UNIVERSITY of SOUTH FLORIDA
Research & Innovation

PROTOCOL TITLE:

Brasthesis™ Prototype for Women Veterans with Upper Limb Amputations

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER/DATE:

_v.6_07.06.23

REVISION HISTORY

***This table should only be used during submission of a Modification application to the IRB.**

Revision #	Version Date	Summary of Changes	Consent Change?
1	v.2_05.17.22	Adding non-Veterans to recruitment procedures	yes
2	v.3_09.07.22	Removing body powered prosthesis as an exclusion criteria	no
3	v.4_10.24.22	Changing PI to Jeffrey Heckman, DO; Clarifying that we request to bring clinical staff in addition to patients for fitting to JAHVH.	yes
4	v.5_11.21.22	Adding caregiver (if necessary) for travel	yes
5	v.6_07.06.23	Add activity tracker information; and add distribution of flyers to national amputee conference for recruitment.	yes

Table of Contents

1.0 Study Summary

1.1 *Please provide a brief summary of the study in the table below. A complete description of the study with detailed information should be provided in the body of the protocol. For sections not applicable to the study, mark them as N/A.*

Study Title	Brasthesis Prototype for Women Veterans with Upper Limb Amputations	
Study Design	Prospective, Case series	
Primary Objective/Purpose	To evaluate the satisfaction of and function and comfort with Brasthesis.	
Secondary Objective(s)/Purpose	To compare Brasthesis to the amputee's traditional harness.	
Research Intervention(s)/ Investigational Agent(s)	Use of a sports bra as a gender-specific harness for upper limb prostheses	
IND/IDE #	N/A	
ClinicalTrials.gov NCT#	Pending	
Study Population	Women with a unilateral upper limb amputation	
Sample Size	10	
Study Duration for individual subjects	8 weeks (4 weeks for fitting and 4 week wearing period)	
Study Specific Abbreviations/ Definitions	CPRS - Computerized Patient Record System FY – Fiscal Year HIPAA – Health Insurance Portability and Accountability Act IRB – Institutional Review Board JAHVH – James A. Haley Veterans' Hospital PHI – Protected Health Information PI – Principal Investigator PM – Project Manager	

2.0 Objectives

2.1 a. Evaluate the satisfaction of and function and comfort with Brasthesis.

b. Use goniometry measures of range of motion and pressure mapping to compare range of motion and interface pressure of Brasthesis with the traditional harness.

2.2 No hypotheses will be tested in this pilot proof-of-concept study.

3.0 Background

3.1 Female Anatomy and Prosthetic Harness.

Limitations exist with the current traditional chest strap due to female anatomy. We know from the sports [1] and seat belt/airbag [2] literature that breast tissue injuries can disrupt the blood flow to the breast resulting in swelling, significant blood loss, hematoma, fat necrosis, and oil cyst hematoma. Injury to the mammary ducts can affect the future or current flow of breast milk [3]. More commonly, smaller superficial arteries along with veins become injured, leading to more localized injury and less serious bleeding and bruising. While there is no known research on whether a prosthetic harness can cause injury to breast tissue, we know that frequent wearing of tight clothing [4] can cause bruising, swelling, and thrombophlebitis. Further, regular physical activity is important in maintaining fitness, injury prevention, and overall well-being. Even without the additional pressure of a prosthetic harness, 50% of women report suffering exercise-induced breast discomfort during exercise which leads to reduced physical activity participation [1].

Both males and females with upper limb loss [5] report musculoskeletal pain, with no difference in reported pain between prosthetic wearers and non-wearers. Women with large breast sizes also report an increased prevalence and severity of musculoskeletal pain exacerbating the pain already caused by amputation(s), a problem exacerbated over the past decade as the mean bra size has increase from a 12B to a 14C; 25% of bras sold are now a D cup or larger [6]. Age is an additional risk factor. Beginning about age 45, breast skin thickness decreases significantly [7]. Breast skin elasticity begins to decrease in the mid-twenties [7].

Gender Comparisons.

Satisfaction in Women with Limb loss (Non-Veteran). Most of the prosthetic satisfaction literature includes men and lower limb loss. In a sample of 362 participants with upper and lower limb trauma-related above elbow amputations (78% men) [8], 30% were dissatisfied with the comfort of their prosthesis. Women were less likely to be satisfied with fit, comfort and appearance [8]. Similarly, of 181 upper limb prosthesis wearers (86% men) [9], nearly 20% were dissatisfied with their prosthesis. Most used their prosthesis for about half of the tasks performed in everyday life [9].

