

Informed Decision Making and Patient Perceptions of VCA

Elisa J. Gordon, PhD, MPH

National Academies of Sciences,
Engineering and Medicine

April 17, 2024



VANDERBILT
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Disclosures

- Department of Defense (RT180041 – Gordon EJ, Initiating Investigator)
- I (and my coauthors) have nothing to disclose.
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Background

- Upper extremity (UE) Vascularized Composite Allotransplantation (VCA) offers a unique restorative treatment option for patients with devastating tissue defects who otherwise do not have conventional reconstructive options available. VCA aims to restore form and function (i.e., motor and mobility function, and sensation of the hand/arm).
- UE transplantation raises multiple ethical issues, particularly, about informed consent, patient selection, and definitions of VCA success.
- Examining the informed consent and decision-making process for UE VCA is important for ensuring patient self-determination.
- Ensuring that the clinical evaluation process accounts for patients' perceptions is essential for making UE VCA treatment patient-centered and increasing patient success.

Study Aims

Aim 1

- **Qualitatively assess the decision making and informed consent processes for UE VCA**

Aim 2

- **Develop prototype educational materials that provide patient-centered information to enhance understanding and reduce undue influence to pursue upper extremity VCA, and that are sensitive to different levels of dysfunction, residual limbs, health literacy levels, and different racial/ethnic groups.**
 - Video, website, and question prompt sheet

Aim 3

- **Formatively evaluate the educational materials through usability testing on amputees' and candidates' understanding, satisfaction, and usability**

Methods

- **Multidisciplinary Research Team:** VCA transplant surgeons, hand surgeons, occupational therapists, social scientists, ethicists
- **Design:** Cross-sectional, sequential mixed-methods study
- **Setting:**
 - Northwestern University, Chicago, IL
 - Johns Hopkins University, Baltimore, MD → NYU, New York, NY
 - Walter Reed National Military Medical Center, Bethesda, MD
- **Participants:** Adults (18+ yrs) with UE amputations, UE VCA Candidates/Participants, and UE VCA Recipients
- **Data Collection:** In-depth telephone interviews, semi-structured interviews, focus groups, usability testing interviews
- **IRB approval, HRPO approval, verbal consent**

Methods

Table 1. Study Participants Across Data Collection Activities

	N (%)
Cognitive Interviews	5 (3.0)
In-Depth Interviews	50 (29.6)
2 Online Focus Groups	7 (4.1)
9 Telephone Focus Groups	37 (21.9)
Semi-Structured Interviews	56 (33.1)
Usability Testing Interviews	14 (8.3)
TOTAL	169

Willingness to Receive an UE Transplant, N=46				
Not At All Willing %	A Little Willing %	Somewhat Willing %	A Lot Willing %	Completely Willing %
17.4	21.7	26.1	10.9	23.9
*Included: people with UE amputations, and UE VCA candidates and participants (n=46). Excluded n=4 UE recipients.				

Results: Decision-Making about Pursuing UE VCA: **Pro**

- Dissatisfaction with current treatment options
- Desire to regain hand functioning
- Desire to be made “whole” or “full” again
- Improve appearance & social integration
- Engage in family interactions “hold kids”
- Regain independence

“Just the ability to do those things I talked about earlier, because I don't like being a burden, and it makes me feel bad about myself when I have to ask all the time for people to help me, and if I could be more independent that would be awesome.” (J013-A)

Results: Decision-Making about Pursuing UE VCA: **Con**

- Concerns about jeopardizing current health and becoming “worse off”
- Psychosocial factors regarding:
 - Adapted to life without UE
 - Commitment to rehabilitation
 - Logistical burdens
 - Interrupting family and work life
 - Need more research studies

“Just the antirejection meds and the possibility of it getting rejected and causing medical issues in my arm that I currently don’t have.”

