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TITLE: Reconstructive Vascularized Composite Allotransplantation: Qualitative Approach to Enhance Patient Reported Outcome Metrics and the Candidate Screening Process

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14. ABSTRACT

Hand transplantation (also known as Vascularized Composite Allotransplantation, or VCA) can potentially restore function and improve quality of life (QOL) for affected individuals. Over the last two decades, science has focused on improving this treatment, and people are finding more success with this surgery. However, the science is less clear on who are the best candidates for this type of surgery. Also, so far doctors have focused mostly on the medical parts of the surgery but have focused less on how recipients feel about their QOL with their new hands. VCA is very different from solid organ transplantation (e.g., kidney transplant). Patients who want hand transplants must be resilient, highly motivated, and determined to succeed in ways that are not required of solid organ transplant recipients. Psychological evaluation before the surgery is important, but scientists do not yet know the most important questions to ask patients. The proposed research intends to take what we know from studying amputees and other organ transplant patients to study people who receive hand transplants. This will also help doctors know what makes someone a good candidate for hand transplantation. The purpose of this project is to understand QOL before and after hand transplant, and to understand what factors make someone a good candidate for this surgery. This project addresses the FY17 Reconstructive Transplant Research Program (RTRP) Qualitative Research Award Focus Area: "Psychosocial considerations and challenges associated with VCA." To date, we have conducted 10 focus groups with VCA stakeholders from a wide variety of specialties and backgrounds. Preliminary results indicate that VCA QOL issues are similar to those reported in other trauma-related clinical groups, such as resilience, depression, anxiety, body image, social isolation, stigma, and participation. Several topics mentioned were unique to the hand transplant patient experience, such as sense of wholeness. This research represents a vital first step in developing a qualitative framework for understanding QOL after VCA.

15. SUBJECT TERMS
Hand Transplant, Patient reported outcomes, quality of life, vascularized composite allotransplantation, amputation, upper extremity

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TABLE OF CONTENTS

1. Introduction 4

2. Keywords 4

3. Accomplishments 4

What were the major goals of the project? 4
What was accomplished under these goals? 4
What opportunities for training and professional development has the project provided? 5
How were the results disseminated to communities of interest? 5
What do you plan to do during the next reporting period to accomplish the goals? 5

4. Impact 6

What was the impact on the development of the principal discipline(s) of the project? 6
What was the impact on other disciplines? 6
What was the impact on technology transfer? 6
What was the impact on society beyond science and technology? 6

5. Changes/Problems 7

Changes in approach and reasons for change 7
Actual or anticipated problems or delays and actions or plans to resolve them 7
Changes that had a significant impact on expenditures 7
Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents ..... **Error! Bookmark not defined.**
Significant changes in use or care of human subjects 7
Significant changes in use or care of vertebrate animals 7
Significant changes in use of biohazards and/or select agents 7

6. Products 7

Publications, conference papers, and presentations 7
Website(s) or other Internet site(s) 8
Technologies or techniques 8
Inventions, patent applications, and/or licenses 8
Other Products 8

7. Participants & Other Collaborating Organizations 8

What individuals have worked on the project? 8
Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period? 10
What other organizations were involved as partners? 10

8. Special Reporting Requirements 11

9. Appendices 11

Appendix A: Presentation Abstracts 12
Appendix B: Quad Chart 16

1. INTRODUCTION

The psychosocial outcomes of hand transplantation remain elusive to clinicians and researchers. Little effort has been devoted to understanding these outcomes over the past 20 years. The purpose of this project is to understand quality of life (QOL) before and after hand transplant, and to understand what factors make someone a good candidate for this surgery. This project addresses the FY17 Reconstructive Transplant Research Program (RTRP) Qualitative Research Award Focus Area: "Psychosocial considerations and challenges associated with VCA." Through the use of focus groups and patient interviews, we are 1) actively determining the QOL domains most important to individuals involved in the VCA process, to enhance the creation and validation of standardized, psychometrically robust, and clinically useful patient reported outcome (PRO) measures for individuals with upper extremity amputation who have received or have been screened for hand transplantation; (2) evaluating the candidate screening process for reconstructive hand transplantation to identify the most important characteristics for successful transplantation.

