has been shown to be lower when using elevated vacuum compared to traditional suction and pin-locking systems, with increasing vacuum pressures correlated to reduced pistoning [10,13–15]. Improved balance and gait when using elevated vacuum systems has also been demonstrated [10,16,17]. Compared to pin-locking and traditional suction sockets, elevated vacuum has demonstrated improved perfusion and preservation of skin barrier function after 16 weeks of use [18]. In fact, several studies have found that elevated vacuum systems do not preclude wound healing, and allow patients to ambulate sooner and for longer periods of time compared to other systems [19–21]. Generally, elevated vacuum systems are viewed favourably by clinicians, however questionnaire results have shown that they are perceived as being "more expensive, heavier, less durable, and require more maintenance" than a standard socket [22]. Several review articles have been published in this area, and while existing evidence for elevated vacuum systems is promising, these reviews have indicated a need for more controlled studies, larger sample sizes, and evaluation of long-term effects [6,22–24].

Recent findings have shown that the level of vacuum (i.e. negative air pressure) is directly related to the amount of pistoning [13], and that changes in pressure may be related to quality of socket fit [25]. However, many studies regarding the effectiveness of elevated vacuum do not monitor socket air pressure. Bench-top testing of both electrical pump systems [26,27] and mechanical elevated vacuum systems [26] highlight model-specific differences in measures of performance such as maximum gauge pressure and air evacuation time [26,27]. These differences may help to explain variability in study findings, such as in the case series by Sanders *et al*. that found inconsistent results across different elevated vacuum systems [12]. Monitoring vacuum pressures while wearing a prosthesis with elevated vacuum could possibly shed light on these differences. For in-lab testing, a pressure monitor (model 2L760, DigiVac, Matawan, NJ) has been used to quantify socket air pressure [26–28]. Because this system is tethered to a

computer system and comes with the cost of increased bulk and weight it may not appropriate for tasks that require free movement, limiting its use to standing, sitting, and treadmill walking. Xu *et al.* (2017) developed a pressure measurement system to induce a specific vacuum level in order to study the effect on gait parameters, but did not report the changes in vacuum pressure throughout the trials [29]. The LimbLogic VS Communicator (Ohio Willow Wood) has been developed to measure socket air pressure in real-time [13,25,30], however it is only designed to interface with the LimbLogic VS system, limiting its usability across a wider range of systems. A discrete monitor that could be used across elevated vacuum systems to measure and log socket air pressure in real-time across of variety of functional tasks could provide valuable quantitative comparisons.

To address these limitations, we developed a light-weight portable socket measurement system capable of capturing internal socket air pressure, temperature, and acceleration. Temperature and acceleration measurements were included to provide insight as to whether socket temperature or movement may impact internal air pressure. Acceleration measurements can also be used to temporally align pressure readings with the gait cycle. This system can either log data to onboard memory, or stream wirelessly and in real-time to a computer. The objective of this paper is to describe the system design, fabrication, and integration of the device, as well as present preliminary results from implementation with three transtibial prosthesis users with mechanical elevated vacuum pumps.

Methods

Ethics approval was obtained through the University of Alberta's institutional review board and participants gave written informed consent prior to participation. Participant recruitment was based on a convenience sample. Inclusion criteria were adults (18 to 75 years of age) with a major lower limb amputation (at or above the ankle), wearing a lower limb prosthesis with a vacuum seal in the socket, and at least K-level 3 (unlimited community ambulator). Exclusion criteria were any skin, pain, or balance conditions that would preclude the ability to wear a prosthetic socket, or cognitive impairments or language barriers precluding providing informed consent or responding to survey questions. Three participants currently using an elevated vacuum system in their prosthesis were recruited through prosthetics shops, with details listed in Table 1. Each prosthesis was evaluated by a certified prosthetist and was deemed to be well-fitting at the time of testing. To confirm quality of fit, participants completed the OPUS Lower Extremity Functional Status Measures survey [31], with results ranging from 50 to 70 out of a total possible score of 80. Note that "short" limb length refers to a tibia length less than 12 cm and "medium" is between 12 and 15 cm [32].

Design and installation of data logger

The socket data logger was developed in-house and contained three sensors; an air-pressure sensor (MPXx6250A, Freescale Semiconductor, range: 20 to 250 kPa absolute, reported accuracy: ± 0.25 kPa), an external temperature probe (LMT86, Texas Instruments, range: -50 to 150˚C, reported accuracy: ± 0.4˚C), and an inertial measurement unit (MPU-9250, InvenSense, range: -8 to 8 G, reported accuracy: ± 0.05 G). Overall dimensions of the device including housing were 18 x 38 x 51 mm with a total weight of 27 g. The device was powered by a lithium polymer battery and communicated using Bluetooth LE in real-time via a custom graphical user interface (GUI) at a frequency of 25 Hz while, simultaneously logging the data to internal on-board memory at the same rate for redundancy. Benchtop validation testing using the Harmony e-pulse (Ottobock, Germany) connected to a sealed empty chamber

Table 1. Participant information and prosthetic components.

	Participant 1	Participant 2	Participant 3
Participant information			
Sex	Male	Male	Male
Weight	225 lbs	175 lbs	210 lbs
Height	5'11"	5'10"	6'2"
Amputation information			
Amputation level	Transtibial	Transtibial	Transtibial
Side of amputation	Right	Left	Right
Type of amputation	Trauma	Vascular	Vascular
Time since amputation	4 years, 1 month	3 years, 4 months	8 years, 4 months
Limb length, geometry	Short, Conical	Medium, Cylindrical	Medium, Cylindrical
Wear and performance			
Hours per day prosthesis worn	16	16	16
Days per week prosthesis worn	7	7	7
OPUS Functional Status Score	50 out of 80	70 out of 80	69 out of 80
Prosthetic components			
Elevated vacuum system	Harmony P3 (Ottobock, 4R147 = K)	Unity Sleeveless Vacuum (Össur)	Triton H (Ottobock, 1C62, Rt. Cat. 3-4-P4N)
Liner	Alpha Design Custom Liner (WillowWood, ALC-DES-EO)	Alpha Classic Liner (WillowWood, ALC-5064-E)	Anatomic 3D PUR Liner (Ottobock, 6Y512 = 265x125-F)
Foot	LP Vari-Flex (Össur, 27R C7)	Pro-Flex LP Torsion (Össur, PLTO425L)	Triton H (Ottobock, 1C62, Rt. Cat. 3-4-P4N)
Sleeve	Extreme Sleeve (Alps, SFK-28-3)	ProFlex Plus Sleeve (Ottobock, 453A = 1–0)	ProFlex Plus Sleeve (Ottobock, 453A40 = 2–7)
Socket type	Thermoplastic temporary socket	Laminated	Environmentally Managed System, Laminated (EMS)

https://doi.org/10.1371/journal.pone.0202716.t001

(approximately 130 cm^3) indicated minimum evacuated pressures of -62.8 ± 1.4 kPa, consistent with measurements in literature [26,27].