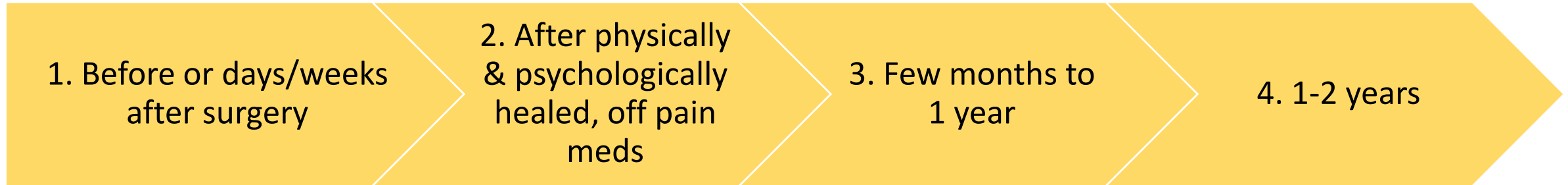
(WR012-A)

Results: Voluntariness (in-depth interviews n=50)

- **18%** “a little”, “somewhat”, “a lot”, or “completely” pressured to get an UE VCA:
 - Healthcare provider encouraged UE VCA despite one individual’s reticence
- Recognized sources of potential pressure to pursue UE VCA:
 - **Family pressure** so that individuals look “normal” again, become independent
 - **Societal pressures** to fit in, maintain a body image with 2 upper limbs, restore a sense of wholeness, and avoid being labeled as disabled
 - **Cultural pressure** Latino community being perceived as less of a man due to missing limb
 - **Medical community pressure** to advance VCA field, ↑ # of UE VCAs performed

Results: Timing of Information Disclosure

Early disclosure



“As soon as possible, as soon as they’re able to think clearly and right.”

Results: Format of Information Disclosure

(n=10/50 interviews with UE VCA recipients/participants/candidates)

- Information commonly provided as pamphlets or verbally with follow-up emails
- Disliked being provided **paper packets**:
 - difficulty “turning pages”
 - information being “overwhelming”
- Suggested providing information:
 - “digital form” i.e., a website
 - “little sections” to be digestible

Results: Perception of Alternatives

(n=8/10 interviews with UE VCA recipients/participants/candidates)

- Sentiment of **no acceptable treatment options**
- For some, prosthetics were not considered a legitimate option:
 - Poor functionality
 - Lack of fine motor skills and sensation
 - High financial cost

UE VCA Information Needs by Major Theme and Subtheme
Broad and Contextual Information about UE VCA
<ul style="list-style-type: none"> • Everything about it • UE VCA history and current state
Pre-UE VCA
<ul style="list-style-type: none"> • Eligibility, waiting list, and evaluation process • Donor and matching process • Transplant team and transplant clinic
Risks of UE VCA
<ul style="list-style-type: none"> • Risks in general • Effect on life and lifespan • Infection and Rejection
UE VCA Procedure
<ul style="list-style-type: none"> • Surgical procedure • Hospital stay and recovery period
Post- UE VCA
Living with a UE VCA
<ul style="list-style-type: none"> • Rehabilitation • Medication and medication side effects • Lifestyle changes
Outcomes of UE VCA
<ul style="list-style-type: none"> • Functionality, sensation, and other outcomes • Success rate • Experiences of UE VCA recipients

Gordon EJ, et al. Ethical and Psychosocial Factors in the Decision-Making and Informed Consent Process for Upper Extremity Vascularized Composite Allotransplantation. Transplant Direct 2023;9(8):e1515.

Gacki-Smith J, et al. Information needs and development of a question prompt sheet for upper extremity vascularized composite allotransplantation. Front Psychol: Special Issue on VCA 2022;13:960373.

35-Item UE VCA-QPS - Sample Questions

TOPICS AND QUESTIONS

The Hand/Arm Transplant Field
1. What is the success rate of upper limb transplantation?
2. How many upper limb transplants have been performed in the US, and how many are still working?
Eligibility and Evaluation Process
3. How do I find out if I am eligible, and what makes someone a good candidate?
4. What are the steps in the evaluation process?
5. How long does it take to get evaluated and put on the waitlist?
Donor-Recipient Matching and Appearance of Hand/Arm Transplant
6. How do doctors decide if the donor is a good match?
7. How do we choose the size, skin tone, gender, etc. of the donor hand(s)/arm(s)?
8. How long will I wait for a donor?
9. How will my new hand/arm look different from the rest of my body?

