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TITLE: Ethical Factors Impacting Patients' Decisions to Pursue VCA

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14. ABSTRACT

Hand and upper limb transplantation (a form of vascularized composite allotransplantation, or VCA) is a newer treatment option that aims to restore motor and mobility function and sensation of the hand/arm. Upper extremity (UE) transplantation raises multiple ethical issues, particularly, about informed consent. The overall long-term objective of the proposed study is to optimize the informed consent process for people with upper limb amputations. The proposed study aims to: 1) Qualitatively assess the decision making and informed consent processes for hand transplantation; 2) Develop prototype educational materials (video, website, question prompt sheet) that provide patient-centered information to enhance understanding and reduce undue influence to pursue hand transplantation, and are sensitive to different levels of dysfunction, residual limbs, health literacy, and different racial/ethnic groups; and 3) Formatively evaluate the educational materials through usability testing on people with upper limb amputations' and UE VCA candidates' understanding, satisfaction, and usability. During the last year, we nearly finished developing our website "Within Reach". It is now 99% complete. We have already distributed the website link to the DOD, PAO, and our research team for a final review. Based on their input and the feedback from our Usability Testing Interviews, we will submit one final set of modifications to the website developers that are expected to be minor stylistic, functional, and content edits. The funds for the website developers are almost fully expended, and there are enough funds remaining only for this final set of edits. In the last year, across all sites, we completed: **n=17 additional** in-depth interviews (for a total of n=50), **n=3 additional** focus groups (for a total of n=9 focus groups with n=37 participants), and **n=50 additional** semi-structured interviews (for a total of n=56). We conducted the necessary number of usability testing interviews to reach saturation (n=14/21). Feedback was positive overall: participants found the website "informative" and sensitive to the needs of people with upper limb amputations. Participants requested improvement to the search function, and insertion of more hyperlinks between website sections, which we plan to accommodate in our final set of edits. During the last year, we also filmed an **additional n=4 videos** (with 1 UE VCA recipient and 3 UE amputees) for a total of n=15 videos, as planned. All videos have been reviewed, segmented, and edited into short video segments, and uploaded to the website. We finalized the Question Prompt Sheet (QPS) and published our paper reporting the results of the semi-structured interviews and QPS. Most semi-structured interview participants (**86%**) reported being completely or very likely to use a UE VCA QPS. Participants had extensive information needs about UE VCA, desiring information about: upper limb transplant eligibility, evaluation, surgery, risks, rehabilitation, and functional outcomes. Through analysis of our in-depth interviews, most participants experienced no undue pressure to pursue upper limb transplantation, most recommended that UE amputees be given information about the option of upper limb transplantation within days or weeks of their amputation, and more than half reported that a person's type of amputation should not factor into whether they are selected for upper limb transplantation.

15. SUBJECT TERMS

Ethics
Hand Transplantation
UE Amputation
Informed Consent
Decision Making
Vascular Composite Allotransplantation (VCA)
Reconstructive transplantation
Education
In-Depth interviews
Focus groups
Thematic analysis
Qualitative research
Communication

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1. INTRODUCTION:

Little is known about the informed consent process for upper extremity (UE) Vascularized Composite Allotransplantation (VCA). Consequently, the amount and type of information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed, under-prepared, and feeling unduly pressured when considering this option. This study aims to examine the decision-making process, psychosocial concerns, and information needs about UE VCA among people with UE amputations, and to develop educational materials (i.e., website, videos, question prompt sheet) to help people with UE amputations make informed treatment decisions.

2. KEYWORDS:

Ethics
Hand Transplantation
UE Amputation
Informed Consent
Decision Making
Vascular Composite Allotransplantation
Vascular composite Allograft
VCA
Reconstructive transplantation
Education
In-Depth Interviews
Focus groups
Thematic analysis
Qualitative research
Communication

3. ACCOMPLISHMENTS:

What were the major goals of the project?

We wish to clarify two important points with regard to our study sites:

1. Walter Reed National Military Medical Center (WR) received one grant award with Dr. Scott Tintle as a partnering Principal Investigator. Henry M. Jackson Foundation (HJF) and Uniformed Services University of the Health Sciences (USUHS) are collaborating with WR as a single study site. In other words, only one patient population and recruitment process has occurred across WR, HJF, and USUHS, acting as 1 study site. These are not 3 different study sites. All reporting below refers to WR on behalf of WR, HJF, and USUHS.
2. Johns Hopkins University (JHU) received two grant awards, with Dr. Macey Levan and Dr. Gerald Brandacher as the partnering Principal Investigators, who are collaborating as a single study site. In other words, only one patient population and recruitment process has occurred at JHU, across both awards, as 1 study site. These are not 2 different study sites. All reporting below refers to JHU on behalf of Dr. Levan and Dr. Brandacher.

Specific Aim 1: Qualitatively assess the informed consent process for upper extremity-VCA transplantation.

Major Task 1: Submit IRB documents for local IRB review

Timeline: 9 months, 100% completed (NU, JHU, WR)

- Milestone #1: HRPO approval

Timeline: 6-9 months, 100% completed (NU, JHU, WR)

Major Task 2: Recruit and consent human subjects

- Subtask 1: Place advertisements in newsletters and fliers in clinics

Timeline: 9 months, 100% complete (NU, JHU, WR)

- Subtask 2: Submit internal requests, and contact collaborators and community clinics to obtain lists of eligible potential participants for recruitment, at all sites
Timeline: 9 months, 100% complete (NU, JHU, WR)
- Subtask 3: Recruit participants and obtain informed consent
Timeline: 10-15 months, 100% complete (NU, JHU, WR)

Major Task 3: Conduct cognitive interviews, in-depth interviews, and online focus groups to assess: UE amputees' information needs, understanding of VCA risks, benefits, alternatives, and procedures, perceptions of voluntariness for UE VCA, candidates' perceptions of the informed consent process, and decision-making about UE VCA

- Subtask 1: Conduct cognitive interviews with (n=12) participants: UE amputees (n=11) and VCA candidates (n=1)
Timeline: 10-11 months, 100% complete (NU only)
- Subtask 2: Revise in-depth interview guide based on cognitive interview feedback
Timeline: 10-11 months, 100% complete (NU, JHU, WR)
- Subtask 3: Submit revised in-depth interview guide for local IRB and HRPO review
Timeline: 11-12 months, 100% complete (NU, JHU, WR)
- Subtask 4: Conduct in-depth interviews with (n=50) participants
Timeline: 12-18 months, 100% complete (NU, JHU, WR)
- Subtask 5: Conduct online focus groups with UE amputees (n=25)
Timeline: 12-18 months, 100% complete (NU only)
- Subtask 6: Transcribe in-depth interviews and online focus groups
Timeline: 12-18 months, 100% complete (NU, JHU, WR)
- Subtask 7: Conduct qualitative data analysis
Timeline: 10-21 months, 100% complete
- Subtask 8: Co-author manuscript on Aim 1 findings
Timeline: 18-24 months, 90% complete
- Milestone #2: Manuscript on informed consent, information needs for VCA
Timeline: 18-24 months, 90% complete

Specific Aim 2: Develop educational materials (video, website, question prompt sheet) that provide patient-centered information about upper extremity VCA