Rejection. In a study [9, 10] of 199 non-Veterans with upper limb loss (84% men), 25% of women and 11% of men discontinued wearing their upper limb prosthesis. The main reasons were dissatisfaction with comfort, function, and control. Discontinued use was more likely in more proximal amputations and in women [10]. In a second study [11] of 191 non-Veterans with upper limb loss (51% men), 31%, not stratified by gender, discontinued wearing their prosthesis. In both studies [9-11], 29% of the sample had an elbow or more proximal amputation. There are no known publications with women as the sole sample, although it is believed that this research is in progress.

A study [12] of 776 Veterans with upper limb loss (97% men) found that women were less likely to have ever used a prosthesis or received training in use of the prosthesis, more likely to use a cosmetic prosthesis, and less likely to use a body-powered prosthesis when compared to men. Device heaviness or fatigue was the most common reason for discontinued use. There were however only two women Veterans with forequarter or shoulder disarticulation enrolled in the study. Another study [13] of 196 Veterans with upper limb loss (98% men) found 40% with transhumeral amputations and 50% with shoulder disarticulations did not use a prosthesis. Prosthetic use was most frequently discontinued because of discomfort, pain, and weight of the device.

A study [14] of 242 males and females with upper limb loss that included 68 (28%) individuals with humeral amputation/shoulder disarticulation found that 80% of women with high-level amputations and 15% of men with high-level amputations discontinued use of their prosthesis. Ninety-five percent of participants reported comfort as a reason for discontinued use. In summary, we only have data for a few women with proximal upper limb amputations and disarticulations. The literature overall identifies comfort as a problem for women with upper limb amputations.

Socket Fit.

The term ‘socket fit’ encompasses the factors that impact prosthetic comfort and stability on the residual limb [15]. Fit and associated comfort have a substantial effect on user satisfaction and prosthetic use [15]. The socket is the crucial junction where the soft tissue of the user's residual limb interfaces with the rigid materials of the prosthesis. Socket fit must, for our purposes, accommodate the female anatomy as well as position the prosthetic device to efficiently transmit intended movements [15]. Socket fit also includes appropriate distribution of pressure across the residual limb. While compression can increase mechanical stability, it can also cause discomfort, tissue irritation, and damage. This challenge is increased for individuals with proximal amputations as the weight of the prosthesis amplifies the demand of the socket and the residual limb [15]. We believe that Brasthesis™ may relieve uncomfortable pressure at the residual limb by increasing the contact area of the harness to include the sports bra. The Revolutionizing Prosthetics 2009 program [16] offered a solution similar to Brasthesis™ to the problem of the tightening around the intact shoulder required by the traditional harness [16]. Recognizing that secure attachment to the body and distribution of weight are critical to comfortable fit and function, designed a shoulder-level socket with full fabric, tee shirt-like suspension.

Socket Pressure.

Accuracy and repeatability of the Tekscan F-Socket has been shown to be accurate with good reliability [17]. Daly et al. [18] were perhaps the first to use the pressure mapping with upper limb amputation research. No correlation was found between patient report of discomfort and pressure data. Schonfield et al. [15] built on the limitations of the Daly study to successfully characterize pressure distribution patterns unique to the participants socket designs. While using pressure mapping to better understand socket-fit is in its early stages, we believe that pressure mapping may be a useful tool to compare harness and socket pressure when wearing Brasthesis™ with the traditional prosthesis. We are not using pressure mapping to measure absolute values, rather, our focus is on how the harness distributes pressure and positions the socket on the residual limb and

thus influencing pressure distribution. Dr. Schonfield will provide expertise on pressure mapping on the proposed project

3.2 Preliminary Prototype. We fit one non-Veteran patient with *Brasthesis ™* during two Zoom sessions. The research team was in Tampa, Florida and the patient and prosthetic team in Texas. The patient had a short trans- humeral amputation, was two years post-trauma, and had five unsuccessful fittings including the Ottobock Active TH Harness, **Figure 1a** and **1b**. The patient described the previous harnessing as "way too bulky and ugly. I tried to put clothes over it and I looked like a football player – I might as well put it over my clothes if I had to use the other one – it kind of defeats the purpose of trying to look normal." The patient's prosthesis is a hybrid with a body powered elbow. The patient uses a lift assist incorporated into the body-powered elbow to ballistically move the elbow into flexion or she can bend forward at the waist and the elbow will move into flexion. Once she locks the elbow into the position she needs for function, she uses electromyographic (EMG) input from one muscle to open and close her myoelectric hand. Contraction of the muscle opens the hand and relaxation of that same muscle closes the hand.