Air pressure measurements in the socket were obtained by connecting the sensor to the socket via the existing tubing (Participants 1 and 3) or exhaust port connector (Participant 2) between the pump and socket, shown in (Fig 1). A narrow tubing diameter was selected (1/16 inches inner diameter) to ensure that the inclusion of the data logger would have minimal impact on the overall volume of the prosthetic socket; the volume increase for a 20 cm length of tubing is 0.4 cm^3, relatively small compared to estimated socket volumes ranging from 33 to 197 cm^3 [27]. Therefore, consistent with Boyle's law and previous prosthetic literature [30], air pressure measurements within this additional tubing are equivalent to the air pressure throughout the prosthetic socket. The temperature probe was placed on the outside of the socket and covered with the prosthetic liner. The housing containing the inertial measurement unit was mounted to the outside of the rigid socket, as was the temperature probe.

Pump performance was evaluated in two conditions; active and inactive. In the active condition, the pump was connected to the socket as per manufacturer's instructions. In the inactive condition, the connection to the pump was replaced by a plug, thereby separating the pump from the socket. Trials were double-blinded; both the participant and researchers did not know the condition of the pump. To ensure the double-blind condition was maintained, a certified prosthetist was responsible for connecting or disconnecting the pump between trials and did not communicate the state of the system until after data analysis was complete. A

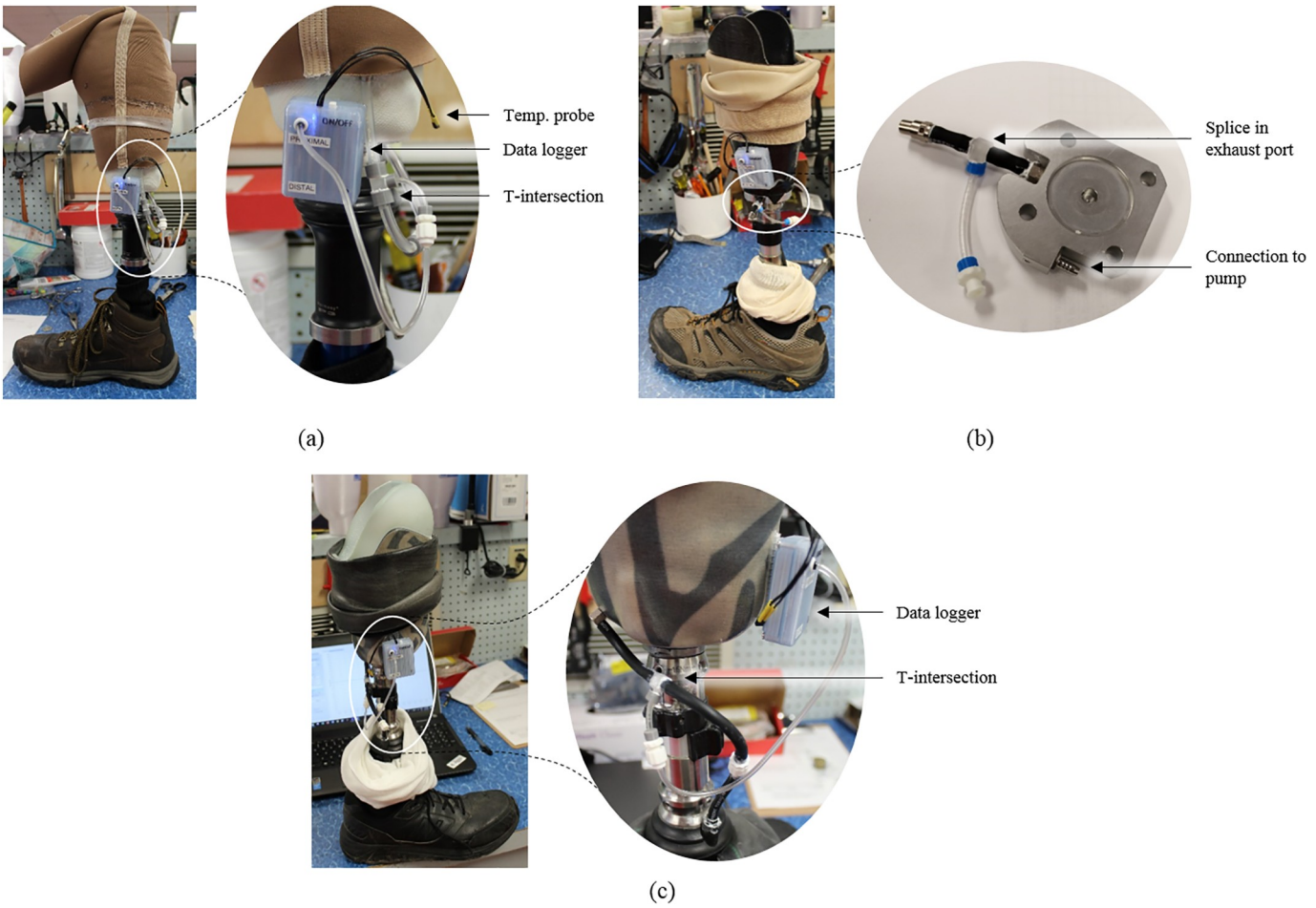

Fig 1. Installation of data logger onto prosthetic socket. Modified sockets for (a) Participant 1, (b) Participant 2, and (c) Participant 3.

https://doi.org/10.1371/journal.pone.0202716.g001

shroud was placed over the entire prosthetic leg to hide any visual clues. There were however minor differences in auditory cues in the different pump conditions.

Functional tasks and subjective surveys

Five mobility tasks were performed for each trial in the same order. Tasks were selected to capture different movements representative of everyday life, including walking, sit-to-stand, turning, and stepping. The first task was a 2-Minute Walk Test, similar to [33], where the participant walked in a large circular hallway (circumference of 190 m) for two minutes. The total distance travelled was measured using a measuring wheel (Rolatape Measuring Systems, Model MM-45M). The participant then completed the Five Times Sit-to-Stand test [34], the 4-Square Step test [35], the L-Test [36], and the Figure-8 test [37]; time to task completion, number of steps, and errors were determined from analysis of video footage. At the beginning of the test session, task instructions were provided to the participant and they were given the opportunity to practice each task until comfortable with their performance. This was done to minimize potential learning effects during the trials. During each trial, the 2-Minute Walk test and 5-Times Sit-to-Stand test were completed once, and the 4-Square Step test, L-Test, and Figure-8 test were completed twice.

At the beginning of each trial, the prosthetist connected or disconnected the pump in a room separate from the participant and researchers. Each condition (pump active or inactive) was evaluated twice for a total of four trials, with order of condition block randomized in pairs. Participants were asked to don their prosthesis as usual, then they completed the functional tasks outlined in the order above. If a mistake was made during one of the functional tasks, that specific task was repeated immediately. Once the functional testing was complete, participants were asked to doff their prosthesis, and a seated break of at least five minutes was enforced prior to the next trial.

After each trial the participant completed a short survey to capture their impressions of the prosthesis under the current condition. The survey was modified from the OPUS Satisfaction with Device Score [38], and used a 5-point Likert scale, from 1 (strongly disagree) to 5 (strongly agree), shown in S1 Table.