Major Task 1: Develop the website

Timeline: 12-26 months, 100% complete

- Subtask 1: Set up server, obtain web domain, establish ADA standards compliance
Timeline: 12 months, 100% complete
- Subtask 2: Establish learning objectives to guide content based on information obtained from Aim 1, clinical expertise in UE, VCA, military health, ethics, and adult learning theories
Timeline: 12-14 months, 100% complete
- Subtask 3: Write initial draft of website content, create and revise prototypes and wireframes of website design and functionality for review in phase 1 telephone focus groups
Timeline: 15-18 months, 100% complete
- Subtask 4: Create graphics, logo, website name, and illustrations, purchase photographs, based on phase 1 focus groups, and for review in phase 2-3 focus groups
Timeline: 15-21 months, 100% complete
- Subtask 5: Submit website content and telephone focus group moderators guide to local IRBs and HRPO for review
Timeline: 19 months, 100% complete (NU, JHU, WR)
- Subtask 6: Recruit and conduct 9 telephone focus groups
Timeline: 19-24 months, 100% complete (NU, JHU, WR)
- Subtask 7: Transcribe telephone focus groups
Timeline, 19-24 months, 100% complete (NU, JHU, WR)
- Subtask 8: Iteratively analyze telephone focus group data to inform revisions of website content and website design for further review in subsequent telephone focus groups
Timeline, 19-26 months, 100% complete
- Subtask 9: Iteratively review and provide feedback on website design, instructional design, and functionality to Advantage Marketing website developers
Timeline: 19-26 months, 99% complete

- Subtask 10: Revise website design and content

Timeline, 19-26 months, 99% complete

Major Task 2: Create Video Testimonials (n=15)

- Subtask 2: Recruit and audition amputees for videotaping
Timeline: 21-24 months, 100% complete
- Subtask 3: Videotape UE amputee and clinician testimonials
Timeline: 21-24 months, 100% complete
- Subtask 4: Edit and link in video testimonials into website
Timeline: 21-24 months, 100% complete

Major Task 3: Develop the Question Prompt Sheet (QPS)

- Subtask 1: Prepare draft of QPS based on Aim 1 results
Timeline: 12-18 months, 100% complete
- Subtask 2: Submit draft QPS and semi-structured interview guide to local IRBs and HRPO for review
Timeline: 19 months, 100% complete (NU, JHU, WR)
- Subtask 3: Recruit and conduct semi-structured interviews for feedback on and refinement of the QPS
Timeline: 19-24 months, 100% complete (NU, JHU, WR)
- Subtask 4: Analyze semi-structured interviews to refine the QPS items for inclusion, exclusion, and wording
Timeline: 19-24 months, 100% complete
- Subtask 5: Further refine QPS
Timeline: 24-26 months, 100% complete
- Milestone #3: Complete VCA-QPS development
Timeline: 26 months, 100% complete

Specific Aim 3. Formatively evaluate the educational materials through usability testing

- Subtask 1: Prepare 6 task scenarios of topics or sections to find on the website during usability testing
Timeline: 25-26 months, 100% complete
- Subtask 2: Submit screenshots of developed website and task scenarios to local IRBs and HRPO for review
Timeline: 26 months, 100% complete
- Subtask 3: Recruit and conduct website usability testing among (n=21) participants: UE amputees (n=10), VCA candidates (n=8), VCA participants (n=2), and VCA recipients (n=1), prioritizing VCA candidates, participants, recipients when possible
Timeline: 27-30 months, 100% complete
- Subtask 4: Data entry of survey data and demographics
Timeline 27-30 months, 100% complete
- Subtask 5: Analyze usability testing qualitative and quantitative data
Timeline: 28-31 months, 100% complete
- Subtask 6: Revise website design, functionalities, and content, as needed, based on usability testing results
Timeline: 28-31 months, 99% complete
- Milestone #4: Complete UE VCA website
Timeline: 31-33 months, 99% complete
- Subtask 7: Co-author manuscript on Aims 2-3 findings
Timeline 31-33 months, 99% complete
- Milestone #5: Manuscript on website development and usability testing for UE VCA
Timeline: 36 months, 99% complete
- Subtask 8: Obtain Creative Commons website licensing
Timeline: 31-33 months, 100% complete
- Subtask 9: Report to NU, JHU, and WR/USU intellectual property departments to report development of intellectual property
Timeline: 31 months, 10% complete
- Subtask 10: Develop brochure on website and disseminate
Timeline: 31-33 months, 99% complete

What was accomplished under these goals?

Specific Aim 1: Qualitatively assess the informed consent process for upper extremity-VCA transplantation.

Major Task 1: Submit IRB documents for local IRB review

- Subtask 2: Submit IRB approval and necessary documents for initial HRPO review
 - Northwestern IRB submitted: 6/9/19
 - Northwestern IRB approved: 7/10/19
 - Johns Hopkins IRB submitted: 10/22/19
 - Johns Hopkins IRB approved: 1/29/20
 - Walter Reed IRB submitted: 11/19/19
 - Walter Reed IRB (administrative review) approved: 4/27/2020
 - CRADA approved 2-19-2021
 - WR drafted the data sharing agreement application (DSAA), which was submitted 3-10-2021 and has been approved for the following two DSAs:
 - 1st DSA approved 6-10-21
 - 2nd DSA approved 6-24-21
 - Command start letter received on 6-28-21
- Milestone #1: HRPO approval
 - Northwestern HRPO approved: 1-8-20
 - Johns Hopkins HRPO approved: Dr. Levan: 6-5-20, Dr. Brandacher: 3-30-20
 - Walter Reed HRPO approved: 11-30-20

Major Task 2: Recruit and consent human subjects

- Subtask 1: Place advertisements in newsletters and fliers in clinics
 - NU research team posted fliers on Reddit, Facebook, and sent emails with the recruitment flier to over 150 support groups across the country
- Subtask 2: Submit internal requests, and contact collaborators and community clinics to obtain lists of eligible potential participants for recruitment, by research staff at all sites
 - NU downloads updated EDW database bi-weekly – has identified n=1 additional potential participant
 - JHU obtained updated list on 8/25/2021 – has identified n=136 potential participants to date
 - WR obtained updated list on 04/2022– has identified n=110 potential participants to date
- Subtask 3: Recruit participants and obtain informed consent by staff
 - WR obtained informed consent from n=11 participants for in-depth interviews, n=11 participants for telephone focus groups, and n=18 participants for semi-structured interviews

Major Task 3: Conduct cognitive interviews, in-depth interviews, and online focus groups to assess: UE amputees' information needs, understanding of VCA risks, benefits, alternatives, and procedures, perceptions of voluntariness for UE VCA, candidates' perceptions of the informed consent process, and decision-making about UE VCA

- Subtask 4: Conduct in-depth interviews with (n=50) participants:
 - WR conducted n=11 in-depth interviews with n=11 UE amputees (for a total of 17)
- Subtask 5: Conduct telephone focus groups with UE amputees (n=25)
 - WR conducted all 3 telephone focus groups (n=11 focus group participants)
- Subtask 6: Transcribe in-depth interviews and online focus groups
 - WR transcribed n=11/11 in-depth interviews and n=3/3 focus groups. All are now completed.
- Subtask 7: Conduct qualitative data analysis
 - NU, JHU, and WR finished conducting analysis of themes from NU, JHU, and WR participant in-depth interviews and completed writing code summaries
 - NU, JHU, and WR completed rapid qualitative analysis of n=9 telephone focus group transcripts
 - All research teams completed rapid analysis templates for each focus group
- Subtask 8: Co-author manuscript on Aim 1 findings

- Qualitative manuscript on Decision Making and Informed Consent: Draft of the Introduction, Methods, Results, and Discussion sections has been prepared and requires further refinement before submission to the journal VCA this fall
- Mixed-methods manuscript on Information Needs and the QPS: Manuscript was completed and published
- Qualitative Manuscript on the Definition of UE VCA Success: This is an additional manuscript, beyond our planned set. The draft of the Introduction, Methods, and Results, and Discussion sections has been prepared and requires further refinement before submission to the journal VCA this fall
- Milestone #2: 3 manuscripts on decision making and informed consent; information needs for VCA and the QPS development; and perceptions of VCA success
 - Drafts of the Decision Making manuscript and the Definitions of VCA Success manuscript are nearly complete; final manuscript preparation is underway.
 - We published the paper on Information Needs and the QPS in the journal *Frontiers in Psychology* in a special issue dedicated to VCA

Specific Aim 2: Develop educational materials (video, website, question prompt sheet) that provide patient-centered information about upper extremity VCA.