We fit the patient with *Brasthesis ™* in one session by adding two straps to the sports bra. We chose the Shefit® sports bra because it provides a front closure and provides more support than other sport bras. Because we were unable to obtain the flexible yet strong fabric and strapping used in high end sports bras, we used two bras to fit one patient: one for the patient to wear and the other to deconstruct and reconstruct strapping to secure the prosthesis to the bra. Shefit® donated bras for our prototype in the preliminary study. To fit Brasthesis *™*, we cut two small d-rings (including fabric) from the second bra and attached one of these to the anterior portion of the socket and the other to the posterior portion of the socket using rivets. See Figures **2a-2d**. All of the straps are removable from the socket of the prosthesis so that the bra can be washed. The patient described *Brasthesis ™* as "This feels great", "It fits great under my shirt", "I don't feel like a football player", "This bra is so comfortable and I can wear clothes over this", "I love it", and "Oh my gosh, I want to cry". The patient wore *Brasthesis ™* home and has been using it regularly and successfully.

The patient returned for a second session to adjust the front zipper closure for independent donning. We discovered during this fitting that strap placement will need to be individualized per women based on the presence and length of the residual limb and the available skin surface area that will be in contact with the prosthetic sensor. For this patient, post-surgery, the fascia of the deltoid and triceps muscles were used to facilitate coverage over the remainder of her humeral bone after amputation. As a result, she has a large area of scarring that makes it difficult to find usable muscles for electromyographic (EMG) use to power her prosthesis. Thus, only one usable muscle site was identified and used for controlling the prosthesis. Her electrode needed to be secured in one particular area to avoid placing the electrode on half regular skin and half scarred skin emphasizing the importance of the right harnessing option to keep the socket in place for good activation of the prosthesis. Fitting this patient has made our design team appreciate how *Brasthesis ™* will need to be individualized for each woman.

References

1. McGhee, D.E. and J.R. Steele, *Breast Biomechanics: What Do We Really Know?* Physiology (Bethesda), 2020. **35**(2): p. 144-156.
2. Majeski, J., *Shoulder restraint injury of the female breast.* Int Surg, 2007. **92**(2): p. 99-102.
3. Sircar, T., et al., *Seat-belt trauma of the breast in a pregnant woman causing milk-duct injury: a case report and review of the literature.* Ann R Coll Surg Engl, 2010. **92**(5): p. W14-5.
4. Vincenza Polito, M., P. De Cicco, and R. Apicella, *Tight Bra in a 34-Year-Old Woman: An Unusual Cause of Mondor's Disease.* Ann Vasc Dis, 2014. **7**(2): p. 149-51.
5. Ostlie, K., et al., *Musculoskeletal pain and overuse syndromes in adult acquired major upper-limb amputees.* Arch Phys Med Rehabil, 2011. **92**(12): p. 1967-1973 e1.
6. McGhee, D.E., *The story of . . . the bra*, in *The Conversation*. 2014, The Conversation, Inc.: Australia.
7. Coltman, C.E., J.R. Steele, and D.E. McGhee, *Effect of aging on breast skin thickness and elasticity: implications for breast support.* Skin Res Technol, 2017. **23**(3): p. 303-311.
8. Pezzin, L.E., et al., *Use and satisfaction with prosthetic limb devices and related services.* Arch Phys Med Rehabil, 2004. **85**: p. 723-729.
9. Ostlie, K., et al., *Prosthesis use in adult acquired major upper-limb amputees: patterns of wear, prosthetic skills and the actual use of prostheses in activities of daily life.* Disabil Rehabil Assist Technol, 2012. **7**(6): p. 479-93.
10. Ostlie, K., et al., *Prosthesis rejection in acquired major upper-limb amputees: a population-based survey.* Disabil Rehabil Assist Technol, 2012. **7**(4): p. 294-303.
11. Biddiss, E.A. and T.T. Chau, *Multivariate prediction of upper limb prosthesis acceptance or rejection.* Disabil Rehabil, 2008. **3**(4): p. 181-192.
12. Resnik, L.J., M.L. Borgia, and M.A. Clark, *A National Survey of Prosthesis Use in Veterans with Major Upper Limb Amputation: Comparisons by Gender.* PM R, 2020. **12**(11): p. 1086-1098.
13. McFarland, L.V., et al., *Unilateral upper-limb loss: satisfaction and prosthetic-device use in veterans and servicemembers from Vietnam and OIF/OEF conflicts.* J Rehabil Res Dev, 2010. **47**(4): p. 299-316.
14. Biddiss, E. and T. Chau, *Upper-limb prosthetics: critical factors in device abandonment.* Am J Phys Med Rehabil, 2007. **86**(12): p. 977-87.
15. Schofield, J.S., et al., *Characterization of interfacial socket pressure in transhumeral prostheses: A case series.* PLoS One, 2017. **12**(6): p. e0178517.
16. Moran, C.W., *Revolutionizing Prosthetics 2009 Modular Prosthetic Limb–Body Interface: Overview of the Prosthetic Socket Development.* Johns Hopkins Applied Technical Digest, 2011. **30**(3).
17. Polliack, A.A., R.C. Sieh, and D.D. Crain, *Scientific validation of two commercial pressure sensor systems for prosthetic socket fit.* Prosthet Orthot Int, 2000. **24**(1): p. 63-73.
18. Daly, W., et al., *Socket pressure and discomfort in upperlimb prostheses: A preliminary study.* Journal of Prosthetics and Orthotics, 2014. **26**(2): p. 99-106.