Data treatment

Analysis was conducted using Excel (Microsoft, 2016) and Matlab (Mathworks, R2017b). Gauge pressure data and acceleration magnitudes were analyzed. For each of the activities, data was broken into individual movements of the gait cycle (i.e. strides) by delineating at maximum pressures within the approximate stride period specified; note that data segments were shifted forward by 10 timesteps (0.4 s) to visually capture the data surrounding the peaks in pressure. The exception is for the sit-to-stand motion where minimum pressures were used to separate movements. The data was then normalized over movement length, creating a scale of 0 to 100% movement completion that allowed for the data to be plotted by condition. Pressure change over time was calculated by determining the slope of the data using simple linear regression. From each individual movement, average and standard deviation values were determined. Two-sample t-tests were used to evaluate differences between active compared to inactive conditions, with variance conditions confirmed using f-tests, and $\alpha = 0.05$. Note that Trial 4 from Participant 3 was excluded from the analysis due to technical challenges resulting from the donning process that resulted in inadequate seal from the sleeve, compromising the suction suspension.

Results

Data analysis was completed for each of the five functional tasks. A detailed description of the 2-Minute Walk test is presented, as the large number of cyclical loading and unloading movements provided the most detail. A summary of the results from the remaining tests is then provided. Finally, functional task performance and qualitative survey responses are presented.

Detailed analysis of 2-Minute Walk test

Gauge pressure data collected during the 2-Minute Walk test for each participant are shown in Fig 2. The thin lines indicate the real-time pressure measurements, which fluctuated substantially with each stride. The thick lines indicate the overall change in pressure. For Participant 1 (Fig 2a), the pressure remained fairly consistent, regardless of pump condition. For Participant 2 (Fig 2b), in both conditions the pressure dropped (vacuum increased) initially, then stabilized to different values depending on pump condition. For Participant 3 (Fig 2c), the pressure was fairly consistent when the pump was inactive and fell continuously when the pump was active.

Data for the 2-minute walk test was broken into individual strides as shown in Fig 3. Early strides are indicated in blue with later strides in yellow. This visualization demonstrates differences in vacuum pressures over time. In the case of Participant 1 (Fig 3a), the use of elevated

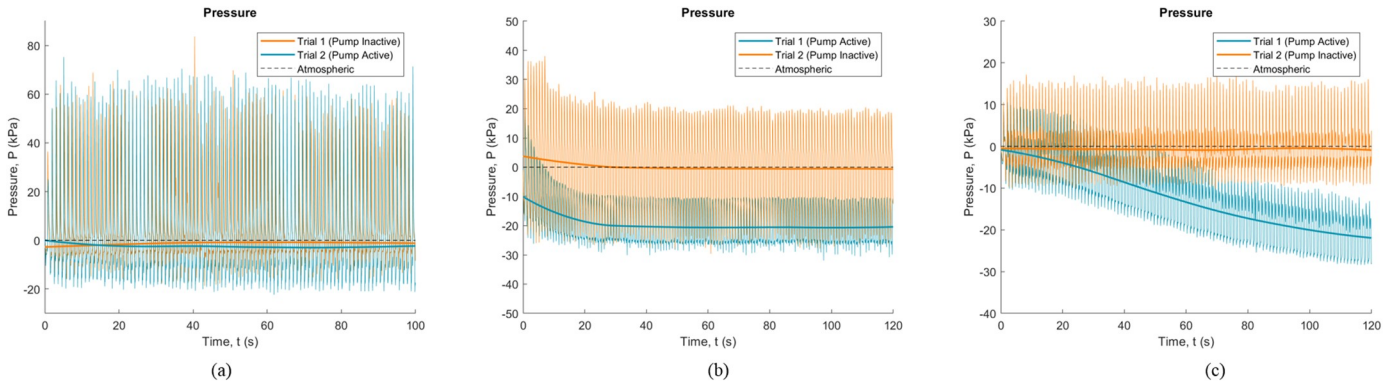

Fig 2. Overall gauge pressure data during 2-Minute Walk test. Data is shown across (a) Participant 1, (b) Participant 2, and (c) Participant 3. Thin lines indicate raw data and thick lines indicate measurements smoothed using the rloess function in Matlab.

https://doi.org/10.1371/journal.pone.0202716.g002

vacuum (pump active) appeared to reduce the variations in pressure occurring with each stride, but not the overall pressures. For Participant 2 (Fig 3b) there was a reduction in overall gauge pressure (increase in vacuum) with subsequent strides in both conditions, with more consistently negative vacuum pressures with the pump active. For Participant 3 (Fig 3c), there was a clear effect of the active pump condition showing progressive reduction in pressures with subsequent strides, compared to the no pump condition which show little to no change.

Average gauge pressure and acceleration data for the 2-Minute Walk test are shown in Fig 4, normalized over the full stride length. As above, Participant 1 (Fig 4a) visually showed