2. KEYWORDS

Hand Transplant, Patient reported outcomes, quality of life, vascularized composite allotransplantation, amputation, upper extremity

3. ACCOMPLISHMENTS

What were the major goals of the project?

Major Tasks		Estimated % Complete
1.1	Obtain IRB approvals	67
1.2	Obtain HRPO approvals	67
1.3	Conduct focus groups at ASRT conference	100
1.4	Recruit and enroll participants for study inclusion from participating sites nationwide	4
1.5	Conduct initial interviews with transplant recipients, candidates, and those who were screened (n = 65)	0
1.6	Conduct thematic qualitative analysis from interviews	50
2.1	Conduct second round of interviews with participants	0
2.2	Analyze cognitive debriefing interview feedback	0
2.3	Revise LIMB-QOL items as needed	50
2.4	Develop new VCA-specific PRO items	50
2.5	Finalize VCA item pools	0
3.1	Conduct expert interviews at participating transplant sites	80
3.2	Conduct final interviews with subset of enrolled participants	0
3.3	Conduct Thematic Qualitative Analysis from interviews	0
3.4	Conduct mixed-methods analysis	0
3.5	Finalize screening process recommendations	0
3.6	Disseminate screening process recommendations	0

What was accomplished under these goals?

<u>Major Tasks 1.1 and 1.2</u>

We have obtained IRB and HRPO approval for conducting focus groups at American Society of Reconstructive Transplantation (ASRT) and at clinical sites across the country. Additional

regulatory approval is being sought for the patient interviews through a separate IRB submission and is pending.

Major Tasks 1.3, 1.6, and 3.1

Our first round of focus groups was completed in Q1 at the ASRT meeting, with 17 transplant experts participating. Additional focus groups are needed to reach content saturation for qualitative analysis. Four focus group sessions with experts were conducted at the University of Pennsylvania May 8-9, 2019, which included 20 total participants. One focus group with six participants was completed at The Johns Hopkins Hospital on June 18, 2019, and a second group with three participants was held August 29, 2019. Two focus groups with 11 participants were held at The University of Louisville on July 15, 2019, and a focus group with four participants was held September 9, 2019 at Brigham and Women's Hospital in Boston. One additional set of focus groups at University of California, Los Angeles is tentatively planned for January, 2020. Concurrently, we are currently evaluating content saturation after completing these focus groups. The audio recordings from the completed groups have been transcribed and full thematic data analyses will be completed once focus group data collection is complete. In the interim, transcripts from completed groups are being analyzed to initiate codebook development.

Major Task 1.4

We have made contact with clinical centers across the United States where hand transplants have been performed, both to arrange for focus groups and to procure these sites to serve as recruitment hubs for patients. Five sites have thus far expressed interest in being involved in this study to help recruit patients. To date, we have had meetings for regulatory planning with representatives from Johns Hopkins University and University of Louisville. The recruitment and inclusion of these sites is an ongoing activity, to ensure sufficient sample size.

Major Tasks 2.3, and 2.4

Subsequent to the focus groups at clinical sites, we have initiated reviewing existing LIMB-QOL items to identify those that appear relevant to QOL topics experts have noted, and where no match is found, we have begun writing new items that can be used in an experimental fashion (since no data have yet been collected on these items) with participants to be interviewed as part of major task 1.5. Examples of new item topics that have been uncovered through the focus group process include "sense of wholeness and sense of self," "sense of normalcy," and satisfaction with hand transplant." These are topics identified above and beyond those who have experienced extremity trauma and upper limb loss.

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

Nothing to report

How were the results disseminated to communities of interest?