Major Task 1: Develop the website

- Subtask 3: Write initial draft of website content, create and revise prototypes and wireframes of website design and functionality for review in phase 1 telephone focus groups
 - Research team re-organized and consolidated website sections to simplify and enhance ease of website navigation
 - Finalized website glossary
 - Created “Did You Know” facts to be placed throughout the website to increase user’s learning according to adult learning theory
 - Website content edits are continuously sent to website developer (Advantage Marketing)
- Subtask 4: Create graphics, logo, website name, and illustrations, purchase photographs, based on phase 1 focus groups, and for review in phase 2-3 focus groups
 - Research team continued to purchase and/or obtained user rights for photos for use on the website
 - Website developer placed newly purchased photos on the website
- Subtask 5: Submit website content and telephone focus group moderators guide to local IRBs and HRPO for review
 - NU submitted on 11-9-21, approved on 11-16-21
 - JHU submitted on 07-01-21, approved on 07-22-21
 - WR submitted for IRB acknowledgement on 1-18-22, Acknowledged on 3-7-22
 - NU submitted to NU IRB on 6-21-22, approved on 6-22-22
 - WR submitted for IRB acknowledgement on 6-23-22, Acknowledged on 7-19-22
 - NU submitted to HRPO on 6-22-22, but because this was a non-substantive modification, our program officer informed us that we did not require HRPO review.
- Subtask 9: Iteratively review and provide feedback on website design, instructional design, and functionality to Advantage Marketing website developers
 - Research team met internally on 10-20-21, 12-2-21, 1-10-22, 4-7-22, 5-11-22, 5-16-22, 5-23-22, and 5-26-22 to identify edits to the website and email edits to marketing team
 - Research team members reviewed each website page and provided extensive revisions to content, formatting, video placement, video captioning, photo captions, reference lists for each website page, superscript citations throughout website, and webpage ordering within the site
 - Research team consolidated feedback from the team and sent feedback to Advantage Marketing from May-September 2022
 - Research team met with Advantage Marketing on 3-10-22, 6-13-22, 6-16-22, and 8-16-22 to provide additional website edits and discuss instructional design and formatting
- Subtask 10: Revise website design and content
 - Advantage Marketing has made various changes to website formatting and design over the course of several months based on research team edits and focus group feedback

- Research team members reviewed and provided feedback on the penultimate website in September 2022
- Penultimate website URL was sent to DOD and PAO for review and approval in September 2022, but awaiting feedback

Major Task 2: Create Video Testimonials (n=15)

- Subtask 2: Recruit and audition amputees for videotaping
 - Over the last year: n=1 UE VCA recipient and n=3 UE amputees were recruited for a video
- Subtask 3: Videotape UE amputee and clinician testimonials
 - Over the last year: n=4 videos were conducted with n=1 UE VCA recipient and n=3 UE amputees
- Subtask 4: Edit and link in video testimonials into website
 - Research staff at all sites have completed selecting video segments for n=15 total videos filmed, and all segments have been edited and uploaded to the website

Major Task 3: Develop the Question Prompt Sheet (QPS)

- Subtask 1: Prepare draft of QPS based on Aim 1 results
- Subtask 2: Submit draft QPS and semi-structured interview guide to local IRBs and HRPO for review
- Subtask 3: Recruit and conduct semi-structured interviews for feedback on and refinement of the QPS (n=60) among UE amputees (n=35), VCA candidates (n=17), VCA participants (n=4), VCA recipients (n=4), prioritizing VCA candidates when possible
- Subtask 4: Analyze semi-structured interviews to refine the QPS items for inclusion, exclusion, and wording
 - Final analysis of quantitative and qualitative data on QPS items was conducted
- Subtask 5: Further refine QPS by:
 - Drs. Gordon & Levan: Prepare questions in <6 grade reading level
 - Research team used the Flesch Kincaid readability test to ensure all QPS items were below a 6th grade reading level
 - Drs. Brandacher and Tintile: Ensured questions cover VCA psychosocial issues, accurately reflect VCA concepts
 - Scientific Advisory Board: Ensured questions cover VCA ethics issues, military perspectives, and disability rights
 - The SAB and research team clinicians reviewed the QPS rankings from semi-structured interviews and provided feedback
 - The QPS was finalized after feedback was reviewed and incorporated as appropriate
- *Milestone #3: Complete VCA-QPS development*
 - The QPS was completed, described in the publication, and uploaded to the Within Reach website

Specific Aim 3. Formatively evaluate the educational materials through usability testing

- Subtask 1: Prepare 6 task scenarios of topics or sections to find on the website during usability testing
 - Research team finalized 5 task scenarios for usability testing
- Subtask 2: Submit screenshots of developed website and task scenarios to local IRBs and HRPO for review
 - NU submitted for IRB review on 4-2-22, approved on 5-16-22
 - NU submitted for HRPO review on 5-16-22, approved on 5-20-22
 - WR submitted for IRB acknowledgement on 5-18-22, Acknowledged on 6-8-22
- Subtask 3: Recruit and conduct website usability testing among (n=21) participants: UE amputees (n=10), VCA candidates (n=8), VCA participants (n=2), and VCA recipients (n=1), prioritizing VCA candidates, participants, recipients when possible
 - Usability testing was performed among n=14 participants (n=7 at NU, n=7 at WR). JHU was unable to complete this task due to delays in single IRB processing and concurrent unavailable staffing given Dr. Levan's move to NYU. However, we reached saturation with the sample of n=14 to support final revisions to the website
- Subtask 4: Data entry of survey data and demographics

- All usability data have been entered into databases
- Subtask 5: Analyze usability testing qualitative and quantitative data
 - All usability quantitative data and qualitative data have been analyzed, were used to inform final website revisions, and are ready to report in the manuscript
- Subtask 6: Revise website design, functionalities, and content, as needed, based on usability testing results
 - All feedback from usability testing is prepared and ready to provide to Advantage Marketing for final revisions (we are waiting for DOD and PAO feedback before submitting revisions to the marketing team)
- *Milestone #4: Complete UE VCA website, and post URL links to it on other transplant-related websites (e.g., ISVCA)*
- Subtask 7: Co-author manuscript on Aims 2-3 findings
 - The Introduction, Methods, Results, and Discussion sections have been written. The manuscript is 95% complete. All research staff have reviewed a first draft and feedback has been incorporated into the manuscript. Final usability testing data will be entered into the manuscript shortly. The manuscript will be submitted imminently thereafter.
- Milestone #5: Manuscript on website development and usability testing for UE VCA
 - The manuscript will be submitted fall 2022
- Subtask 8: Obtain Creative Commons website licensing
 - This has been completed and the Creative Commons logo is in the website footer
- Subtask 9: Report to NU, JHU, and WR/USU intellectual property departments to report development of intellectual property
 - NU has already, and WR, and JHU will reach out to their respective intellectual property departments as soon as the website is approved by PAO and DOD
- Subtask 10: Develop brochure on website and disseminate
 - A third draft has been completed, will be revised this fall, and uploaded onto the website

Conclusion: We wish to emphasize several key points about our substantial progress in this study:

1. We have completed all data collection activities and all data analyses.
2. Total number of participants recruited by data collection activity across study sites is shown in the table below:

	WR	NU	JHU	Total recruited	Targeted Enrollment
Cognitive Interviews	0	5	0	5	12
In-Depth Interviews	17	16	17	50	50
2 Online Focus Groups	0	7	0	7	25
9 Telephone Focus Groups	11	12	14	37	9 focus groups; 45 participants
Semi-Structured Interviews	18	19	19	56	60
Usability Testing Interviews	7	7	0	14	21
TOTAL	53	66	50	169	228

3. The only remaining study activities to complete during this no cost extension period [10-1-22 to 12-31-22] are to:
 - a. Consolidate and submit PAO, research team, and usability testing feedback to Advantage Marketing to make final revisions to the website [this step has been completed as of 10-20-22]
 - b. Obtain PAO approval for the website [PAO approval was obtained on 10-19-22]
 - c. Disseminate the website upon receiving PAO approval and going live with the website
 - d. Finalize and submit our manuscripts for publication in peer-reviewed journals

It will be very easy to complete these steps moving forward.