4.0 Safety Endpoints

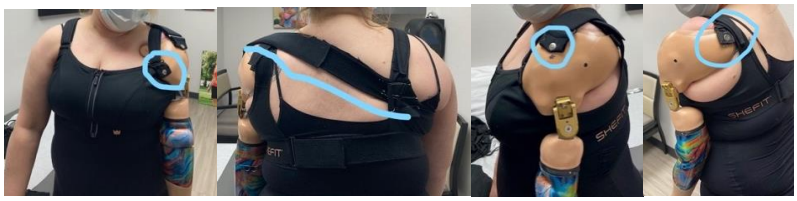
4.1 Primary endpoints are satisfaction, function, and comfort.

The secondary endpoints are the interface pressure that drives comfort and range of motion that drive functional movement.

5.0 Study Interventions, Investigational Agents, and FDA-Regulated Products *(as applicable)*

5.1 The study intervention is our patent-pending harness that we have named 'Brasthesis' for women amputees. The patent was submitted 12/6/2021. Brasthesis adapts a heavy-duty sports bra to replace commercially available prosthetic harnesses. See photos of commercially available, top, and Brasthesis below.

5.2 Drug/Device Handling: N/A. While a prosthesis is considered a device, the harness attaching the prosthesis to the residual limb is not considered device.



Devices	Drugs/Biologics
☐ FDA Approved Device – Approved Use	☐ FDA Approved Drug/Biologic – Approved Use
☐ FDA Approved Device – Unapproved Use	☐ FDA Approved Drug/Biologic – Unapproved Use
☐ Investigational Device – Non-Significant Risk	☐ Investigational Drug/Biologics
☐ Investigational Device – Significant Risk	☐ Placebo
☐ Humanitarian Use Device Exemption	☐ Other Drugs/Biologics
☐ Other Devices	

5.3 N/A.

5.4 N/A.

5.5 N/A.

6.0 Procedures Involved

6.1 This project will use a case series design to fit five women with unilateral upper limb loss with Brasthesis (harness). The proposed project will offer three fitting options: (1) We will fit patients face to face at the James A Haley VA Hospital (JAHVH), (2) We have requested travel funds to bring patients, caregiver (if necessary), and clinical staff to JAHVH for fitting, an option we found successful with previous prosthetic arm studies, and (3) We will use a VA

approved video conferencing system/software, e.g., Veteran Video Connect, with the research team at one location and the patient and patient's prosthetic team at a second location (as we did for our prototype during the COVID-19 restrictions). Option 3 will only be used if we have difficulty recruiting with options 1 and 2.