A poster presentation was made at the Military Health Sciences Research Symposium on August 20, 2019, in Kissimmee Florida.

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

In year 2 of this project, we will conduct remaining focus group meetings at cooperating clinical sites and will then complete the qualitative analyses. We will obtain IRB and HRPO approvals for conducting individual patient participant interviews, finalize site-specific agreements for data sharing and other administrative concerns, and will initiate the patient participant interviews.

4. IMPACT

What was the impact on the development of the principal discipline(s) of the project?

To date we have conducted 12 focus groups with stakeholders in hand transplantation from the following backgrounds and professions (see Figure 1).

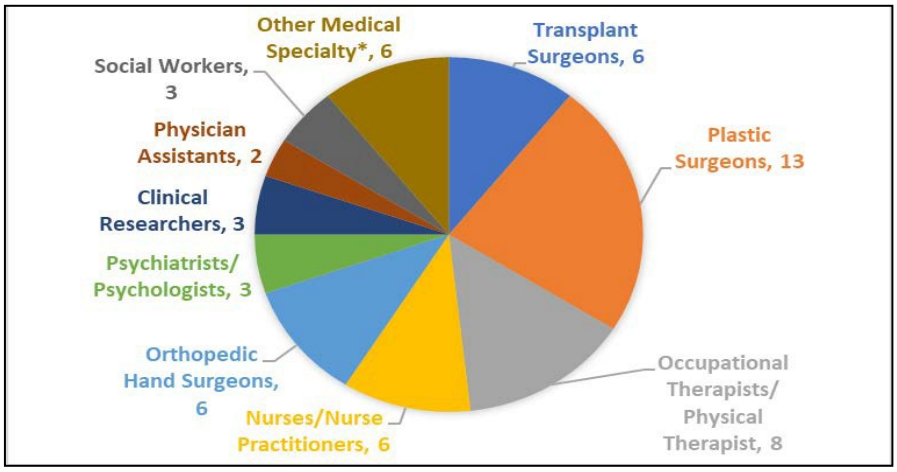

Figure 1. Focus Group Participant Backgrounds and Specialties

Based on preliminary qualitative data analyses we have conducted from the focus groups held, it appears that hand transplant QOL issues are similar to those reported in other trauma-related clinical groups, such as physical function (e.g., fine motor, self-care, independence in activities of daily living), as well as many psychosocial domains, including resilience, depression, anxiety, body image, social isolation, stigma, and participation. In addition, several topics mentioned were unique to the hand transplant patient experience (see Table 1).

Table 1. Major Themes Identified in the Focus Groups Unique to Hand Transplant Population
Sense of wholeness
Embodiment and acceptance of the donor hand post-surgery
Gratitude for being a transplant patient
Satisfaction with transplant (includes satisfaction with function, sensation, and appearance)
Challenge of dealing with extensive rehabilitation requirements
Potential transplant complications (e.g., rejection, consequences of immunosuppression such as skin cancer, kidney disease, diabetes and other chronic illness)

This research represents a vital first step in developing a qualitative framework for understanding QOL after hand transplant.

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

Nothing to Report

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

Nothing to Report

Changes that had a significant impact on expenditures

Nothing to Report

Significant changes in use or care of human subjects.

Nothing to Report

Significant changes in use or care of vertebrate animals.

Nothing to Report

Significant changes in use of biohazards and/or select agents.

Nothing to Report

6. PRODUCTS

Publications, conference papers, and presentations

Journal publications. Nothing to Report

Books or other non-periodical, one-time publications. Nothing to Report

Other publications, conference papers, and presentations.

One conference poster was presented during the reporting period:

> Tintle SM, Tulsky DS, Levin LS. Tyner CE, Slotkin J, Dearth CL, Horan, AD, Dooley ME, Husson E, & Kisala PA. (2019, August) Toward the Development of Patient-Reported Outcome Measures for Vascularized Composite Allotransplantation of the Hand. Poster presented at the Military Health System Research Symposium, Kissimmee, Florida.