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

Overall, this project has offered the research team many opportunities for training and professional development over the past year including:

- Learning how to recruit study participants and obtain informed consent
- Learning how to conduct in-depth interviews
- Learning how to conduct semi-structured interviews
- Learning how to conduct and moderate focus groups
- Learning how to conduct usability testing
- Learning how to perform rapid qualitative analysis
- Learning how to perform thematic qualitative analysis and writing code summaries
- Learning how to use NVIVO qualitative analysis computer data analysis software
- Learning how to prepare a poster or a paper presentation
- Learning how to present a poster or a paper presentation at a national professional conference
- Learning how to prepare manuscript drafts
- Learning how to disseminate research findings beyond presentations and publications
- Learning how to collaborate with a research team across multiple study sites
- Learning how to complete work according to a timeline

How were the results disseminated to communities of interest?

Over the past year, published **1** peer-reviewed paper, and gave **8** paper presentations and **3** poster presentations at **7** different professional conferences.

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

During the next reporting period, we plan to do the following:

1. Hold monthly research team meetings October - December, 2022
2. We will finalize planned and additional manuscripts and submit them for publication, as soon as possible, before December 31, 2022, including the following manuscripts:
 - Decision-Making
 - Website Development
 - Definitions of Patient Success
 - Patient Selection
 - Changes in Occupation Following UE Amputation among Civilian and Military Groups
3. The website is now 99% completed. We sent the website to the DOD, PAO, and all members of the research team for one final review in September 2022.
 - a. Our next step is to synthesize the feedback and submit the final edits to the website developers, Advantage Marketing, as soon as we receive approval from DOD and PAO.
 - b. We will incorporate the feedback received from usability testing with the last set of edits to the website developers given an agreement with the website developers based on limited available remaining funding for this work.
 - c. The website developers will teach the Northwestern research team how to make minor content changes for future edits as need be.
4. Our focus will then be to broadly disseminate the website. We plan to disseminate the website through publishing the manuscript on its development, which is 99% complete, posting a URL link to the website on the American Society of Reconstructive Transplantation's website, informing study participants of the website's completion to spread the word, informing new patients at hand surgery and physical therapy clinics, distributing pamphlets about the website in clinics at Northwestern, Johns Hopkins, and Walter Reed, disseminating to online and in-person support groups throughout the US

and through a Walter Reed email distribution list, and disseminating via word-of-mouth through providers and clinicians at collaborating sites.

5. Present 3 papers about VCA Informed Consent; UE VCA QPS; and UE VCA “success” at the ASRT November, 2022
6. We will complete the project by December 31, 2022 and submit the Final Report at or near that time.

4. IMPACT:

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

We developed a UE VCA Question Prompt Sheet (QPS) and an educational website (“Within Reach”) that is nearly complete. Through in-depth interviews, semi-structured interviews, and focus groups, we gained insights into UE amputees’ information needs, psychosocial concerns, and decision-making processes for UE VCA. People with UE amputations have extensive UE VCA information needs, and desire information about upper limb transplant eligibility, evaluation, surgery, risks, rehabilitation, and functional outcomes. The UE VCA QPS supports patient-centered care by empowering patients to ask questions important to them, promoting patient-provider communication, and increasing patient knowledge.

The Within Reach website addresses upper limb amputees’ UE VCA information needs and psychosocial concerns in a patient-centered, neutral manner, i.e., neither “for” nor “against” UE VCA. Our study findings indicate that psychosocial factors influencing decisions to pursue UE VCA include: regaining functionality and the associated independence, increasing social and physical confidence, and enabling more active familial involvement. Psychosocial factors and concerns influencing decisions to NOT pursue UE VCA include: health or limb function becoming “worse off” from UE VCA, the rigorous commitment required for undergoing UE VCA and rehabilitating, and having already adapted to life without upper limb(s). The Within Reach website includes videos of UE VCA recipients, UE amputees, and health care professionals that support the information provided. Additionally, the UE VCA QPS is available for download from the website. The Within Reach website can facilitate informed decision-making for people with UE amputations considering UE VCA.

The Within Reach website, videos, and UE VCA QPS makes UE VCA information more accessible to people with UE amputations in order to facilitate informed decision-making and the informed consent process for those considering UE VCA.

What was the impact on other disciplines?

Findings suggest a need to better inform and prepare patients in decision making and in the informed consent process for UE VCA. Providing patient-centered educational resources, such as our educational website, Within Reach, and the VCA-Question Prompt Sheet (QPS), prior to or soon after undergoing UE amputation may provide an opportunity for patients to make more informed treatment decisions. Findings from this research may inform future research in other types of VCA organ programs to identify information needs and improve the decision-making process for patients. Our findings revealed patient-centered UE VCA treatment goals, which can inform the development of patient reported outcomes measures for UE VCA and inform clinical practice. Our findings also revealed ways to engage individuals with UE amputations in research and to make online resources more accessible for these individuals.

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

- **Delay in transcription program approval:**

WR has been transcribing in-depth interviews and usability testing interviews by hand because no external company or software platform is available to the study team to use. All transcriptions have been completed. This issue is outside the team's control.

- **IRB delays:**

- NU and WR continued to face IRB delays. This issue is outside the team's control.
- Dr. Levan moved from JHU to NYU, which required sIRB review, a data use agreement, a partnering site review process, and a data trust review. However, the review processes could not be completed in a reasonable time frame before the end of the study, and NYU was not approved to perform Usability Testing interviews, which would have required sharing identifiable patient data between NYU and JHU. JHU did not have the staff needed to perform the Usability Testing interviews because the JHU staff moved to NYU.

Changes that had a significant impact on expenditures

- Because NYU did not have sIRB approvals, they did not complete the Usability Testing interviews. Thus, expenditures are lower than expected.

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

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.

Gacki-Smith J, Kuramitsu B, Downey M, Vanterpool K, Nordstrom MJ, Luken M, Riggleman T, Altema W, Fichter S, Cooney CM, Dumanian GA, Jensen SE, Brandacher G, Tintle S, Levan M, Gordon EJ. Information needs and development of a question prompt sheet for upper extremity vascularized composite allotransplantation: A mixed methods study. Special Issue on VCA. Frontiers in Psychology 2022; Sep 5;13:960373. doi: 10.3389/fpsyg.2022.960373.

Books or other non-periodical, one-time publications.

Nothing to report

Other publications, conference papers and presentations.