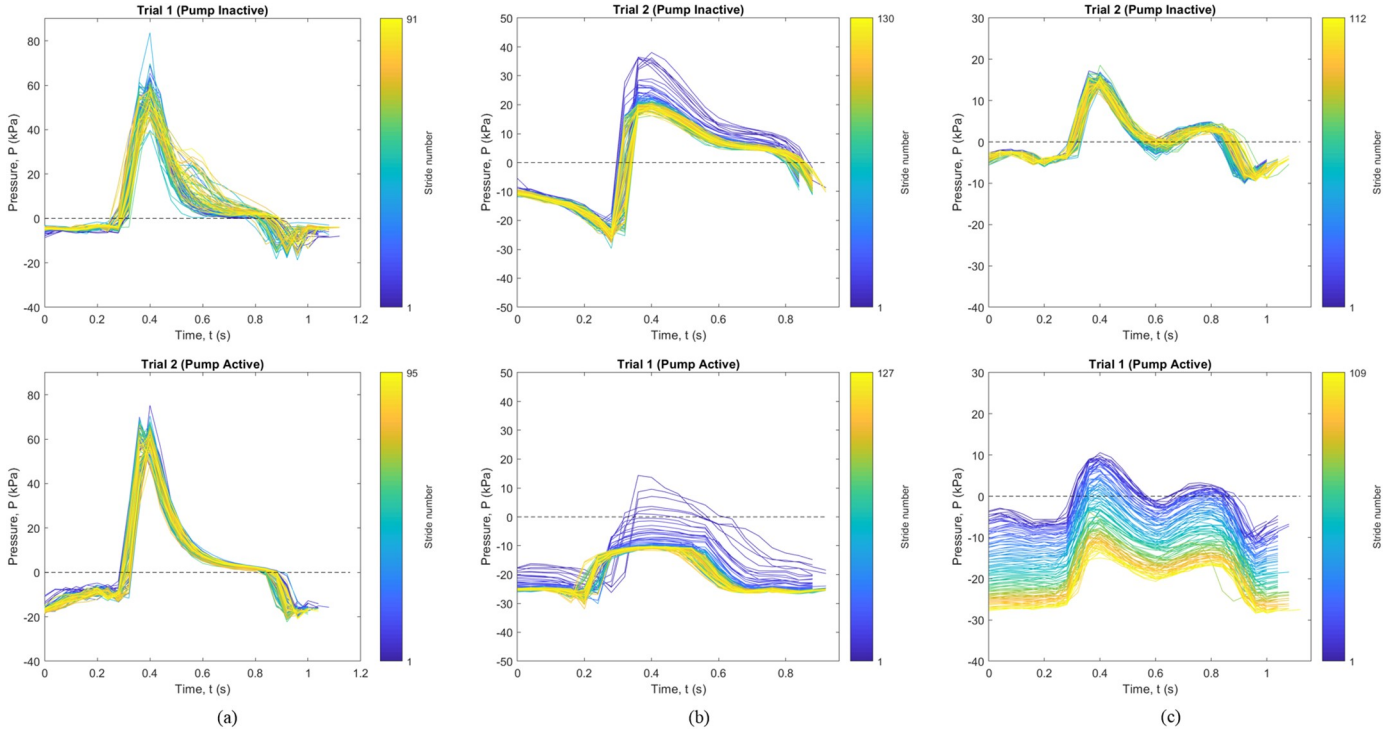

Fig 3. Individual gauge pressure stride data during 2-Minute Walk test. Data is shown with pump inactive (top) and pump active (bottom), across (a) Participant 1, (b) Participant 2, and (c) Participant 3. Blue indicates the first stride and yellow the last, with the legend indicating total stride count.

https://doi.org/10.1371/journal.pone.0202716.g003

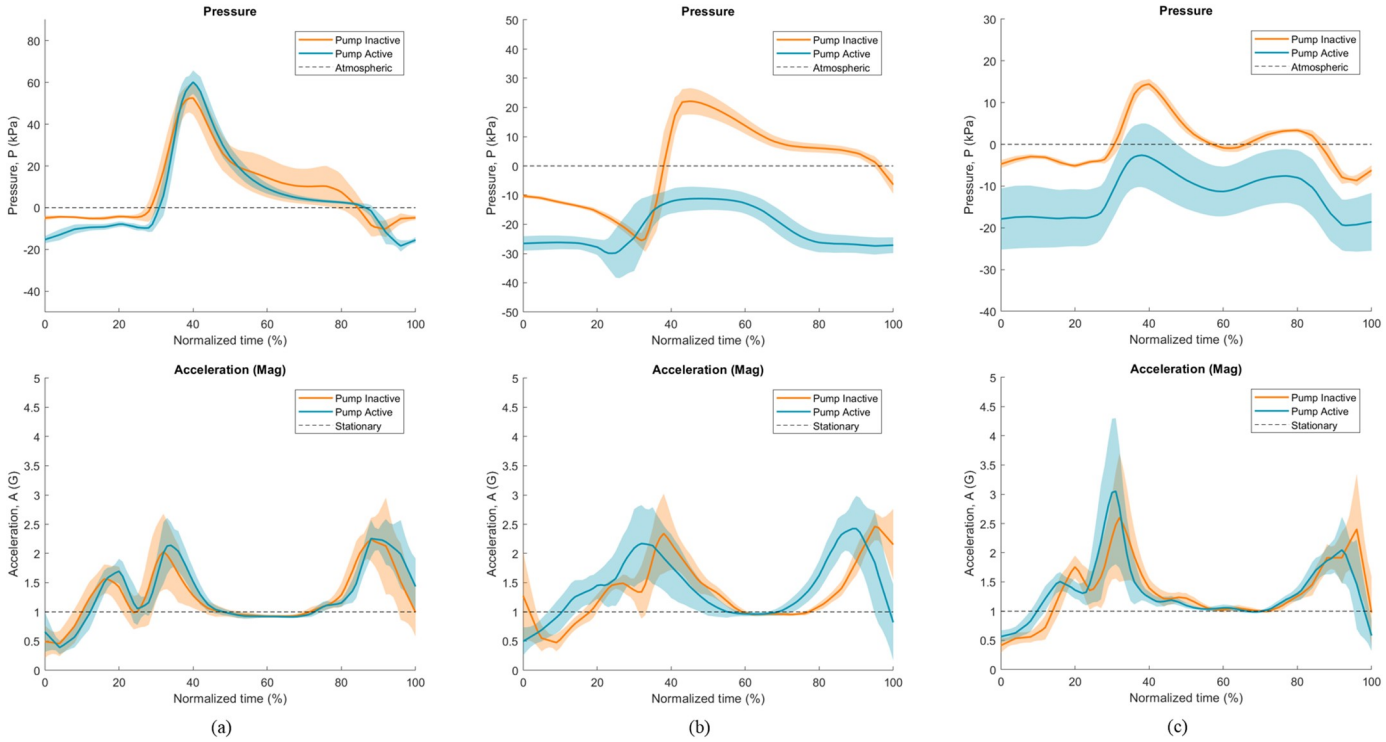

Fig 4. Normalized individual stride data during 2-Minute Walk test. Data is shown for gauge pressure (top) and magnitude of acceleration (bottom), across (a) Participant 1, (b) Participant 2, and (c) Participant 3. Dark lines indicate average measurements, with shaded areas indicating standard deviation.

https://doi.org/10.1371/journal.pone.0202716.g004

small differences in absolute pressure between conditions, and lower pressure variation with the pump active. Participants 2 (Fig 4b) and 3 (Fig 4c) showed large differences in pressure between conditions, where the active elevated vacuum reduced overall pressure. Across all three participants, peaks in pressure were followed by drops; these drops coincided with stable acceleration measurements, where acceleration magnitude was close to 1.0 G.

Values and statistical results from the data analysis of gauge pressure and acceleration are presented in Table 2. Gauge pressure was statistically lower (vacuum higher) while the elevated vacuum system was active, though the effect size varied by participant. Pressure change over the duration of the walk was significantly different for both Participants 1 and 3, where the active pump condition showed an overall reduction in socket pressure. There significant differences in acceleration magnitude between conditions for Participants 1 and 2, though effect size may not be clinically significant.

For further insight into differences with vacuum pressures during the 2-Minute Walk test, we analyzed the first 5 and last 5 strides of the task (Table 3). In all instances, there were

Table 2. Average measured results over individual strides during 2-Minute Walk test. Reported as mean ± standard deviation. Significant differences are highlighted. Abbreviations are as follows: press. (pressure), accel. (acceleration), mag. (magnitude).

		Participant 1			Participant 2			Participant 3		
		Inactive	Active	P-value	Inactive	Active	P-value	Inactive	Active	P-value
2-Minute Walk	Gauge press. (kPa)	8.5 ± 2.9	4.6 ± 1.3	< 0.001	-0.1 ± 1.4	-21.7 ± 3.2	< 0.001	0.1 ± 0.3	-12.4 ± 6.7	< 0.001
	Accel. mag. (G)	1.2 ± 0.1	1.3 ± 0.0	< 0.001	1.3 ± 0.1	1.4 ± 0.1	< 0.001	1.3 ± 0.1	1.3 ± 0.1	0.743
	Press. change (kPa / min.)	1.6 ± 0.3	-0.5 ± 0.2	0.016	-1.6 ± 0.0	-2.6 ± 0.5	0.096	0.1 ± 0.2	-11.7 ± 0.0	0.014

https://doi.org/10.1371/journal.pone.0202716.t002

Table 3. Average gauge pressure data across initial and final strides during 2-Minute Walk. Reported as mean ± standard deviation. Significant differences are highlighted.