Additionally, one conference presentation abstract was submitted and accepted during the reporting period, and will be delivered during the subsequent reporting period:

> Tyner, CE, Slotkin, J, Dearth, CL, Tintle, SM, Levin, LS, & Tulsky, DS (accepted). Health-related quality of life after hand transplantation: Preliminary analysis from focus groups of multi-disciplinary transplantation team members. Poster accepted for presentation at the 26th Annual Conference of the International Society for Quality of Life Research (ISOQOL), San Diego, California.

Abstracts for both of these presentations are provided in Appendix A.

Website(s) or other Internet site(s)

Nothing to Report

Technologies or techniques

Nothing to Report

Inventions, patent applications, and/or licenses

Nothing to Report

Other Products

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Walter Reed National Military Medical Center (WR)

Name:	**CDR Scott Tintle, MD**
Project Role:	Initiating PI at WR
ORCID ID:	none
Nearest person month worked:	2
Contribution to project:	CDR Tintle oversaw all aspects of the project-related activities, including: weekly team teleconferences, contributing to the creation of IRB#1, submitted through University of Delaware (UD), and facilitation of the data collection at the focus group meetings.

Name:	**Christopher L. Dearth, PhD**
Project Role:	Co-Investigator at WR
ORCID ID:	none
Nearest person month worked:	2
Contribution to project:	Dr. Dearth participated in the weekly team teleconferences and assisted CDR Tintle with efforts related to creation of IRB#1, and facilitation of the data collection at the focus group meetings.

Name:	**Heidi Mahatan, MA**
Project Role:	Project Manager at WR
ORCID ID:	none
Nearest person month worked:	1
Contribution to project:	Ms. Mahatan participated in the weekly team teleconferences and assisted CDR Tintle with efforts related to facilitation of the data collection at the focus group meetings.

Name:	**Jenny Nguyen, BS**
Project Role:	Research Coordinator at WR
ORCID ID:	none
Nearest person month worked:	1

Contribution to project: Ms. Nguyen participated in the weekly team teleconferences and assisted CDR Tintle with efforts related to facilitation of the data collection at the focus group meetings.

Name: **Elizabeth Husson, CCRC**
Project Role: Project Manager at WR
ORCID ID: none
Nearest person month worked: 1
Contribution to project: Ms. Husson participated in the weekly team teleconferences and assisted CDR Tintle with efforts related to facilitation of the data collection at the focus group meetings. She left the project in March 2019 due to employment change.

University of Delaware (UD)

Name: **David Tulsky, PhD**
Project Role: Collaborating PI
ORCID ID: none
Nearest person month worked: 2
Contribution to Project: Dr. Tulsky oversaw all aspects of the project-related activities at UD, including: weekly team teleconferences, creation, submission, and approval of IRB#1 at UD, facilitation of the data collection at the focus group meetings, and initiation of qualitative analyses.

Name: **Jerry Slotkin, PhD**
Project Role: Co-I
ORCID ID: none
Nearest person month worked: 2
Contribution to Project: Dr. Slotkin participated in weekly team teleconferences, oversaw UD IRB protocol submission, and oversaw project planning and execution.

Name: **Callie Tyner, PhD**
Project Role: Co-I
ORCID ID: 0000-0003-2945-392X
Nearest person month worked: 2
Contribution to Project: Dr. Tyner participated in weekly team teleconferences, facilitated submission of IRB and HRPO protocols for UD, contributed to overall project planning, and served as a focus group facilitator.

Name: **Pamela Kisala, MA**
Project Role: Co-I
ORCID ID: 0000-0003-3234-795X
Nearest person month worked: 1
Contribution to Project: Ms. Kisala assisted in preparing regulatory documents at UD, prepared the team for the focus groups, and initiated preliminary qualitative analyses.