1. **Gordon E**, Kuramitsu B, Gacki-Smith J, Ferzola A, Vanterpool K, Kunkle C, Hewitt M, Schultheis A, Riggleman T, Taylor J, Cooney C, Tintle S, Brandacher G, Levan M. Psychosocial and Ethical Factors Affecting Patients' Decision Making about Upper Extremity Vascularized Composite Allotransplantation. Paper accepted for oral presentation at Tissue Engineering and Regenerative Medicine International Society (TERMIS) virtual World Congress in Maastricht, The Netherlands, November 17, 2021.
2. B. Kuramitsu, C. Berumen, A. Ferzola, H. Sung, D. Scarton, T. McHugh, A. Schultheis, T. Riggleman, J. Taylor, C. Cooney, M. Henderson, S. Tintle, G. Brandacher, **E. Gordon**. Patients' Psychosocial Perceptions, Information Needs, and Decision Making about Upper Extremity VCA. Paper accepted for a 5-minute Podium Presentation at the American Society for Reconstructive Transplantation Meeting in Bethesda, MD. Hybrid meeting. November 18, 2021.
3. Hewitt M, Riggleman T, Nordstrom M, Dodd LD, Kuramitsu B, Gacki-Smith J, Vanterpool K, Downey M, Cooney C, Dumanian G, Jensen S, Tintle S, Brandacher G, Levan M, **Gordon E**. Awareness and Perceptions of Vascularized Composite Allotransplantation (VCA) Among Military Personnel with Upper Extremity Amputations: A Qualitative Approach. Poster presented at the Association of Military Surgeons of the United States (AMSUS), February 22, 2022.
4. Downey M, Kuramitsu B, Gacki-Smith J, Vanterpool K, Luken M, Nordstrom M, Riggleman T, Cooney C, Levan M, Tintle S, Brandacher G, Jensen S, Dumanian G, **Gordon E**. Patient Definitions of Transplant "Success" of Upper Extremity VCA. Poster presented at the American Transplant Congress (ATC) meeting, Boston, MA, June 5, 2022.
5. Levan M. Psychosocial Factors in the Decision Making and Informed Consent Process for Upper Extremity VCA. Paper (Invited) presented at American Transplant Congress (ATC) meeting in Boston, Massachusetts, on June 7, 2022.
6. Downey M, Kuramitsu B, Gacki-Smith J, Vanterpool K, Luken M, Nordstrom M, Riggleman T, Cooney C, Levan M, Tintle S, Brandacher G, Jensen S, Dumanian G, **Gordon E**. Patient Definitions of Transplant "Success" of Upper Extremity VCA. Mini-oral paper presented (virtually) at The Transplantation Society (TTS) meeting in Buenos Aires Sept. 10th-14th, 2022.

7. M. Nordstrom, M. Luken, M. Hewitt, T. Rigglesman, S. Fichter, B. Kuramitsu, J. Gacki-Smith, K. Vanterpool, M. Downey, C. Cooney, G. Dumanian, S. Jensen, S. Tintle S, G. Brandacher, M. Levan, **EJ. Gordon**. Treatment Options for Upper Extremity Limb Loss: Ethical and Psychosocial Factors Affecting Patients' Decision Making about Vascularized Composite Allotransplantation. Poster presented at the Military Health Systems Research Symposium (MHSRS) meeting, Kissimmee, FL. September 13, 2022. Abstract # MHSRS-22-07470.
8. Gacki-Smith J, Kuramitsu BR, Downey M, Vanterpool KB, Nordstrom MJ, Luken M, Rigglesman T, Altema W, Fichter S, Cooney CM, Dumanian GA, Jensen SE, Brandacher G, Tintle S, Levan M, **Gordon EJ**. Empowering Patients with Upper Extremity Amputations to Communicate with Providers about VCA. Paper accepted for a 6-minute Podium Presentation. American Society for Reconstructive Transplantation 7th Biennial meeting. Chicago, IL. November 4, 2022.
9. **Gordon EJ**. Moderator (**Invited**), Session III: Psychologists. American Society for Reconstructive Transplantation 7th Biennial meeting. Chicago, IL. November 4, 2022.
10. **Gordon EJ**. *Informed Consent in VCA*. (**Invited**) Session III: Psychologists. American Society for Reconstructive Transplantation 7th Biennial meeting. Chicago, IL. November 4, 2022.
11. Downey M, Gacki-Smith J, Kuramitsu BR, Vanterpool KB, Nordstrom MJ, Luken M, Rigglesman T, Fichter S, Altema W, Langlee W, Cooney CM, Jensen SE, Dumanian GA, Levan M, Tintle S, Brandacher G, **Gordon EJ**. Patient Definitions of Transplant "Success" of Upper Extremity VCA. Paper accepted for a 6-minute Podium Presentation. American Society for Reconstructive Transplantation 7th Biennial meeting. Chicago, IL. November 5, 2022.

Website(s) or other Internet site(s)

www.WithinReach.info

This website is 99% completed. We will make the website available to the public this fall.

Technologies or techniques

Nothing to report

Inventions, patent applications, and/or licenses

Nothing to report

Other Products

1. We developed the UE VCA Question Prompt Sheet (QPS), which is available to download from the Within Reach website. We intend for VCA transplant programs to send the QPS to VCA candidates expressing interest in initiating UE VCA evaluation and to VCA participants who initiated UE VCA evaluation to empower them to ask questions about UE VCA.
2. We developed a pamphlet that showcases the Within Reach website features, which is available to download from the Within Reach website. We intend for health care professionals treating individuals with UE amputations (e.g., prosthetists, surgical hand clinics, UE VCA programs) to provide the pamphlet in patient waiting rooms to ensure that patients can learn about the website.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

What individuals have worked on the project?

Name: Dr. Elisa Gordon
Project Role: Initiating Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0003-0969-1998
Nearest person month worked: 2.30
Contribution to Project: No Change

Name: Brianna Kuramitsu
Project Role: Research Study Coordinator, Sr.
Nearest person month worked: 4.60
Contribution to Project: No Change

Name: Jessica Gacki-Smith
Project Role: Research Project Manager
Nearest person month worked: 5.90
Contribution to Project: No Change

Name: Dr. Greg Dumanian
Project Role: Co-Investigator, Hand surgeon
Researcher Identifier: 0000-0002-0389-5191
Nearest person month worked: 0.24
Contribution to Project: No Change

Name: Dr. Sally Jensen, PhD
Project Role: Co-Investigator, Psychologist
Researcher Identifier: 0000-0002-2078-3263
Nearest person month worked: 0.60
Contribution to Project: No Change

Name: Jefferson Uriarte
Project Role: Research Project Coordinator
Nearest person month worked: 0.46
Contribution to Project: Assisted with Research Coordinator role, including contributing to website development and processing financial transactions.

Name: Dr. Macey Levan (Henderson)
Project Role: Partnering Principal Investigator
Researcher Identifier: 0000-0002-4239-1252
Nearest person month worked: 0.90 at JHU (7.5% through 02/14/2022); 0.12 at NYU (2/15/2022-9/29/2022)
Contribution to Project: No Change

Name: Dr. Dorry Segev
Project Role: Co-Investigator
Researcher Identifier: 0000-0002-1924-4801
Nearest person month worked: 0.24 at JHU (2% effort through 01/31/2022)
Contribution to Project: No Change

Name: Dr. Gerald Brandacher
Project Role: Partnering Principal Investigator
Researcher Identifier: 0000-0001-7790-441X
Nearest person month worked: 0.90
Contribution to Project: No Change

Name:	Dr. Daniel Warren
Project Role:	Partnering Principal Investigator
Nearest person month worked:	0.12 starting 02/15/2022 at JHU
Contribution to Project:	No Change
Name:	Karen Vanterpool
Project Role:	Senior Research Scientist
Nearest person month worked:	0.00
Contribution to Project:	No Change
Name:	Carisa Cooney
Project Role:	Co-Investigator, Psychologist
Researcher Identifier:	0000-0002-5475-206X
Nearest person month worked:	0.12
Contribution to Project:	No Change
Name:	Max Downey
Project Role:	Senior Research Coordinator
Nearest person month worked:	2.64 CM at JHU (22% Avg. through 02/14/2022); 5.4 at NYU (4/18/2022-9/29/2022)
Contribution to Project:	No Change
Name:	Dr. Scott Tintle
Project Role:	Partnering Principal Investigator at WRNMMC
Nearest person month worked:	0.4
Contribution to Project:	No Change
Name:	Michelle Nordstrom, OTR/L
Project Role:	Registered Occupational Therapist
Nearest person month worked:	0.3
Contribution to Project:	No change
Name:	Derek Soloway
Project Role:	Program Manager
Nearest person month worked:	0.13
Contribution to Project:	No change
Name:	Lauren Dodd
Project Role:	Program Coordinator
Nearest person month worked:	0.13
Contribution to Project:	No change
Name:	Shannon Fichter
Project Role:	Clinical Research Coordinator
Nearest person month worked:	0.29
Contribution to Project:	No change
Name:	Michelle Luken
Project Role:	Sr. Clinical Research Associate
Nearest person month worked:	0.20
Contribution to Project:	Responsible for qualitative data analysis.
Name:	Tiffany Riggleman
Project Role:	Research Certified Occupational Therapist Assistant
Nearest person month worked:	0.10
Contribution to Project:	No Change

Name:	Withney Altema
Project Role:	Clinical Research Assistant II
Nearest person month worked:	0.63
Contribution to Project:	No Change

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

No changes to report.