Gacki-Smith J, Kuramitsu BR, Downey M, Vanterpool KB, Nordstrom MJ, Luken M, Riggelman 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. Front Psychol: Special Issue on VCA 2022;13:960373.

This educational website was developed for all people with upper limb amputations based on a collaboration between Northwestern University, Johns Hopkins University, and Walter Reed National Military Medical Center, funded by the US Department of Defense.



Terrance White, with unilateral, below-elbow limb loss, is pursuing hand/arm transplantation.

Inform Yourself About Hand/Arm Transplantation

Learn More



Ms. Carter, with bilateral, below-elbow limb loss (11 years after amputation), talks about her concerns about taking anti-rejection medication.

Vanterpool KB, Gacki-Smith J, Kuramitsu B, Downey M, Nordstrom MJ, Luken M, Riggleman T, Fichter S, Altema W, Brucker JB, Cooney CM, Dumanian G, Jensen S, Levan M, Tintle SM, Brandacher G, Gordon EJ. Within Reach -- A Patient-Centered Website to Foster Informed Decision Making about Upper Extremity Vascularized Composite Allotransplantation: Development and Usability Testing. JMIR Form Res. 2023;7:e44144.

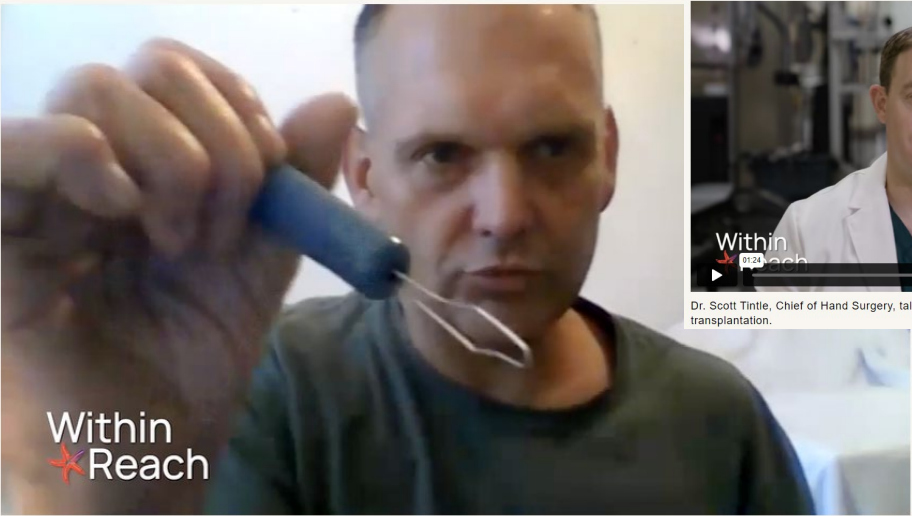
Videos of Health Care Professionals



Angie Duckworth, Transplant Social Worker, talks about the risk of re-amputation.



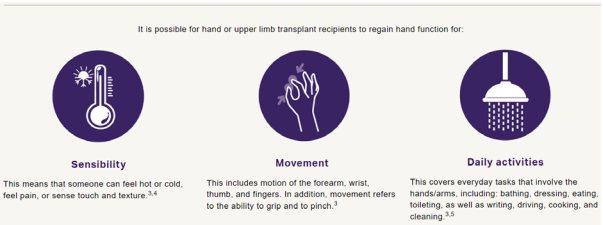
Jaimie Shores, Hand/Arm Transplant Surgeon, explains the purpose of hand/arm transplantation.



Mr. Pollock, a bilateral, upper limb transplant recipient (11 ½ years after transplantation), demonstrates and explains how his hands function.