Name: **Aaron Boulton, PhD**
Project Role: Co-I
ORCID ID: none
Nearest person month worked: 1
Contribution to Project: Dr. Boulton participated in initial discussions of data analysis plans.

Penn Medicine (PM)

Name: **L. Scott Levin, MD**
Project Role: Collaborating PI
ORCID ID: 0000-0001-9108-5182
Nearest person month worked: 1
Contribution to Project: Dr. Levin oversaw all aspects of the project-related activities at PM, including: weekly team teleconferences, contributing to the creation, submission, and approval of IRB#1 submitted at UD, and facilitation of the data collection at the focus group meetings.

Name: **Annamarie Horan, PhD**
Project Role: Co-I
ORCID ID: 0000-0003-3000-5841
Nearest person month worked: 1
Contribution to Project: Dr. Horan participated in weekly team teleconferences, contributed to the creation of the UD IRB#1 protocol submission, and oversaw project planning and execution at PM.

Name: **Mary Dooley, PhD**
Project Role: Co-I
ORCID ID: 0000-0002-0647-6187
Nearest person month worked: 1
Contribution to Project: Dr. Dooley participated in weekly team teleconferences, contributed to the creation of the UD IRB#1 protocol submission, and oversaw project planning and execution at PM.

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

Walter Reed National Military Medical Center (WR)
CDR Scott Tintle, MD – *No change*
Christopher L. Dearth, PhD – *No change*
Heidi Mahatan, MA – *No change*
Jenny Nguyen, BS – *No change*

What other organizations were involved as partners?

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

Collaborative Awards

n/a

Quad Charts

See Appendix B

9. APPENDICES

See Appendix A for attached abstracts from research presentations described in question 6.

See Appendix B for Quad Chart.

Appendix A: Presentation Abstracts

One conference poster was presented during the reporting period:

Tintle SM, Tulsky DS, Levin LS. Tyner CE, Slotkin J, Dearth CL, Horan, AD, Dooley ME, Husson E, & Kisala PA. (2019, August) Toward the Development of Patient-Reported Outcome Measures for Vascularized Composite Allotransplantation of the Hand. Poster presented at the Military Health System Research Symposium, Kissimmee, Florida.

Abstract

Background: More than 300 United States service members have sustained upper extremity amputations resultant from combat operations since 2001. Many Service Members with limb loss have achieved optimal outcomes - including high levels of function and quality of life (QOL), and in some cases the ability to return to duty - using conventional prosthetics. Others, due to a multitude of factors, are unable to achieve full recovery and remain at suboptimal functional levels. Hand transplantation (also known as Vascularized Composite Allotransplantation, or VCA) offers the potential for significantly improved function and QOL for these injured Service Members. To date, VCA research has emphasized the biological/physiological likelihood of graft survival and strategies for post-operative immunomodulatory therapies. There is much less data available on the process of candidate selection outside of the clinical and laboratory domains. Similarly, there is minimal data on how recipients feel about their VCA and about their post-transplantation QOL.

Patients who seek hand transplants must be resilient, highly motivated, and determined to succeed in ways that are not required of solid organ transplant recipients. In addition to the visibility of the transplanted extremities, which causes a tremendous emotional response for the patients, hand transplant patients must endure grueling physical therapy for 4-6 hours per day for many years to enhance healing and function. These unique challenges faced by hand transplant recipients underscore the need for sensitive and specific outcome measures and the development of a standardized screening process that is sensitive to a holistic approach to the patient experience. This study will address these important issues by using qualitative methods to obtain input from important stakeholders (multi-disciplinary transplant teams, transplant candidates, and transplant recipients), which will guide future VCA care and research in this area. In particular, this study has achieved these goals in part by conducting advisory panel meetings with experts who are involved in the VCA process. The preliminary results from these panel discussions will be presented herein.