		Participant 1			Participant 2			Participant 3		
		Inactive	Active	P-value	Inactive	Active	P-value	Inactive	Active	P-value
Initial 5 strides	Min. press. (kPa)	-13.8 ± 2.0	-18.5 ± 1.2	< 0.001	-24.9 ± 1.9	-28.9 ± 5.3	0.022	-9.8 ± 0.7	-10.1 ± 0.3	0.005
	Max. press. (kPa)	58.1 ± 10.9	66.7 ± 7.2	0.035	38.6 ± 3.6	4.3 ± 5.2	< 0.001	15.0 ± 0.9	9.6 ± 0.6	0.001
Final 5 strides	Min. press. (kPa)	-12.9 ± 1.8	-20.5 ± 1.7	< 0.001	-27.5 ± 3.2	-34.6 ± 7.7	0.002	-9.3 ± 0.4	-28.3 ± 0.1	< 0.001
	Max. press. (kPa)	54.5 ± 3.4	61.8 ± 4.3	0.007	20.0 ± 1.7	-12.2 ± 1.8	< 0.001	15.7 ± 0.8	-13.5 ± 1.0	< 0.001

https://doi.org/10.1371/journal.pone.0202716.t003

significant differences in gauge pressure between the active versus inactive conditions. Differences in pressures between the active and inactive conditions were more pronounced for the last 5 strides of the test compared to the first 5 strides, particularly for Participants 2 and 3. Notably, the maximum air pressure for Participant 2 and 3 for the last 5 strides of the task with the pump active maintained negative values, meaning that the socket was sub-atmospheric throughout the entire gait profile, in contrast to the positive values in the inactive pump condition.

Analysis of remaining functional tests

Values and statistical results from the data analysis of gauge pressure and acceleration for the remaining four tasks are presented in Table 4. Differences between pump active and inactive were smaller during the shorter duration tasks compared to the 2-Minute Walk test.

Temperature measurements of the external socket ranged between 22 and 27˚C, however there was no correlation to pump condition.

Functional task performance

Functional task performances are summarized in S2 Table. There were no significant differences in performances based on pump condition ($p > 0.05$ for all comparisons). Functional task performance in both conditions and across all participants fell within normative walking distances during the 2-Minute Walk test [33]. Performance during the L-Test and Figure-8 test exceeded reported values based on populations of transtibial amputees and people with mobility disabilities, respectively [36,37]. Task durations of the 5 Times Sit-to-Stand and 4-Square Step tests were longer than values reported in normative adult populations [35,39].

Table 4. Average measured results over individual strides during remaining functional tests. Reported as mean ± standard deviation. Significant differences are highlighted. Abbreviations are as follows: press. (pressure), accel. (acceleration), mag. (magnitude).

		Participant 1			Participant 2			Participant 3		
		Inactive	Active	P-value	Inactive	Active	P-value	Inactive	Active	P-value
5 Times Sit-to-Stand	Gauge press. (kPa)	2.7 ± 0.7	0.6 ± 0.4	< 0.001	-0.7 ± 0.5	-4.0 ± 2.9	0.042	-1.8 ± 1.1	-10.1 ± 1.0	< 0.001
	Accel. mag. (G)	1.0 ± 0.00	1.0 ± 0.01	0.193	1.0 ± 0.00	1.0 ± 0.01	0.112	1.0 ± 0.01	1.0 ± 0.00	0.303
4-Square Step Test	Gauge press. (kPa)	5.7 ± 4.0	6.6 ± 2.9	0.264	1.3 ± 5.0	-5.7 ± 4.7	< 0.001	0.8 ± 1.0	-4.5 ± 1.2	< 0.001
	Accel. mag. (G)	1.2 ± 0.13	1.1 ± 0.03	< 0.001	1.2 ± 0.12	1.1 ± 0.11	0.311	1.1 ± 0.05	1.1 ± 0.04	0.919
L-Test	Gauge press. (kPa)	9.3 ± 3.3	7.0 ± 2.9	< 0.001	7.0 ± 6.2	-11.0 ± 5.6	< 0.001	0.9 ± 0.7	-4.3 ± 1.1	< 0.001
	Accel. mag. (G)	1.3 ± 0.16	1.2 ± 0.07	< 0.001	1.3 ± 0.12	1.3 ± 0.13	0.521	1.2 ± 0.08	1.2 ± 0.10	0.207
Figure-8 Test	Gauge press. (kPa)	7.7 ± 4.6	6.0 ± 1.9	0.149	3.4 ± 3.4	-9.3 ± 3.5	< 0.001	0.2 ± 0.6	-2.9 ± 0.9	< 0.001
	Accel. mag. (G)	1.3 ± 0.16	1.3 ± 0.12	0.433	1.2 ± 0.11	1.3 ± 0.10	0.282	1.2 ± 0.06	1.2 ± 0.07	0.586

https://doi.org/10.1371/journal.pone.0202716.t004

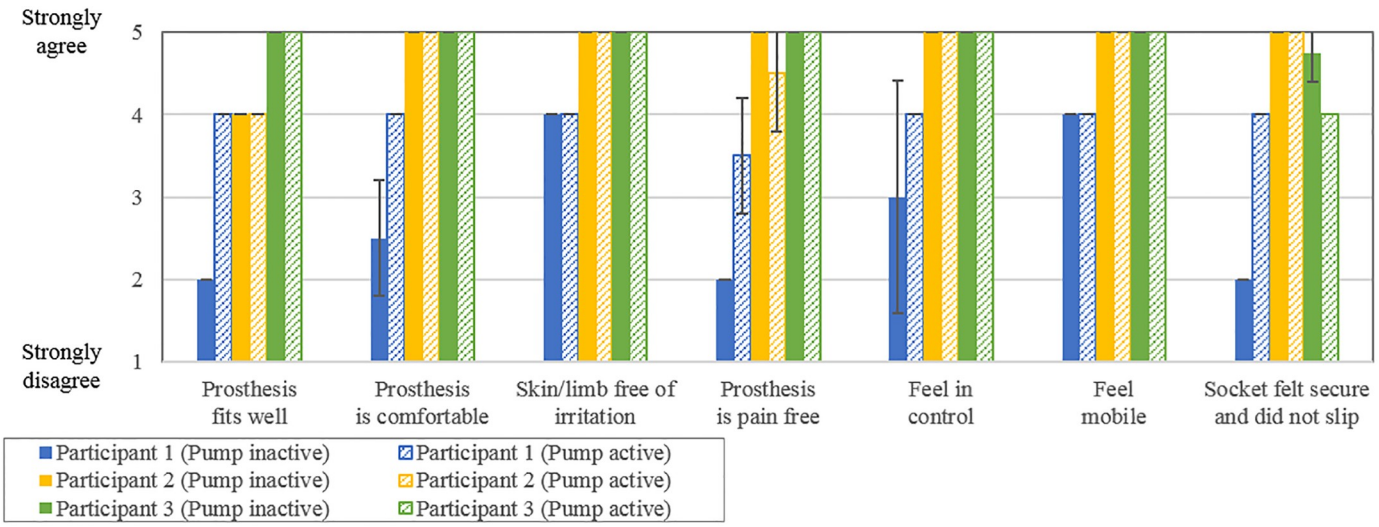

Fig 5. Comparison of qualitative survey scores. Solid colour bars indicate inactive pump condition scores and hatched bars indicate active pump condition scores, with error bars indicating standard deviation.