Dr. Scott Tintle, Chief of Hand Surgery, talks about successful outcomes of hand/arm transplantation.




www.WithinReach.info

Patient preferences of patient selection criteria for upper extremity vascularized composite allotransplantation: A qualitative study

SAGE Open Medicine
Volume 11: 1–11
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DOI: 10.1177/20503121231181236
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Karen B. Vanterpool¹, Jessica Gacki-Smith², Max C. Downey¹, Michelle Nordstrom³, Michelle Luken^{3,4}, Tiffany Riggleman³, Shannon Fichter^{3,4}, Withney Altema^{3,4}, Sally E. Jensen⁵, Gregory A. Dumanian⁵, Carisa M. Cooney⁶, Macey L. Levan¹, Scott Tintle³, Gerald Brandacher⁶ and Elisa J. Gordon⁷ 

Preferred criteria for selection of UE VCA candidates:

- Younger age
- Good physical health
- Mental stability
- Willing to “put in the work”
- Specific amputation characteristics (e.g., unilateral limb loss)
- Social support

Patient definitions of transplant success in upper extremity vascularized composite allotransplantation: A mixed-methods study

SAGE Open Medicine
Volume 11: 1–11
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DOI: 10.1177/20503121231184677
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Max C Downey¹, Jessica Gacki-Smith², Brianna Kuramitsu², Karen B Vanterpool¹, Michelle Nordstrom³, Michelle Luken^{3,4}, Whitney Langlee⁵, Tiffany Riggleman^{3,4}, Shannon Fichter^{3,4}, Withney Altema^{3,4}, Sally E Jensen⁶, Gregory A Dumanian⁶, Carisa M Cooney⁷, Macey L Levan^{1,8}, Scott Tintle³, Gerald Brandacher⁷ and Elisa J Gordon⁹

- Patients defined UE VCA success as:
 - Restoring function and sensation to enable new activities
 - Accepting the transplanted limb into one's identity and appearance
 - Not having transplant rejection
 - Attaining greater quality of life compared to prosthetics
 - Ensuring benefits outweigh risks

Discussion

- People with UE amputations desired extensive information about UE VCA, primarily on risks, the rehabilitation process, and functional outcomes
- Our UE VCA-QPS can be used by people with UE amputations and UE VCA programs to:
 - Address information needs, foster patient-provider communication about UE VCA, facilitate patient-centered care, and enhance informed decision-making, and empower people with UE amputations
- Future research should assess the impact of the UE VCA-QPS on patient-provider communication and informed decision-making about UE VCA

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. Information needs and development of a question prompt sheet for upper extremity vascularized composite allotransplantation: A mixed methods study. Front Psychol. 2022 Sep 5;13:960373.

Recommendations

- **Improve Patient Education & Informed Consent Process**
- **Clinical Practice**
- **Inform OPTN Policy**

Future Research

Evaluate the impact of Within Reach and QPS on patients' informed treatment decision making about UE VCA (e.g., decisional conflict, willingness, satisfaction, etc.)

Research Team

Northwestern University

Elisa J. Gordon, PhD, MPH

Greg Dumanian, MD

Sally Jensen, PhD

Jessica Gacki-Smith, MPH

Brianna Kuramitsu, MSW

Johns Hopkins University

Gerald Brandacher, MD

Carisa Cooney, MPH, CCRP

New York University

Macey Levan, JD, PhD

Karen Vanterpool, PhD, MPH

Max Downey, BS

Walter Reed National Military Medical Center

Scott Tintle, MD

Michelle Nordstrom, MS, OTR/L

Michelle Luken, DSc, OTR/L, BCMH, CSCS

Tiffany Riggleman, COTA/L

Shannon Fichter, MS

Withney Altema, MHS

Derek Soloway, MHA, LAT, ATC

Delaney Dodd, BS

Thank You.

Questions?



Elisa.Gordon@VUMC.org



708-646-7973