Methods: This study uses a grounded-theory-based qualitative approach to better understand the QOL factors most important to individuals who are candidates for, or who have received, hand transplantation. This study also uses qualitative methods to understand the criteria currently employed in hand transplant candidate selection, to identify factors associated with successful patient selection, and to get input on the qualities of a standardized outcome measure for this population. Focus groups with transplant experts were held at the biennial meeting of The American Society for Reconstructive Transplantation (ASRT) in November 2018 in Chicago, IL. The sessions were audio-recorded and transcribed for qualitative analysis. Sessions were moderator-led and began with open-ended questions about factors important to QOL generally in these patients. Analytic methods used are well-documented in prior qualitative research to develop new patient reported outcome measures for medical rehabilitation populations (Kisala & Tulsky, 2010). This process begins by conducting a systematic thematic analysis of

interview transcripts. Open Coding is used to review the meeting transcripts, identify major content areas, and develop an initial list of relevant topics or "subdomains." These subdomains provide an initial structure for identifying themes in the interview transcripts. Axial Coding is used to review and merge themes that have been identified, and to relate codes to one another in a hierarchical way. This iterative process consists of multiple revisions and results in a "codebook," with verbatim quotes and definitions to support each code. Last, Selective Coding involves "selectively" coding all transcripts to identify all instances of all codes included in the codebook, using NVivo software. By exhaustively coding transcript text, this research allows for determining the relative frequency of mention of various topics. Results allow for development of a qualitative framework for understanding QOL in individuals involved in the VCA process, as well as to identify the most appropriate outcomes measures for a VCA population.

Results: Three focus group sessions with 17 participants total, representing national and international VCA facilities, were completed. The background/specialties of the participants were diverse, covering many of the key domains of the multi-disciplinary care team, including: 3 transplant surgeons, 3 plastic surgeons, 3 occupational therapists, 2 psychiatrists, 1 orthopedic hand surgeon, 1 immunologist, 1 rheumatologist, 1 physician assistant/transplant coordinator, 1 physiatrist, and 1 clinical research manager. Participants had an average of 8.75 years of experience with hand transplantation (screening or surgeries), and had collectively screened nearly 800 potential candidates. Major themes that emerged from these focus group discussions included both the tangible and intangible benefits imbued to recipients, such as feeling "whole" or restored physically, socially, and emotionally. Examples included restored sense of touch, being able to hold hands with loved ones, and other socially relevant benefits. Embodiment and acceptance of the donor hand was brought up in each of the groups as an important milestone that providers observe in recipients. Gratitude and other topics relevant to being a transplant recipient more generally were discussed. Some challenges that patients face were also raised, primarily dealing with the extensive rehabilitation requirements post-surgery as well as the health complications that can arise due to long-term immunosuppression.

Conclusion: This research represents a vital first step in understanding how hand transplant surgery impacts QOL. This work has several additional steps planned, which will culminate in recommendations for patient reported outcome measures specific for hand transplant candidates and recipients. Future focus groups will be conducted with hospital staff at VCA sites across the country. Interviews will also be conducted with patients, including current and former candidates as well as recipients. Current partnering hospitals for patient interviews and staff focus groups include the University of Pennsylvania, University of Louisville, The Johns Hopkins University, Brigham and Women's Hospital, University of California Los Angeles, and Duke University.

Abstract disclaimer: The views expressed in this article are those of the author and do not reflect the official policy or position of the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, the Department of the Air Force, the Department of the Navy, and Department of Defense or the U.S. Government.

Learning objectives:

1. Provide insight into the use of hand transplantation for service members with upper limb loss

2. Describe the clinically unmet need for improved outcome measures, particularly patient reported outcomes, associated with hand transplantation

3. Demonstrate the capability of the Hand Transplant Outcomes Program in facilitating the comprehensive evaluation of the hand transplant process, with the goal of delivering near term materiel and knowledge products aimed at improving the care of injured service members

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Additionally, one conference presentation abstract was submitted and accepted during the reporting period, and will be delivered during the subsequent reporting period:

> Tyner, CE, Slotkin, J, Dearth, CL, Tintle, SM, Levin, LS, & Tulsky, DS (accepted). Health-related quality of life after hand transplantation: Preliminary analysis from focus groups of multi-disciplinary transplantation team members. Poster accepted for presentation at the 26th Annual Conference of the International Society for Quality of Life Research (ISOQOL), San Diego, California.