What other organizations were involved as partners?

Shirley Ryan AbilityLab (SRAL)
Chicago, IL

Contribution to the project: NU collaborates with an SRAL clinician to assist with recruitment. NU posts fliers advertising the study for opt-in recruitment in the SRAL library.

David Rotter Prosthetics
Joliet, IL

Contribution to the project: David Rotter (prosthetist) shares fliers advertising the study to his clients to aid with recruitment, participated in a video.

Advantage Marketing
Chicago, IL

Contribution to the project: Assist with hosting, the design, and the development of the educational website "WithinReach.info"

8. SPECIAL REPORTING REQUIREMENTS:

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES:

Appendix 1.

- Downey M, Gacki-Smith J, Kuramitsu BR, Vanterpool KB, Nordstrom MJ, Luken M, Riggleman T, Fichter S, Altema W, Langlee W, Cooney CM, Jensen SE, Dumanian GA, Levan M, Tintle S, Brandacher G, **Gordon EJ**. Patient Definitions of Transplant “Success” of Upper Extremity VCA. Paper accepted for a 6-minute Podium Presentation. American Society for Reconstructive Transplantation 7th Biennial meeting. Chicago, IL. November 5, 2022.

Background: Little is known about how to measure the “success” of upper extremity (UE) vascularized composite allotransplantation (VCA), an innovative treatment for people with UE amputations. While providers have defined UE VCA “success” by quantitative functional, clinical, and quality-of-life (QoL) metrics, patients’ definitions are lesser known. Our study assessed patients’ definitions of UE VCA “success.”

Methods: We conducted in-depth interviews and focus groups among people with acquired UE amputations and UE VCA candidates, participants, and recipients at three sites to assess transplant “success” and collect demographic data. Transcripts were analyzed using thematic analysis.

Results: We conducted 50 interviews (61.7% participation rate) and 9 focus groups among 37 participants (75.5% participation rate), including people with acquired UE amputations (83.3%), UE VCA candidates and participants (11.1%), and UE VCA recipients (5.6%). Most were male (73.6%), White (70.8%), had a mean age of 45 years, and had a unilateral (68.1%) and below-elbow amputation (51.4%). Transplant “success” was defined in 6 ways: 1) Restoring function and sensation to enable activities: “I can bring a glass to my lips and drink. I can open a door.... I can drive my car” (functional/QoL); 2) Accepting the transplanted limb into the recipient’s identity: “...if I can deal with living with it, knowing that it’s not actually my hand” (psychosocial); 3) Surgical attachment of the donor limb to the recipient without rejection: “I’m leaning towards, came out of the surgery, and all the systems are connected” (clinical); 4) Ensuring that the benefits outweigh the risks: “The addition of the functionality would have to outweigh... the side-effects of the anti-rejection drugs” (functional/QoL); 5) Attaining better outcomes compared to prosthetics: “...if you [are] just having basically a useless limb hanging there... it’d be worse than your prosthetic” (functional/QoL).

Conclusions: Our findings suggest that participants have multiple definitions of UE VCA “success” pertaining to improvements in the recipient’s daily living experience, compared to no treatment and/or prosthetics. Informed consent should address whether patients’ desired outcomes can be realized with UE VCA.

Appendix 2.

- Gacki-Smith J, Kuramitsu BR, Downey M, Vanterpool KB, Nordstrom MJ, Luken M, Riggleman T, Altema W, Fichter S, Cooney CM, Dumanian GA, Jensen SE, Brandacher G, Tintle S, Levan M, **Gordon EJ**. Empowering Patients with Upper Extremity Amputations to Communicate with Providers about VCA. Paper accepted for a 6-minute Podium Presentation. American Society for Reconstructive Transplantation 7th Biennial meeting. Chicago, IL. November 4, 2022.

Background: Patient-provider communication can be ineffective because many patients feel intimidated or do not know what questions to ask providers. Many individuals with upper extremity (UE) amputations do not receive sufficient information about their treatment options, particularly vascularized composite allotransplantation (VCA). A question prompt sheet (QPS) is a list of questions that can empower patients to ask questions they find important, promote patient-provider communication, and increase patient knowledge, thereby fostering patient-centered care. This study developed a UE VCA-QPS and examined the UE VCA information needs among people with UE amputations.

Methods: We conducted a multi-site, cross-sectional, sequential mixed-methods study among people with acquired UE amputations. In-depth interviews were first conducted to examine patients' information needs about UE VCA, which were synthesized through qualitative content analysis into a list of items for the initial UE VCA-QPS draft. The initial draft UE VCA-QPS included 130 items across 18 topics. Thereafter, semi-structured interviews were conducted to rate the importance of each item for inclusion in the VCA-QPS and elicit qualitative rationales for each rating. Quantitative data were analyzed by descriptive statistics. The multidisciplinary research team reviewed the subsequent draft UE VCA-QPS to reduce the number of items, improve wording, remove repetitive items, and ensure that items were clinically relevant.

Results: Eighty-nine people participated (63.9% participation rate), including people who had not pursued UE VCA (85%), UE VCA candidates and participants (9%), and UE VCA recipients (6%). Most were male (73%), White (74%), and had a mean age of 46 years, had a unilateral (84%) and below-elbow amputation (56%). Participants expressed interest in learning about UE VCA eligibility, evaluation process, surgery, risks, rehabilitation, and functional outcomes. The final UE VCA-QPS included 35 items, organized into 9 topics. Items were written at a $\leq$ 6th grade reading level. Most semi-structured interview participants (86%) were 'completely' or 'very' likely to use a UE VCA-QPS.

Conclusions: Our findings suggest that people with UE amputations desire much information about myriad aspects of UE VCA. Future research should assess whether the UE VCA-QPS helps to meet patients' information needs and foster informed decision-making for UE VCA.

Appendix 3.

- Gordon EJ. Moderator (Invited), Session III: Psychologists. American Society for Reconstructive Transplantation 7th Biennial meeting. Chicago, IL. November 4, 2022.
- Gordon EJ. *Informed Consent in VCA*. (Invited) Session III: Psychologists. American Society for Reconstructive Transplantation 7th Biennial meeting. Chicago, IL. November 4, 2022.

Appendix 4.

- Nordstrom M, Luken M, Hewitt M, Rigglesman T, Fichter S, Kuramitsu B, Gacki-Smith J, Vanterpool K, Downey M, Cooney C, Dumanian G, Jensen S, Tintle S, Brandacher G, Levan M, **Gordon EJ**. Treatment Options for Upper Extremity Limb Loss: Ethical and Psychosocial Factors Affecting Patients' Decision Making about Vascularized Composite Allotransplantation. Poster presented at the Military Health Systems Research Symposium (MHSRS) meeting, Kissimmee, FL, September 13, 2022. Abstract # MHSRS-22-07470.