https://doi.org/10.1371/journal.pone.0202716.g005

Qualitative survey responses

Responses to the qualitative survey are summarized in Fig 5. Despite our attempts to blind the participants to the condition of the pump, Participant 1 was able to correctly identify pump condition in all trials. Survey responses of Participant 1 indicated a preference towards the use of the elevated pump, with a perceived improvement in prosthesis fit and comfort, reduced pain and perception of slippage, as well as a greater feeling of control. Participant 2 misidentified the pump conditions for Trials 1 and 2 and was correct for Trials 3 and 4. Participant 3 misidentified every pump condition. Survey responses from Participants 2 and 3 did not indicate a clear preference towards either pump condition.

Discussion

We have developed and applied a device that is able to capture real-time socket pressure and acceleration data while worn non-intrusively and without restricting mobility. This study has demonstrated the performance of the data logger and allowed for the evaluation of air pressure within three different mechanical elevated vacuum systems while worn and performing standardized functional mobility tasks. The use of the pumps resulted in significant changes to socket air pressure over time, where each participant demonstrated different gait profiles and pressure ranges.

With the pump active, both Participants 2 and 3 demonstrated a substantial decrease in socket air pressure over the duration of the 2-Minute Walk test. For Participant 2, the air pressure dropped then plateaued after approximately 50 steps. However, for Participant 3, the pressure dropped continually over the duration of the trial. The air pressure in both participants' sockets reached a similar final negative pressure range at the end of the task. With the pump inactive, the air pressure values at the end of the trials were similar to those at the beginning; the maximum pressure continued to fluctuate above atmospheric pressure. However, with the pump active, air pressure readings were consistently negative for the final 5 strides, indicating that the elevated vacuum was maintaining a sub-atmospheric pressure throughout the full stride. Interestingly, these two participants had difficulties distinguishing when the pump was

active, and questionnaire results did not show a clear preference towards either condition. It was surprising that the participants with apparently effective vacuum systems could not accurately detect when the pump was active.

In contrast, the air pressure in Participant 1's socket did not change substantially over the 2-Minute Walk test, in both active and inactive pump conditions. However, with the pump active there was a more consistent pressure profile. This participant was the most successful at correctly identifying pump condition, and questionnaire results indicated a strong preference towards the pump being active. Differences between participants may be due to a combination of factors other than pump design, including socket fit and material properties, limb geometry, donning process, and gait pattern, to name a few. In particular, this participant had a short conical limb with less soft tissue coverage, in comparison to the other 2 participants. Future work should investigate the effect of soft tissue compliance and volume on effectiveness of vacuum systems.

Similar pressure trends were seen during the other walking-based tasks (Figure-8 and L-test), though they were not as pronounced due to the shorter task duration. Some average acceleration magnitudes were significantly different between conditions; however, these differences were very small and may not be clinically relevant. The 5-Times Sit-to-Stand activity yielded lower variance in pressure and acceleration compared to other activities, likely because the prosthetic leg was planted against the floor rather than suspended from the limb in swing phase.

Using the measured acceleration readings, changes in socket air pressure can be roughly correlated to phases of the gait cycle. Willemsen *et al*. demonstrated that stable accelerations equivalent to gravity correspond to stance, variable readings to swing, and that peaks occur during push off and foot down [40]. We can therefore infer that peak positive pressures occurred just following initial contact of the foot in early stance, with pressure decreasing during stance. The most negative pressures (highest vacuum) were observed throughout swing. This is similar to the pressure profiles measured by Chino *et al*., where nine transtibial amputees using suction sleeves were evaluated [41]. It may be valuable in future work to synchronize the pressure profiles with specific phases of the gait cycle.

Pressure ranges reported in literature vary depending on the type of pump used. Our measured results did not attain negative pressures as low as the benchtop testing conducted by Komolafe *et al*. [27], which evaluated different mechanical pumps using a material testing system and found that a vacuum pressure of -57.6 kPa could be achieved in less than 50 loading cycles or 80 seconds. Xu *et al*. [29] recommended a moderate level of 50 kPa to optimize comfort and gait symmetry; their pressures were manually pulled rather than induced by the mechanical pump. The minimum pressures observed at the completion of the 2-Minute Walk test during our study were -34.6 ± 7.7 kPa. This may be due to differences between idealistic 'bench-top' testing conditions and real-world prosthetic sockets worn by participants; loading profiles and rates were substantially different, and it is likely that the seal of a socket on an amputated limb is inferior to an idealized system. Chino *et al*. found minimum pressures using a suction sleeve ranged between -7 and -31 kPa over ten gait cycles [41]. In contrast, air pressures created by electrical elevated vacuum pumps have been reported to range between -27 to -85 kPa [9–11,13,19,20,25,26,28,30]. This disparity indicates there may be large differences in air pressure between systems, and more evaluation is needed to better understand the impact of these differences on prosthesis user function.

Functional task performances were compared to reported data. All three participants met or exceeded reported scores for the walking-based tasks (2-Minute Walk, L-Test, and Figure-8) but demonstrated reduced performance for both the 5 Times Sit-to-Stand and 4-Square Step tests. There were no significant differences in task performances between pump

conditions, suggesting that the short-term use of elevated vacuum may not have a measurable impact on functional mobility. This is in contrast with the more longer term study conducted by Samitier *et al*. [17] that found improvements in functional task scores of 16 transtibial participants after 4-weeks of training with an elevated vacuum system, when compared to their previous system.

Limitations and future work

This study quantified socket air-pressure across three elevated vacuum systems within worn prosthetic sockets, during specific tasks allowing unconstrained movement in the clinical lab environment. The data logger tool, testing protocols, and analyses presented contribute to the clinical and research communities by helping to quantify the operation of elevated vacuum systems, and to bridge the gap between the measurement of mechanical pump operation and overall system performance and function.

The main limitation of this study is that it is a case series where the elevated vacuum components and fittings were not controlled; while this inherently makes it difficult to draw specific conclusions, the large variability between users has demonstrated the need to question whether or not these systems work effectively in all users. Future studies should be controlled to allow for specific conclusions to be drawn.

The short duration of the study is also a limitation; the next step is to study trends over longer periods of time. Collecting the data within a clinical lab environment may have affected the participants' use of their prosthesis; it will be particularly useful to collect data outside of the laboratory or clinical setting in the future. This will allow further inferences regarding the pressure changes that occur within a socket not only during various movements, but also during daily living tasks and throughout a longer wearing time. The on-board acceleration measurements could be used to determine compliance, activity level, or to monitor falls, as suggested in literature [42,43]. The temperature sensor may provide insight into the impact of different environments on vacuum performance; inclusion of a second temperature probe could allow differences in internal socket temperature and environmental temperature to be studied. It may also be interesting to integrate our system with additional sensors, such as limb-socket interface pressure sensors or strain gauge sensors to quantify forces and moments applied to the prosthesis and residual limb [43].