Abstract

Aims: Hand transplantation (HT) is a quality-of-life-enhancing procedure, unlike solid organ transplant surgeries that are life-saving. Historically, research on HT outcomes has focused almost exclusively on biological and physiological factors; very little research has systematically documented how HT affects health-related quality of life (HRQOL). The current qualitative study intends to address this unmet clinical gap by gathering input from stakeholders within the multidisciplinary transplant team for three aims: (1) to understand the HRQOL-related factors most important to individuals who are candidates for, or who have received, HT; (2) to understand the criteria currently employed in HT candidate selection; and (3) to get input on the qualities needed for a standardized outcome measure for HT.

Methods: A grounded-theory-based qualitative approach was employed. Focus groups with transplant experts were held at the 2018 meeting of The American Society for Reconstructive Transplantation. The sessions were audio-recorded and transcribed. Systematic thematic analysis of interview transcripts was done using Open Coding to identify major content areas, Axial Coding to develop code hierarchy, and Selective Coding to tally the frequency of mention of each code using NVivo software.

Results: Three focus group sessions were completed with 17 participants total, reflecting diverse specialties including surgery, occupational therapy, psychiatry, immunology, rheumatology, and rehabilitation. Major themes from the group discussions included both the tangible and intangible benefits imbued to recipients, such as feeling “whole” or restored physically, socially, and emotionally. Embodiment and acceptance of the donor hand was discussed in each of the groups as an important milestone of post-surgical success. Gratitude and other topics relevant to being a transplant recipient generally were discussed. Challenges that patients face were raised, primarily dealing with the extensive rehabilitation requirements post-surgery as well as the health complications that can arise due to long-term immunosuppression.

Conclusion: The impacts of HT can be profound, with unique physical, emotional, and social benefits and challenges that are not adequately captured by current outcomes measures. This study has uncovered several domains of HRQOL that are worthy of further study, including feelings of restoration, embodiment of the transplanted tissue, and the decisional burden faced with this elective procedure.

Appendix B: Quad Chart

Reconstructive Vascularized Composite Allotransplantation: Qualitative Approach to Enhance Patient Reported Outcome Metrics and the Candidate Screening Process

Log Number: RT170101P1; Award Number: W81XWH18-2-0067

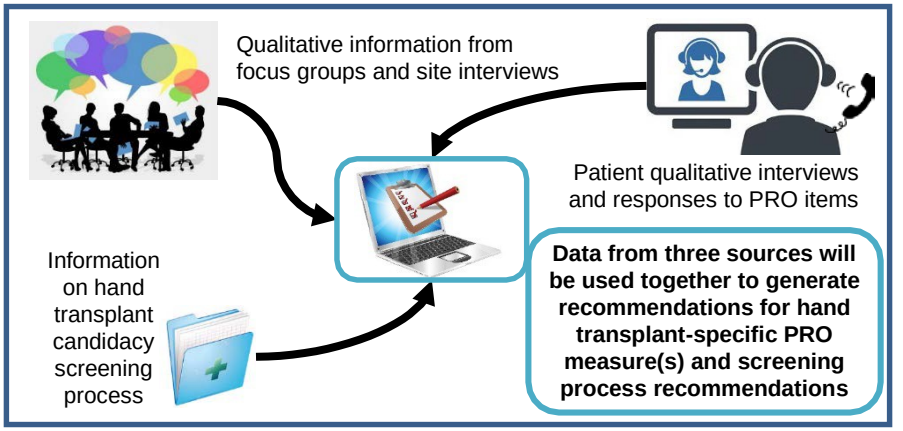
PI: L. Scott Levin, MD. **Organization:** University of Pennsylvania **Award Amount:** : $260,833

Specific Aims & Approach

Aim 1: Determine the psychosocial/QOL outcome domains most important to individuals involved in the VCA process. We will conduct focus groups with VCA clinicians and interviews with patients involved in the VCA process to identify the most critical psychosocial and QOL domains to be assessed in individuals at all stages of the VCA process (e.g., screening, candidacy, transplantation, rehabilitation).