Background

Limb loss is a common combat injury among United States military service members (SMs). From 2001 to 2017, US SMs sustained a total of 302 upper extremity (UE) amputations that were caused primarily by explosions, motor vehicle crashes, and penetrating gunshot wounds.¹ From 2001 to 2011, SMs with UE amputations were assigned an average disability rating of 75 (of 100), which indicates that they were unable to perform in many occupational or social settings, and only about 11% of all SMs with at least one amputation returned to duty.^{2,3} Individuals with UE amputations may face challenges related to engaging in activities of daily living, their physical environment, employment, social life, transportation, and more.⁴ Many also experience psychosocial complications including depression, anxiety, employment challenges, social isolation, body image disturbance, and military concerns over honor.⁵⁻⁷ Restoring SMs' function and well-being, in addition to benefitting the individual's quality of life, benefits the military by increasing service readiness, improving return-to-duty rates, and reducing healthcare costs.

One possible treatment option for UE limb loss is hand or upper extremity transplantation as one form of Vascularized Composite Allotransplantation (VCA). Upper extremity VCA entails transplanting an entire hand/forearm/arm from a deceased organ donor onto a recipient. VCA has been used to treat multiple severe tissue defects due to trauma or infection with the goals of restoring function and improving quality of life. Overall, functional outcomes from UE VCA appear to be highly encouraging.^{8,9,10} Despite the positive outcomes, there are also surgical, medical, and psychosocial risks. Allograft failure and rejection may require reconstruction or even limb removal. Additionally, VCA requires a lifelong commitment to anti-rejection medications and long-term rehabilitation regimens. Psychosocial adaptation and the accompanying financial costs will vary across individuals.¹¹

Given the risks and potential benefits of this procedure, the informed consent process is extremely important before undergoing treatment. However, the informed consent process for UE VCA has yet to be standardized. Consequently, the information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed and under-prepared for decision making about UE VCA. This study examined decision making and psychosocial factors affecting decisions about UE VCA among people with UE amputations.

Methods

We conducted in-depth telephone interviews among people with acquired UE amputations to assess psychosocial factors informing decision making about UE VCA. Interviews were conducted by research staff at Northwestern University and Johns Hopkins University. Participants were recruited via medical record review, social media advertisements, advertisements by support groups across the country, and flyers posted in various clinics on site. Interview topics covered personal history, awareness and perceptions of UE VCA, information needs, the decision-making process, perceptions of voluntariness and patient selection, and interest in using educational materials such as a website, videos, and a question prompt sheet. Interviews lasted between one and two hours. Thematic analysis and a grounded theory approach were used to analyze qualitative data.

Results

To date, 18 people completed in-depth interviews (82% participation rate), including 3 undergoing UE VCA evaluation as VCA "participants" or "candidates". Most were male (78%), had a mean age of 48 years, had a unilateral amputation (78%), and had undergone amputation a mean of 10 years earlier. Half (50%) were 'a lot' or 'completely' willing to pursue VCA. Psychosocial factors influencing decisions to pursue VCA included: expecting an increase in social and physical self-esteem; seeking independence with activities of daily living;

enabling more active involvement as a parent; family or friend enthusiasm; and prosthetic device problems. Psychosocial factors influencing decision making not to pursue VCA included: feeling mentally unprepared for a transplant; having already adapted to life without upper limb(s); concerns about the long-term commitment to taking immunosuppressants; discouragement from family or friends; concerns about the rigorous rehabilitation process; concerns about receiving a graft that appears mismatched in size or skin color; concerns that the transplant may be unsuccessful; concerns about health or limb function becoming “worse off” from the UE VCA; and concerns about logistical barriers to accessing transplant and rehabilitation services. Participants would justify getting an UE VCA if the UE VCA success rate was high and risks were low, and if participants currently struggled with managing daily tasks.

Conclusion

Preliminary findings suggest that people with UE amputations hold clinical and psychosocial concerns that diminish their enthusiasm for UE VCA. These findings are currently being used to inform the development of educational materials that aim to provide comprehensive, objective information to SMs and civilians with UE amputations, their families, and the general public. Addressing patients’ psychosocial concerns may help to set appropriate expectations, and improve understanding of the risks and benefits associated with UE VCA, and ultimately foster informed decision making about UE VCA.

Appendix 5.

- Downey M, Kuramitsu B, Gacki-Smith J, Vanterpool K, Luken M, Nordstrom M, Riggelman T, Cooney C, Levan M, Tintle S, Brandacher G, Jensen S, Dumanian G, **Gordon E**. Patient Definitions of Transplant “Success” of Upper Extremity VCA. Mini-oral paper presented (virtually) at The Transplantation Society (TTS) meeting in Buenos Aires, Sept. 10-14, 2022.
<https://cm.tts2022.org/virtual/lecture/707>

Purpose: Little is known about how to measure “success” of upper extremity (UE) vascularized composite allotransplantation (VCA) given its relative novelty and low frequency. While providers define UE VCA “success” as survival, functional, and quality-of-life outcomes, patients’ definitions have been little examined. Our study assessed patients’ definitions of transplant “success”.

Methods: We conducted focus groups among people with acquired UE amputations and UE VCA candidates, participants, and recipients at two sites to assess transplant “success.” Focus group transcriptions were analyzed using thematic analysis. A post-focus group survey assessed demographics.

Results: We conducted 6 focus groups among 26 participants (90% participation rate), including people with acquired UE amputations (n=20), UE VCA candidates who did not pursue it (n=3), a waitlisted UE VCA participant (n=1), and UE VCA recipients (n=2). Most were male (62%), white (85%), and had a unilateral amputation (77%), with a mean age of 49. Transplant “success” was defined in 5 ways: 1) The surgical attachment of the donor limb without complication: “an arm has been transplanted onto your body without rejection”; 2) Restoring function and sensation in the transplanted limb to restore activities: “I can bring a glass to my lips and drink. I can open a door. Turn a doorknob. I can drive my car”; 3) Ensuring the transplant process (e.g., surgery, hand therapy, immunosuppression) ran smoothly: “you’re in rehab and moving forward and making the process work”; 4) Gaining greater function and quality of life with UE VCA compared to no treatment or prosthetics: “How many different tasks can I do with my new hand versus residuals?”; and 5) Ensuring that functional and quality-of-life benefits outweighed the risks (e.g., recovery, side effects, financial): “The addition of the functionality would have to outweigh... whatever other negatives there might be, like recovery time, and what the side effects of the anti-rejection drugs would be”.

Conclusions: Our findings suggest that people with UE amputations define transplant “success” based on desired treatment processes and outcomes, comparing UE VCA to alternatives. Patient-provider discussion about definitions of transplant “success” may help patients determine if UE VCA is the right treatment for them.

Appendix 6.

- Levan M. Psychosocial Factors in the Decision Making and Informed Consent Process for Upper Extremity VCA. Paper (Invited) presented at American Transplant Congress meeting in Boston, MA, June 7, 2022.

Appendix 7.

- Downey M, Kuramitsu B, Gacki-Smith J, Vanterpool K, Luken M, Nordstrom M, Riggelman T, Cooney C, Levan M, Tintle S, Brandacher G, Jensen S, Dumanian G, **Gordon E**. Patient Definitions of Transplant “Success” of Upper Extremity VCA. Poster presented at the American Transplant Congress (ATC) meeting, Boston, MA, June 5. 2022.

Purpose: Little is known about how to measure “success” of upper extremity (UE) vascularized composite allotransplantation (VCA) given its relative novelty and low frequency. While providers define UE VCA “success” as survival, functional, and quality-of-life outcomes, patients’ definitions have been little examined. Our study assessed patients’ definitions of transplant “success.”

Methods: We conducted focus groups among people with acquired UE amputations and UE VCA candidates, participants, and recipients at two sites to assess transplant “success.” Focus group transcriptions were analyzed using thematic analysis. A post-focus group survey assessed demographics.