Future work may also involve determining correlations between socket air pressure and measurements of the residual limb. For example, residual limb volume loss has been demonstrated in seated [9] and standing [12] tasks. It would be valuable to understand how this loss may be related to average pressures versus cyclical pressure changes, and also to different soft tissue characteristics of residual limbs. It will be valuable to investigate pressure differences between mechanical and electrical pumps, as electrical pumps may be set to greater vacuum pressures than the mechanical pumps evaluated in this study, and will likely generate different pressure profiles. Additionally, future studies should investigate factors that contribute to the effectives of different elevated vacuum systems, such as limb geometry, tissue stiffness, gait and movement strategy, and activity level.

In the future, these techniques should be useful for clinicians, developers, and researchers to address questions related to elevated vacuum system performance. As a clinical tool, this could be used to quickly identify leaks in a socket, understand user compliance, and determine trends in performance throughout the day. There is also a potential for benefit in remote health-care applications [43], or to provide information to developers regarding the impact of various prosthetic components and manufacturing techniques.

Supporting information

S1 Table. Qualitative survey questionnaire. Modified from the OPUS Satisfaction with Device Score (38).
(DOCX)

S2 Table. Functional modbility task results. Functional task performance across entire trial, reported as mean ± standard deviation.
(DOCX)

S1 Dataset. Supplementary data.
(XLSX)

Acknowledgments

The authors would like to thank the Glenrose Rehabilitation Hospital for providing space to conduct the testing as well as the following prosthetics shops for their assistance with participant recruitment: Edmonton Prosthetic Services, Northern Alberta Limb, and the Prosthetic and Orthotic Care Company. They also acknowledge Ossur for loaning the plate (Ossur Icelock 544 Plate Unity) used to collect data for Participant 2. Thank you to Stéphane Magnan and Fraaz Kamal for their assistance with developing the data logger.

Author Contributions

Conceptualization: Katherine R. Schoepp, Jonathon S. Schofield, David Home, Michael R. Dawson, Jacqueline S. Hebert.

Data curation: Katherine R. Schoepp, McNiel Keri.

Formal analysis: Katherine R. Schoepp.

Funding acquisition: Paul D. Marasco, Jacqueline S. Hebert.

Investigation: Jonathon S. Schofield, David Home, Michael R. Dawson, McNiel Keri.

Methodology: Katherine R. Schoepp, Jonathon S. Schofield, David Home, Michael R. Dawson, Edmond Lou, Jacqueline S. Hebert.

Project administration: Katherine R. Schoepp, Jacqueline S. Hebert.

Resources: David Home, Edmond Lou, Jacqueline S. Hebert.

Software: Katherine R. Schoepp, Edmond Lou.

Supervision: Paul D. Marasco, Jacqueline S. Hebert.

Visualization: Katherine R. Schoepp.

Writing – original draft: Katherine R. Schoepp.

Writing – review & editing: Katherine R. Schoepp, Jonathon S. Schofield, Michael R. Dawson, Edmond Lou, McNiel Keri, Paul D. Marasco, Jacqueline S. Hebert.

References

1. Ziegler-Graham K, MacKenzie EJ, Ephraim PL, Travison TG, Brookmeyer R. Estimating the prevalence of limb loss in the United States: 2005 to 2050. Arch Phys Med Rehabil. 2008; 89(3): 422–429. https://doi.org/10.1016/j.apmr.2007.11.005 PMID: 18295618
2. Mak AF, Zhang M, Boone DA. State-of-the-art research in lower-limb prosthetic biomechanics-socket interface: a review. J Rehabil Res Dev. 2001; 38(2): 161–174. PMID: 11392649

3. Legro MW, Reiber G, del Aguila M, Ajax MJ, Boone DA, Larsen JA, et al. Issues of importance reported by person with lower limb amputations and prostheses. J Rehabil Res Dev. 1999; 36(3): 155–163. PMID: 10659798
4. Klute GK, Kantor C, Darrouzet C, Wild H, Wilkinson S, Iveljic S, et al. Lower-limb amputee needs assessment using multistakeholder focus-group approach. J Rehabil Res Dev. 2009; 46(3): 293–304. PMID: 19675983
5. Levy SW. Skin Problems of the Amputee. In: Bowrker JH, Michael JW, editors. Atlas of Prosthetics: Surgical, Prosthetic, and Rehabilitation Principles. 2nd ed. St Louis, MO: Mosby Yearbook; 1992. pp. 681–688.
6. Kahle JT, Orriola JJ, Johnston W, Highsmith MJ. The Effects of Vacuum-assisted Suspension on Residual Limb Physiology, Wound Healing, and Function: A Systematic Review. Technol Innov. 2013; 15(4): 333–341.
7. Lang M, Conyers D. Utilization of negative pressure for socket suspension in upper extremity prosthetics. Proceedings of the MEC'08 Conference, UNB. 2008.
8. Arndt B, Caldwell R, Fatone S. Use of a partial foot prosthesis with vacuum-assisted suspension: A case study. J Prosthetics Orthot. 2011; 23(2): 82–88.
9. Goswami J, Lynn R, Street G, Harlander M. Walking in a vacuum-assisted socket shifts the stump fluid balance. Prosthet Orthot Int. England; 2003; 27(2): 107–113.
10. Board WJ, Street GM, Caspers C. A comparison of trans-tibial amputee suction and vacuum socket conditions. Prosthet Orthot Int. England; 2001; 25(3): 202–209.
11. Beil TL, Street GM, Covey SJ. Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets. J Rehabil Res Dev. United States; 2002; 39(6): 693–700.
12. 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. J Rehabil Res Dev. 2011; 48(10): 1231–1248. PMID: 22234667
13. Gerschutz MJ, Hayne ML, Colvin JM, Denune JA. Dynamic Effectiveness Evaluation of Elevated Vacuum Suspension. J Prosthetics Orthot. 2015; 27(4): 161–165.
14. Klute GK, Berge JS, Biggs W, Pongnumkul S, Popovic Z, Curless B. Vacuum-assisted socket suspension compared with pin suspension for lower extremity amputees: effect on fit, activity, and limb volume. Arch Phys Med Rehabil. 2011; 92(10): 1570–1575. https://doi.org/10.1016/j.apmr.2011.05.019 PMID: 21963124
15. Darter BJ, Sinitski K, Wilken JM. Axial bone-socket displacement for persons with a traumatic transtibial amputation: The effect of elevated vacuum suspension at progressive body-weight loads. Prosthet Orthot Int. 2016; 40(5): 552–557. https://doi.org/10.1177/0309364615605372 PMID: 26423107
16. Kuntze Ferreira AE, Neves EB. A comparison of vacuum and KBM prosthetic fitting for unilateral transtibial amputees using the Gait Profile Score. Gait Posture. England; 2015; 41(2): 683–687.
17. Samitier CB, Guirao L, Costea M, Camos JM, Pleguezuelos E. The benefits of using a vacuum-assisted socket system to improve balance and gait in elderly transtibial amputees. Prosthet Orthot Int. 2016; 40(1): 83–88. https://doi.org/10.1177/0309364614546927 PMID: 25261489
18. Rink C, Wernke MM, Powell HM, Gynawali S, Schroeder RM, Kim JY, et al. Elevated vacuum suspension preserves residual-limb skin health in people with lower-limb amputation: Randomized clinical trial. J Rehabil Res Dev. 2016; 53(6): 1121–1132. https://doi.org/10.1682/JRRD.2015.07.0145 PMID: 28355039
19. Hoskins RD, Sutton EE, Kinor D, Schaeffer JM, Fatone S. Using vacuum-assisted suspension to manage residual limb wounds in persons with transtibial amputation: a case series. Prosthet Orthot Int. 2014; 38(1): 68–74. https://doi.org/10.1177/0309364613487547 PMID: 23685916
20. Traballesi M, Delussu AS, Fusco A, Iosa M, Averna T, Pellegrini R, et al. Residual limb wounds or ulcers heal in transtibial amputees using an active suction socket system. A randomized controlled study. Eur J Phys Rehabil Med. 2012; 48(4): 613–623. PMID: 22641248
21. Brunelli S, Averna T, Delusso S, Traballesi M. Vacuum assisted socket system in transtibial amputees: Clinical report. Orthopädie-Technik Q. 2009;2.
22. Gholizadeh H, Lemaire ED, Eshraghi A. The evidence-base for elevated vacuum in lower limb prosthetics: Literature review and professional feedback. Clin Biomech (Bristol, Avon). 2016; 37: 108–116.
23. Safari MR, Meier MR. Systematic review of effects of current transtibial prosthetic socket designs-Part 1: Qualitative outcomes. J Rehabil Res Dev. United States; 2015; 52(5): 491–508.
24. Safari MR, Meier MR. Systematic review of effects of current transtibial prosthetic socket designs—Part 2: Quantitative outcomes. J Rehabil Res Dev. 2015; 52(5): 509–526. https://doi.org/10.1682/JRRD.2014.08.0184 PMID: 26436733