Aim 2: Enhance the selection and validation of standardized, psychometrically robust, and clinically useful patient-reported outcome (PRO) measures for traits and symptoms that are of critical importance to VCA patients. Individuals currently or formerly involved in the VCA process will review items from the ExTrA-QOL measurement system to evaluate 1) the relevance/appropriateness of included constructs and 2) the wording, construct representativeness, and content coverage of the ExTrA-QOL items.

Aim 3: Optimize the VCA candidate screening process by identifying and standardizing the most important clinical and psychosocial characteristics to consider for successful transplantation. We will conduct another series of clinician focus groups and individual patient interviews to understand, evaluate, and optimize the current VCA screening process. We will utilize ExTrA-QOL and other current measures and variables as needed to recommend a standardized and data-supported method for screening.



Accomplishments: Over the past year, 12 focus groups have been conducted with hand transplant experts, with more groups planned for 2020. The most important hand transplant outcome domains have been preliminarily identified from focus group data. Administrative and regulatory applications are in process for planned patient interviews.

Timeline and Cost

Major Tasks	Sites	Year 1	Year 2	Year 3
1.1 Obtain IRB approvals	WR, UD, PM	✓		
1.2 Obtain HRPO approvals	WR, UD, PM	✓		
1.3 Conduct focus groups at ASRT conference	WR, UD, PM	✓		
1.4 Recruit and enroll participants for study inclusion from participating sites nationwide	WR, PM			
1.5 Conduct initial interviews with transplant recipients, candidates, and those who were screened	UD			
1.6 Conduct thematic qualitative analysis from interviews	UD			
2.1 Conduct second round of interviews with participants	UD			
2.2 Analyze cognitive debriefing interview feedback	UD			
2.3 Revise ExTrA-QOL items as needed	UD			
2.4 Develop new VCA-specific PRO items	UD			
2.5 Finalize VCA item pools	UD			
3.1 Conduct expert interviews at participating transplant sites	UD			
3.2 Conduct final interviews with subset of enrolled participants	UD			
3.3 Conduct Thematic Qualitative Analysis from interviews	UD			
3.4 Conduct mixed-methods analysis	UD			
3.5 Finalize screening process recommendations	WR, UD, PM			
3.6 Disseminate screening process recommendations	WR, UD, PM			
Estimated Budget ($K)		**$117,813**	**$121,879**	**$21,141**

Updated: 29-Oct-2019 NOTE: WR = Walter Reed, UD = University of Delaware; PM = University of Pennsylvania Medicine

Goals/Milestones

Year 1 Goals

- ☑ Obtain regulatory approvals (IRB & HRPO)
- ☑ Conduct focus groups at ASRT conference
- ☑ Engage with partnering sites for recruiting patients
- ☐ Identify most important domains for hand transplant outcomes

Year 2 Goals

- ☐ Enroll transplant recipients, candidates, and those previously screened (n = 65)
- ☐ Conduct expert groups and interviews at participating transplant sites

Year 3 Goals

- ☐ Revise ExTrA-QoL items and develop new hand transplant-specific items based on feedback
- ☐ Finalize hand transplant-relevant item pools
- ☐ Finalize and disseminate screening process observations and recommendations

Comments/Challenges/Issues/Concerns

None noted

Budget Expenditure to Date Projected Expenditure: ***$111,170***
Actual Expenditure: ***$91,448***