6.2 Outcomes data will be collected via survey and brief interview. Pressure mapping and range of motion data will be collected using pressure mapping technology and a goniometer. One focus group will be held after all patients have been fitted. All data will be analyzed descriptively. Subjects will be given the option to consent to having photos taken post intervention for educational and/or technology development purposes.

6.2

☒Audio/Video Recording	☐Physical Exam
☐Blinding	☐Radiation or Radiation-Producing Machines (e.g. X-ray, CT, etc.)
☐Control Group	☐Radioactive Materials (e.g. Radiopharmaceuticals)
☐Deception	☐Randomization
☒Focus Groups	☒Record, Chart, or Dataset Review
☒Follow-Up Call	☐Specimen Analysis
☒Interviews	☐Specimen Collection
☐New Innovative Practice/Therapy	☒Surveys and/or Questionnaires
☐New Investigational Procedure (e.g. a new surgical procedure)	☐Other Biomedical Procedures

- At baseline, after signing of informed consent, the project manager will work with the participant over the phone to order two bras from the Shefit® website, using sizing provided on the website. One Shefit® bra will be for the participant to wear and the other bra will be deconstructed for strapping and d-rings.
- During this baseline phone meeting, the project manager will ask how many days per week and hours per day the participant wears their prosthesis with traditional harness. The project manager will explain, as delineated in the informed consent document, that she will contact the participant weekly during the four-week wear period for the purpose of checking in, i.e., checking on Brasthesis wearing time and problems that may have occurred during the week.
- During this baseline phone meeting, the two sub-surveys of the Orthotic and Prosthetic User Survey (OPUS) and the one-item Socket Comfort Scale will be administered. The socket comfort scale is a one-item analog 0-10 self report rating scale. There is no published pdf for this one-item scale. The score is included in the Data Collection Sheet Item #12.
- The project manager will extract demographic and clinical information from the medical record.

- The participant will be scheduled for a fitting at a prosthetic clinic, either at the JAHVH study site or their home VA prosthetic clinic, the clinic regularly attend in/ near their place of residence. The fitting process will begin with introductions. The participant will don the prosthesis/traditional harness. We measure functional range of motion (shoulder flexion/extension and abduction/adduction) with a goniometer while participants are wearing their conventional prosthetic harness.
- Also at the fitting visit, we will use the Tekscan Artec Studio system to quantify pressure between the prosthetic socket and residual limb and around the contralateral axilla while wearing the traditional harness. Pressure mapping entails attaching a paper thin, flexible sensor, trimmed to match anatomical contours with double sided adhesive tape directly to the skin to securely cover each participant's residual limb and in the contralateral axilla region then mapping pressure at three positions: (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].
- The subject will then don the Shefit® bra over the traditional harness. We will mark where the traditional harness and Shefit® overlap. D-rings from the spare bra will be riveted at the marked spots (for our prototype, the patient required two d-rings anterior and posterior). Once the d-rings have been riveted to the prosthesis, the participant will don modified Shefit bra/Brasthesis. At this point the custom fitting will begin which will vary from participant to participant. Our prototype patient had gaping at the top of the socket that was successfully addressed by adding a strap from the spare bra cross the participant's back. The participant guided the prosthetist as to where she needed support. The prosthetist riveted a third central d-ring to accommodate a diagonal backstrap. This individualization may vary for each of the five subjects and is the primary purpose for this proof of concept study.
- We will replace the front zipper with a commercially available magnetic bra closure for one-handed donning, if desired
- Participants will be provided a Jawbone UP 24 or OPOS1 activity tracker by the prosthetist once the prosthesis has been successfully fit using Brasthesis. Jawbone API software or OPOS1 software provides direct export of accelerometer that contains no PHI or PII (deidentified) data to approximate wear time to the hour of each day.
- The prosthetic and research teams will be available should the participant need adjustment to the harness and prosthetic fit, per standard care.
- At the end of the four-week wearing period, the participant will return to the clinic. Range of motion measurement and pressure mapping will be repeated but this time with the Brasthesis rather than the traditional harness.

- The outcome measures administered at baseline will be completed again post-intervention. The project manager will conduct a brief interview for the participant and prosthetic team to understand the experience of being fit with and using Brasthesis. This interview will be audio recorded.
- The participant will be told that after all five participants have completed Brasthesis, a focus group will be held for the purpose of brainstorming how to proceed with the manufacturing and marketing of Brasthesis. This focus group will be audio recorded.