Results: We conducted 6 focus groups among 26 participants (90% participation rate), including people with acquired UE amputations (n=20), UE VCA candidates who did not pursue it (n=3), a waitlisted UE VCA participant (n=1), and UE VCA recipients (n=2). Most were male (62%), white (85%), and had a unilateral amputation (77%), with a mean age of 49. Transplant “success” was defined in 5 ways: 1) The surgical attachment of the donor limb without complication: “an arm has been transplanted onto your body without rejection”; 2) Restoring function and sensation in the transplanted limb to restore activities: “I can bring a glass to my lips and drink. I can open a door. Turn a doorknob. I can drive my car”; 3) Ensuring the transplant process (e.g., surgery, hand therapy, immunosuppression) ran smoothly: “you’re in rehab and moving forward and making the process work”; 4) Gaining greater function and quality of life with UE VCA compared to no treatment or prosthetics: “How many different tasks can I do with my new hand *versus* residuals?”; and 5) Ensuring that functional and quality-of-life benefits outweighed the risks (e.g., recovery, side effects, financial): “The addition of the functionality would have to outweigh... whatever other negatives there might be, like recovery time, and what the side effects of the anti-rejection drugs would be”.

Conclusions: Our findings suggest that people with UE amputations define transplant “success” based on desired treatment processes and outcomes, comparing UE VCA to alternatives. Patient-provider discussion about definitions of transplant “success” may help patients determine if UE VCA is the right treatment for them.

Appendix 8.

- Hewitt M, Riggleman T, Nordstrom M, Dodd LD, Kuramitsu B, Gacki-Smith J, Vanterpool K, Downey M, Cooney C, Dumanian G, Jensen S, Tintle S, Brandacher G, Levan M, **Gordon E.** Awareness and Perceptions of Vascularized Composite Allotransplantation (VCA) Among Military Personnel with Upper Extremity Amputations: A Qualitative Approach. Poster presented at the Association of Military Surgeons of the United States (AMSUS), February 22, 2022.

Introduction: Upper extremity (UE) vascularized composite allotransplantation (VCA) is a relatively new procedure with >130 performed worldwide.¹ To date, UE VCA has shown promising results: restoring motor function, touch, and improved quality of life to recipients.² However, UE VCA poses several risks including immunosuppressant side effects, rejection, and long-term rehabilitation.² From 2001-2017, US service members sustained a total of 302 upper limb amputations.³ Therefore, it is important for military personnel to understand the UE VCA procedure, risks, and potential benefits as an option for restoring their quality of life.

Methods: We conducted qualitative interviews with Veterans with acquired UE amputations to assess their awareness and perceptions of VCA. All participants were receiving rehabilitation and treatment services at Walter Reed National Military Medical Center (WRNMMC).

Results: Four Veterans participated (100% participation rate). Participants were male (100%), white (75%), and Hispanic (50%). All participants had unilateral, above elbow amputations, and an average of 12 years since their amputation. All had heard of UE VCA. One individual had never discussed UE VCA with a provider, and had only heard about it through media resources (Internet, online article, etc.). The remaining three individuals all had conversations, of varying degree and depth, with providers in regard to UE VCA. The three individuals who spoke with providers were offered VCA, but expressed disinterest in pursuing it. No participant knew of others seeking UE VCA at the time of the interview. All participants perceived UE VCA as providing potentially better control over the UE than prosthetics could provide. The perceived benefits of UE VCA included the potential for two-handed activities and that fine motor skills would improve after UE VCA.

Conclusion: Our preliminary findings suggest that some US service members were aware of UE VCA. Clinicians seem to be an important resource for information. Next steps in this study will incorporate interview findings in conjunction with findings from Northwestern University and Johns Hopkins University in order to create educational materials including a website, videos, and a question prompt sheet.

Appendix 9.

- Kuramitsu B, Berumen C, Ferzola A, Sung H, Scarton D, McHugh T, Schultheis A, Riggleman T, Taylor J, Cooney C, Henderson M, Tintle S, Brandacher G, **Gordon EJ**. Patients' Psychosocial Perceptions, Information Needs, and Decision Making about Upper Extremity VCA. Paper accepted for a 5-minute Podium Presentation at the American Society for Reconstructive Transplantation Meeting in Bethesda, MD. Hybrid meeting. November 18, 2021.

Background: Little is known about the informed consent process for upper extremity (UE) Vascularized Composite Allotransplantation (VCA). Consequently, the amount and type of information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed, under-prepared, and feeling unduly pressured when considering this option. This study examines the decision-making process, psychosocial concerns, and information needs about UE VCA among people with UE amputations.

Methods: We conducted cognitive and in-depth interviews among people with UE amputations at one academic medical center and one rehabilitation clinic. Interviews focused on psychosocial factors affecting decision making for UE VCA, information needs about UE VCA, and perceptions of undue influence to pursue UE VCA. Thematic analysis was used to analyze qualitative data.

Results: Eight individuals participated (50% rate). Most were male (75%), had a mean age of 48.5 years. Most participants had a unilateral transradial amputation (62.5%) at a mean of 5 years prior. Psychosocial factors influencing decision making about UE VCA included: having the "right mindset," concerns about immunosuppressants, and maintaining support of caregivers. Most participants reported the best time to be informed about UE VCA is near the time of amputation, i.e., before the scheduled surgery (n=4), or within the first couple weeks or months thereafter (n=7), because they would be less receptive to it after adapting to their amputation. Participants desired information about the process of getting an UE VCA, expectations for functionality and recovery, and recipient experiences of getting an UE VCA. Most unilateral participants believed that people with bilateral amputations should be prioritized in patient selection for UE VCA, whereas bilateral participants did not believe unilateral versus bilateral should matter. While participants reported no undue influence to pursue UE VCA, some identified the need for a job, unavailable prosthetic device, and case worker or family member enthusiasm as potentially exerting undue influence on them.

Discussion and Conclusion: Preliminary findings suggest that people with UE amputations have limited knowledge about UE VCA. Addressing patients' information needs and psychosocial concerns may enhance decision-making and informed consent.

Appendix 10.

- **Gordon EJ**, Kuramitsu B, Gacki-Smith J, Ferzola A, Vanterpool K, Kunkle C, Hewitt M, Schultheis A, Riggleman T, Taylor J, Cooney C, Tintle S, Brandacher G, Levan M. Psychosocial and Ethical Factors Affecting Patients' Decision Making about Upper Extremity Vascularized Composite Allotransplantation. Paper accepted for oral presentation at Tissue Engineering and Regenerative Medicine International Society virtual World Congress in Maastricht, The Netherlands, November 17, 2021.

Background

The informed consent process for upper extremity (UE) Vascularized Composite Allotransplantation (VCA) has yet to be standardized. Consequently, the information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed and under-prepared for decision making about UE VCA. This study examined decision making and psychosocial factors affecting decisions about UE VCA among people with UE amputations.

Methods

We conducted in-depth interviews among people with acquired UE amputations. Open-ended questions assessed psychosocial factors informing decision making about UE VCA. Thematic analysis was used to analyze qualitative data.

Results

To date, 12 people completed in-depth interviews (75% participation rate). Most were male (71%) and had a mean age of 49 years. Most had a unilateral amputation (75%) and had undergone amputation a mean of 8 years earlier. Forty-two percent of participants were 'completely' or 'a lot' willing to pursue VCA. Psychosocial factors influencing decisions to pursue VCA included: expecting an increase in social and physical confidence; seeking independence with activities of daily living; enabling more active involvement as a parent; family or friend enthusiasm; and prosthetic device problems. Psychosocial factors influencing decision making not to pursue VCA included: feeling mentally unprepared for a transplant; having already adapted to life without upper limb(s); concerns about the long-term commitment to taking immunosuppressants; discouragement from family or friends; concerns about the rigorous rehabilitation process; concerns about receiving a graft that appears mismatched in size or skin color; concerns that the transplant may be unsuccessful; concerns about health or limb function becoming "worse off" from the UE VCA; and concerns about logistical barriers to accessing transplant and rehabilitation services.

Conclusion

Preliminary findings suggest that people with UE amputations hold concerns that diminish their enthusiasm for UE VCA. Addressing patients' psychosocial concerns may foster informed decision making about UE VCA.