Brasthesis™ Prototype for Women Veterans with Upper Limb Amputations

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Data Collection and Analysis

Aim 1. After signing of informed consent and during the same phone conversation as configuration of the bra order, the project manager will administer the baseline measures and obtain demographic and clinical data not available in the Computerized Patient Record System (CPRS). See Table 1. *The project manager will ask how many days per week and hours per day the participant wears their prosthesis with traditional harness (Aim 1, Research Question (RQ) 1.1).* The project manager will explain, as delineated in the informed consent document, that she will contact the participant weekly during the four-week wear phase for the purpose of tracking *Brasthesis™ wearing time. We will also employ an activity tracker as a quantitative proxy of prosthesis wear time. Similar systems have been employed in other prosthesis studies [20, 21] and the software provides direct export of accelerometer data to approximate wear time to the hour of each day. Participants will be provided a activity tracker by the prosthetist once the prosthesis has been successfully fit using Brasthesis™.* The pre to post change ordinal data will be analyzed using quantitative descriptive analyses.

Other outcomes with valid and reliable measures include: satisfaction, measured with the Orthotic Prosthetic Users Survey (OPUS) Satisfaction with Device Scale [22] (Appendix 4), function, measured with the OPUS Upper Extremity Functional Status Scale [22] (Appendix 5) and comfort, measured with the Socket Comfort Score [23], a numeric rating 0-10 scale where 0 is the least comfortable and 10 the most comfortable). See Appendix 6 for our initial data coding plan. The pre to post change ordinal data will be analyzed using quantitative descriptive analyses. The results will be tabled and graphed.

At the end of the four-week wearing period, PI will conduct semi-structured *group* interviews (Aim 1, RQ 1.5) with the participants and fitting prosthetic team for the purpose of improving the fitting process. *The semi-structured interview will have three overall discussion points: (1) barriers encountered while fitting Brasthesis™, (2) the strap placement prosess taking into consideration the presence and length of the residual limb and the available skin surface area available for contact with the prosthetic sensor, and (3) comparison of Brasthesis™ with traditional prosthesis.* Interviews will be tape recorded and transcribed. The text interview data will be analyzed using qualitative descriptive methods [24] based on the phenomenology framework [25] which is well suited for patient experience of care analyses. The first interview (first participant) will be coded line by line so that initial codes come from the data rather than pre-selected codes. The initial codes of the first interview will serve as a codebook that will be used and adjusted as need with the remaining four interviews. Once all five interviews have been coded, the codes will be organized into themes. Interview data will be analyzed descriptively [24, 25].

Also at the end of the four-week wearing period, the activity trackers will be removed from the prosthesis by the prosthetist. Data will be downloaded by the prosthetist and engineer. Data will be analyzed descriptively and tabled and graphed.

Table 1 Variables

Variable	RQ	Definition	Source, Timepoint
Outcomes			
Wearing time	*1.1*	*Days/week, hours/day, Traditional versus Brasthesis™*	Weekly communication
		activity tracker	Automated

Satisfaction	*1.2*	*OPUS Satisfaction with Device [22] (Appendix 4)*	*Traditional – pre Brasthesis - post*
Function	*1.3*	*OPUS UE Functional Status [22] (Appendix 5)*	
Comfort	*1.4*	*Socket Comfort Score [23], 0-10 numeric rating scale*	
Barriers	*1.5*	Described by participants and clinicians	Post interview (QL)
Pressure	2.1,2.2	Tekscan F-Socket (Appendix 7)	Prosthetist, engineer, post
Demographic and Clinical Variables			
Age	All	Age on date of baseline data collection	CPRS, baseline interview
Sex		Male, female, other	
Race/ethnicity		Caucasian, African American, Hispanic, other	
Time since		In years: index event – date at baseline collection	
Amputation level		transhumeral, shoulder, interscapulothoracic	
Prosthesis type		Myoelectric, hybrid, cosmetic	
Bra size		*Size of She-fit® bra ordered*	
OPUS=Orthotics and Prosthetics User's Survey, UE=upper extremity, QL=qualitative, CPRS=Computerized Patient Record System			

Aim 2. *An effective harness must help hold the prosthetic socket securely on the limb, facilitate a functional range of motion, and remain comfortable when worn [26]. Therefore, on the day of the post wearing period group interview, we will perform a series of quantitative tests to characterize how Brasthesis™ affects key biomechanical measures related to prosthesis fit, function, and comfort. We will first quantify the functional range of motion participants can achieve while wearing Brasthesis™ and their conventional prosthetic harness. Movements relevant to upper limb prosthesis use such as maximum shoulder flexion/extension and abduction/adduction values [27] will be captured using goniometers and these values compared across both harnessing systems. As Brasthesis™ is designed to accommodate female anatomy, we anticipate it will not encumber range of motion when compared to a conventional harness and likely even improve it.*

Prosthesis fit, suspension, and comfort are three factors that are directly related to the pressure distribution developed at the interface between the prosthesis and the user's body [15, 28]. We will characterize pressure distributions when participants wear Brasthesis™ and their traditional harnesses. Following our previous work [15], we will employ a Tekscan VersaTek system that allows for measurements of pressures at two simultaneous locations across the body. We will quantify pressure development between the prosthetic socket and residual limb to characterize socket fit and changes in suspension, as well as around the contralateral axilla, an area that often bears prosthetic related loads and is commonly associate with discomfort in female prosthesis users. At each location, a Tekscan 9811E sensor will be used which is a "paper thin," flexible sensor, that can be trimmed to match anatomical contours and provides 96 discrete pressure measurements. Following our existing protocols [5] and prior to participants donning their prosthesis, we will adhere sensors using double sided adhesive tape directly to the skin to securely cover each participant's residual limb and in the contralateral axilla region. Using our existing laser scanner, we will create a 3D map that registers the location of each pressure sensor on the anatomy of the participant. Participants will then don their prosthesis and Brasthesis™ (or traditional harness) and Pressure measurements will then be performed following our previous protocols in which, (1) prepressure will be measured wearing the prosthetic liner with the residual limb

positioned neutral at their side, (2) wearing prosthesis with 90 degrees prosthetic elbow flexion, and (3) full elbow extension with shoulder flexion in the plane of the scapula [5].

Using MATLAB and Paraview software, we will import the sensor placement data and the pressure measurement data to create color-coded 'heat maps' that directly link pressure values to the three-dimensional anatomy of each participant. Using threshold filters and numerical integration we will isolate regions of particular interest (ex. regions where control electrodes must firmly contact the tissue), as well as regions developing maximum pressures, and calculate their surface areas. For each participant we will compare the maximum and mean pressures, the anatomical regions developing these values, and the surface areas which they are distributed across when wearing Brasthesis™ compared to their traditional harness. We anticipate that the design of Brasthesis™ will more equally distribute pressure across the contralateral axilla and thorax regions over larger surface areas. We further anticipate seeing minimal differences in pressure maps between the socket and residual limb indicating little change in prosthesis suspension.