6.3 All procedures will be performed solely for research purposes except for the prosthetic clinic visits for Brasthesis and prosthetic adjustment as needed. Returning to the amputation clinic for Brasthesis/harness or prosthetic adjustment are standard care.

6.4 Participants will be under the care of experience amputee and prosthetic clinicians including occupational therapists, physicians, prosthetists, and engineers who will be able to efficiently and empathetically address any challenge that may occur during the Brasthesis fitting process and wearing period.

Participants can return to the use of their traditional harness at any time. They will not be withdrawn from the study if they return to using their traditional harness as data on why participants use or do not use Brasthesis are needed to address research questions.

Participants can contact the project manager, an occupational therapist with extensive upper limb amputation and prosthetic experience, at any time.

6.5 Aim one of this project will capture existing data:

- Data to be collected is displayed in the Table below and the uploaded data capture sheet.

Table 1 Variables

Variable	RQ	Definition	Source, Timepoint
Outcomes			
Wearing time	1.1	Days/week, hours/day, Traditional versus Brasthesis™	Weekly communication
		Jawbone Up 24 or OPOS1 activity tracker	Automated
Satisfaction	1.2	OPUS Satisfaction with Device	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,	
Time since		In years: index event – date at baseline	
Amputation		transhumeral, shoulder, interscalulothoracic	

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			

6.6 No biological specimens will be collected.

6.7 The only semi-long-term follow-up will be the focus group once all five participants have completed the 4-week wearing period. The focus group will be audio recorded using the TEAMS recording feature. Once transcribed, the audio recording will be destroyed.

6.8 No Humanitarian Use Devices (HUD).

7.0 Data and Specimen Storage for Future Research

7.1 No data or specimens will be banked for future use.

7.2 N/A

7.3 N/A

8.0 Sharing of Results with Subjects

8.1 Study results will be shared with subjects and subject's primary care physicians upon request. Shared data will be encrypted and will remain behind the VA firewall.

9.0 Study Timelines

9.1 It should take up to 2-4 weeks to fit Brasthesis (one to three prosthetic clinic visits). The Brasthesis wearing period is 4-weeks. Data collection could add a week before and a week after the wearing period depending on scheduling.

9.2 The entire project will take one to two years including dissemination of findings.

10.0 Inclusion and Exclusion Criteria

10.1 Potential subject will self-identify with the project manager whether they meet the inclusion criteria. Inclusion and exclusion criteria are observable.

10.2 The inclusion criteria are: (1) mid to short transhumeral, shoulder, or interscapularthoracic unilateral amputation, (2) have an existing myoelectric, hybrid, body-powered or cosmetic prosthetic limb that they use or have abandoned. The additional resources to train a participant with no prosthetic experience is beyond the scope of this study.

10.3 The exclusion criteria: (1) open wounds in the upper torso or extremities, (2) women who do not have an existing prosthesis would exceed the time resources for a SPIRE funding mechanism.

10.4 A subject will be ineligible to continue participation if they develop a condition on their residual body part that disallows them to wear a prosthesis, such as a bone spur or open sore.

10.5 No students, employees, socially and/or economically disadvantaged, or wards of the state will be included.

11.0 Vulnerable Populations

11.1 No vulnerable populations will be included.

12.0 Local Number of Subjects

12.1 We will recruit up to 10 subjects.

12.2 Five subjects are needed to complete the research.

13.0 Recruitment Methods

13.1 We are proposing three recruitment paths to be initiated at the beginning of the project. The first path is to recruit through our current prosthetic patients and those of our prosthetic research colleagues in VISNs 2 and 20. Second, the Director of our Regional Amputation Center, PI Heckman, will present the study at a regularly scheduled National Amputation System of Care meeting. The Amputation System of Care network will provide a point of contact at each site to receive an email from the study project manager with a pertinent study description and contact information for women Veterans interested in the study. An IRB-approved study flyer with study contact information will be distributed electronically to all recruitment sites and will be included in the approach letters. The third path is to send approach letters to women Veterans with upper limb loss, identified in the VA Amputation Cube, following VA HIPAA policy. Patients will be identified by sex, upper limb unilateral limb loss, and elbow and above disarticulation/ amputation. A list will be generated of the patients meeting these criteria.