25. Wernke MM, Schroeder RM, Haynes ML, Nolt LL, Albury AW, Colvin JM. Progress Toward Optimizing Prosthetic Socket Fit and Suspension Using Elevated Vacuum to Promote Residual Limb Health. Adv wound care. 2017; 6(7): 233–239.
26. Major MJ, Caldwell R, Fatone S. Comparative Effectiveness of Electric Vacuum Pumps for Creating Suspension in Transfemoral Sockets. J Prosthetics Orthot. 2015; 27(4): 149–153.
27. Komolafe O, Wood S, Caldwell R, Hansen A, Fatone S. Methods for characterization of mechanical and electrical prosthetic vacuum pumps. J Rehabil Res Dev. 2013; 50(8): 1069–1078. https://doi.org/10.1682/JRRD.2012.11.0204 PMID: 24458892
28. Major MJ, Caldwell R, Fatone S. Evaluation of a Prototype Hybrid Vacuum Pump to Provide Vacuum-Assisted Suspension for Above-Knee Prostheses. J Med Device. 2015; 9(4): 445041–445044.
29. Xu H, Greenland K, Bloswick D, Zhao J, Merryweather A. Vacuum level effects on gait characteristics for unilateral transtibial amputees with elevated vacuum suspension. Clin Biomech (Bristol, Avon). 2017; 43: 95–101.
30. Gerschutz MJ, Haynes ML, Colvin JM, Nixon D, Denune JA, Schober G. A Vacuum Suspension Measurement Tool for Use in Prosthetic Research and Clinical Outcomes: Validation and Analysis of Vacuum Pressure in a Prosthetic Socket. J Prosthetics Orthot. 2010; 22(3): 172–176.
31. Heinemann AW, Bode RK, O'Reilly CO. Development and measurement properties of the Orthotics and Prosthetics Users' Survey (OPUS): a comprehensive set of clinical outcome instruments. Prosthet Orthot Int. 2003; 27(3): 191–206. https://doi.org/10.1080/03093640308726682 PMID: 14727700
32. Arwert HJ, van Doorn-Loogman MH, Koning J, Terburg M, Rol M, Roebroeck ME. Residual-limb quality and functional mobility 1 year after transtibial amputation caused by vascular insufficiency. J Rehabil Res Dev. 2007; 44(5): 717–722. PMID: 17943683
33. Bohannon RW, Wang Y-C, Gershon RC. Two-minute walk test performance by adults 18 to 85 years: normative values, reliability, and responsiveness. Arch Phys Med Rehabil. 2015; 96(3): 472–477. https://doi.org/10.1016/j.apmr.2014.10.006 PMID: 25450135
34. Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. J Gerontol. 1994; 49(2): M85–94. PMID: 8126356
35. Dite W, Temple VA. A clinical test of stepping and change of direction to identify multiple falling older adults. Arch Phys Med Rehabil. 2002; 83(11): 1566–1571. PMID: 12422327
36. Deathe AB, Miller WC. The L test of functional mobility: measurement properties of a modified version of the timed "up & go" test designed for people with lower-limb amputations. Phys Ther. 2005; 85(7): 626–635. PMID: 15982169
37. Hess RJ, Brach JS, Piva SR, VanSwearingen JM. Walking skill can be assessed in older adults: validity of the Figure-of-8 Walk Test. Phys Ther. 2010; 90(1): 89–99. https://doi.org/10.2522/ptj.20080121 PMID: 19959654
38. Shirley Ryan AbilityLab. Satisfaction With Device Score. Orthotics Prosthetics Users Survey. 2015.
39. Bohannon RW. Reference values for the five-repetition sit-to-stand test: a descriptive meta-analysis of data from elders. Percept Mot Skills. 2006; 103(1): 215–222. https://doi.org/10.2466/pms.103.1.215-222 PMID: 17037663
40. Willemsen AT, Bloemhof F, Boom HB. Automatic stance-swing phase detection from accelerometer data for peroneal nerve stimulation. IEEE Trans Biomed Eng. 1990; 37(12): 1201–1208. https://doi.org/10.1109/10.64463 PMID: 2289794
41. Chino N, Pearson JR, Cockrell JL, Mikishko HA, Koepke GH. Negative pressures during swing phase in below-knee prostheses with rubber sleeve suspension. Arch Phys Med Rehabil. 1975; 56(1): 22–26. PMID: 1115589
42. Redfield MT, Cagle JC, Hafner BJ, Sanders JE. Classifying prosthetic use via accelerometry in persons with transtibial amputations. J Rehabil Res Dev. 2013; 50(9): 1201–1212. https://doi.org/10.1682/JRRD.2012.12.0233 PMID: 24458961
43. Hafner BJ, Sanders JE. Considerations for development of sensing and monitoring tools to facilitate treatment and care of persons with lower-limb loss: a review. J Rehabil Res Dev. 2014; 51(1): 1–14. https://doi.org/10.1682/JRRD.2013.01.0024 PMID: 24805889