If we cannot identify and consent five female Veteran amputees, we will recruit non-Veteran female amputees by dispersing IRB approved flyer to prosthetist colleagues. We will distribute IRB approved flyers at a national amputee conference. Non-Veterans may be required for this study because female upper extremity amputees are a small portion of the general population. Therefore, we may require non-Veterans to meet our enrollment goal. Veterans will be given preference. Non-Veterans will be used if we are unable to meet enrollment goals.

13.2

☐ Email	☐ Online/Social Media Advertisement
☒ Flyer	☒ Record Review
☒ Letter	☐ Other
☐ News Advertisement	

- Flyer and approach letters uploaded.

13.3 N/A. Special and vulnerable populations not recruited.

14.0 Withdrawal of Subjects

14.1 A subject may be withdrawn or preferably partially withdrawn from the research without their consent if they develop a condition on their residual body part that disallows them to wear a prosthesis, such as a bone spur or open sore.

14.2 The decision to withdraw will be made between the patient and the study physician.

14.3 Partial withdrawal is an option where the subject will discontinue wearing Brasthesis but will continue with the interview and focus group participation.

15.0 Risks to Subjects

15.1 Based on our preliminary prototypes, the intervention should be more comfortable than standard care. To date, no physical risks associated with wearing a prosthetic harness have been published.

Many upper limb amputees have rejected their prostheses due to discomfort or difficulty using the prosthesis. Women amputees who have abandon their previous are eligible to enroll in this research. There is a risk that they will experience the discomfort and learning challenges again.

All research has inherent risks to privacy and/or confidentiality.

15.2 There are no risks to an embryo or fetus should the subject be or become pregnant.

15.3 There are no risks to others who are not subjects.

16.0 Potential Benefits to Subjects or Others

16.1 Individual subjects may experience increased comfort and function when using the Brasthesis harness as compared to the traditional harness, which in turn can increase function.

16.2 The study has the potential to offer women with an amputation a more comfortable, less expensive prosthetic harness option.

17.0 Data Management and Confidentiality

17.1 Because there will be only five subjects, descriptive analyses will be used.

17.2 All data will be stored electronically on the backed-up and protected JAHVH S-drive/Research/R drive Research/PROJECTS CURRENT/Winkler Team/Brasthesis. There will be no paper data. All staff will be current on their privacy training. Identifiable data will be stored separately from informed consent documents and the crosswalk file. Only authorized team members (PI, project manager) will have access to protected data and documents. All data will remain at the JAHVH in the research protected environment for analysis. Access will be terminated for personnel who are no longer part of the research team. The project manager and PI will monitor compliance and to ensure that the HIPAA, IRB, and VA rules and regulations are being followed and met. The PI will be responsible for all incident reporting to the IRB and R&D Committee, ISSO and Privacy officer as appropriate.

17.3 Procedures that will be used to ensure the accuracy and quality of collected data include:

- Discussion of data at twice monthly research team meetings
- A single person collecting and entering data
- Opportunities exist to collect missing data

17.4 Handling data study-wide:

- See Table 1 in 6.5 for data collected. Identifiable information includes names, date of birth, telephone number, email address, medical record number (lastname+last 4 of SSN), and voice recording.
- Data will be stored per current VA policy RCS-10.
- Data will be destroyed per VA policy RCS-10.
- Confidential data will not be shared with anyone outside of the research group.

17.5

☐Obtaining Signed Authorization	☒Waiver of HIPAA Authorization for Recruitment/Screening Purposes Only
☐Obtaining Online or Verbal Authorization (Alteration of HIPAA Authorization)	☐Data Use Agreement
☐Waiver of HIPAA Authorization for Entire Study	☐Business Associate Agreement

- No PHI will be disclosed or received from individuals outside of the research group.
- For our requested waiver:
    - Data will be acquired from the VHA Proclarity Analytics Server Amputation Cube (for the approach letters for recruiting purposes).
    - Inclusion criteria: VISN, Facility, FY, Upper Limb, Female, Amputation level
    - FY 2012 – FY 2022
    - Only the PI and the project manager will have access to identifiers which will be located in a password protected file in the research project folder on the protected JAHVH research S-drive.
    - For potential subjects who enroll, their name will be added to the crosswalk file that will be stored with the informed consent documents and separate from data. Data for potential subjects who decline to enroll will be destroyed immediately per VA policy. Data for potential subjects who cannot be contacted will be destroyed at six months into the study per VA policy, providing a 6-month response period.

- PHI will not be reused/disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research which use/disclosure of PHI would be permitted by the HIPAA privacy regulations.
- It is not practicable to obtain signed HIPAA Authorizations from the subjects before using their PHI because we are going back 10 years in the records. We anticipate that we will not have current contact information for many of the potential subjects. It is not practicable as not all subjects will be eligible. Signed authorization will be obtained from subjects who are eligible and agree to participate.
- The study cannot be conducted without access to and use of subjects' PHI because we may not have a large enough sample size to successfully complete the study. We need access to PHI to verify eligibility.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

18.1 The surveys/questionnaires/interview/focus groups will ask questions about satisfaction with and comfort of a new and traditional prosthetic harnesses and function skills. The study is not enrolling new amputees who have never been fitted for a prosthesis. We do not anticipate that these questions will be unsettling but should a subject need counseling or other assistance, the study will be completed in a medical environment with a physician specializing in amputation on the team. Resources will be readily available for counseling or other assistance referrals.

18.2 N/A. This research does not involve more than minimal risk to subjects.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Subjects will be interacting with the research and clinical teams, both comprised of licensed clinicians (physiatry, prosthetics, occupational therapy). The clinical team is the subjects standard care team. The research team is at the JAHVH. Should a subject not want to interact with one of the research team members, the situation will be discussed at a research team meeting. It may be necessary to unenroll the subject. Limits placed on to whom the subjects provide personal information will be honored. The licensed occupational therapist program manager who will be collecting data has extensive amputation, prosthetic, and research experience and has regularly received VA recognition for her empathy with Veterans.

19.2 The research team is permitted to access any sources of information about the subjects because they are VA employees.

20.0 Compensation for Research-Related Injury

20.1 N/A. The research does not involve more than minimal risk to subjects.

21.0 Subject Costs and Compensation

21.1 The only cost that will be incurred is travel to the VA. We are able to reimburse travel expenses (mileage, airfare, meals, hotel, etc.) for the subject and caregiver (if necessary). The Brasthesis harness will be provided at no cost to the subject.

21.2 Other than travel, no payments will be made to subjects.

22.3 The VA Medical Center is not responsible for any research-related injury treatment costs of a non-Veteran. The non-Veteran and his or her insurance or third-party payer cannot be a responsible party.

22.0 Consent Process

22.1

☒Obtaining Signed Consent (Subject or Legally Authorized Representative)	☐Obtaining Consent Online (Waiver of Written Documentation of Consent)
☐Obtaining Signed Parental Permission	☐Obtaining Verbal Consent (Waiver of Written Documentation of Consent)
☐Obtaining Signed Assent for Children or Adults Unable to Consent	☒Waiving Consent and/or Parental Permission (Waiver of Consent Process - RECRUITMENT ONLY)
☐Obtaining Verbal Assent for Children or Adults Unable to Consent	☐Waiving Assent/Assent is Not Appropriate

22.2 Informed consent process:

- The consent process will most likely take place over the phone. Potential subjects will contact the project manager who will answer questions and mail a blank informed consent for review. The potential subject will have up to one week to sign the consent and return the project manager in the provided addressed and postage paid envelop.
- If the potential subject has not responded within two weeks of mailing the blank consent document, the project manager will call the potential subject to answer further questions.
    - The project manager and the PI will be involved in the consent process.
    - There will be no limit on the time devoted to the consent discussion.
    - The informed consent document itself and the person obtaining informed consent will explain that participation is voluntary and that they have the option of trying the Brasthesis harness or continuing to use their traditional harness.
    - The project manager obtaining informed consent is a licensed clinician with years of experience treating patients, responding empathetically, reading body language, creating an environment where patients feel safe to ask questions.

22.3 N/A. We will not be obtaining consent online or verbally.

22.4 Justification was provided in 17.5.

22.5 N/A. We will not be obtaining consent from non-English speaking subjects.

22.6 N/A. We will not enroll individuals who have not attained the legal age for consent.

22.7 N/A. Project does not involve HUD.

23.0 Setting

23.1 All research procedures will be performed at the JAHVH. Fitting of the Brasthesis harness may take place at other VA facilities via VideoConnect with the JAHVH-based research team and the subjects' home clinical team.