OPTN Vascularized Composite Allograft (VCA) Committee
Meeting Summary
April 24, 2023
Chicago, IL, O'Hare Hilton

Sandra Amaral, MD, MHS, Chair

Vijay Gorantla, MD, Ph.D., Vice-Chair

Introduction

The Vascularized Composite Allograft Committee ("Committee") met in Chicago, Illinois on 04/24/2023 to discuss the following agenda items:

1. Breakout Group Drafting
2. Breakout Group Report Out
3. Penile Transplantation versus Conventional Reconstruction – Decisions and Dilemmas
4. New Projects

The following is a summary of the Committee's discussions.

1. Breakout Group Drafting

The Committee broke out into groups to discuss and draft segments of the guidance document.

Summary of discussion:

There was no discussion surrounding this item.

Next steps:

Members will report out on the proposed edits to the guidance document.

2. Breakout Group Report Out

Data summary:

Members provided an update on their progress in editing sections of the guidance document. This report out summarized the work performed collaboratively within each section's group over the past 1.5 hours.

Summary of discussion:

VCA Background

Members restructured the section by first defining what VCA meant as a term and what was included within the field. Next, early landmark VCA transplants were described, using their outcomes to share the benefit of VCA transplant. Each transplant with historical significance both inside and outside of the United States was also outlined based on its impact to the field.

The guidance document then transitions to describe how VCA came to be underneath the OPTN purview and provides a link to covered VCAs.

A member proposed adding abdominal wall to the list of landmark VCA transplants. A second member asked if the OPTN had purview over abdominal wall transplants; the Chair replied that it was still technically up in the air, but most organizations informed the OPTN when it was performed. It was suggested that the document include a line suggesting programs become familiar with what VCA are covered by the OPTN. The Vice-Chair supported this suggestion, noting that this would help the Committee be familiar with what current practices are occurring in the field.

Donor ID

Members changed the title from "Donor Identification" to "Considerations for the Identification and Initial Evaluation of Potential VCA Donors". This was done to help draw parallels between the identification of solid organ donors and the identification of VCA donors. Then, the specific requirements for each VCA type were outlined in a table (e.g., reproductive history for uterus donors).

For any living VCA donors, VCA living donors would need to follow current OPTN living donor policies.

The Vice-Chair asked if there was any guidance on crossmatching donors and recipients, specifically wondering if programs were transplanting based on virtual crossmatch results. A member noted that most VCA transplants were performed off physical crossmatches, but some programs had transplanted based on virtual results alone.

A member suggested including example questions that may not be as commonly thought of, such as hypospadias for penile transplant, or surgical complications for penile or uterine transplant.

Recovery and Post-Recovery

Members of this group felt that this section should be very overarching, given the nature of a guidance document. They noted that there may be special considerations for VCA transplants which may also require moving the donor to a specialized recovery center.

This section also addresses how to approach multiple VCA recoveries at the same time.

A member noted that this section is intended to spark conversations between OPOs and transplant programs on how VCA recovery should be pursued within their area.

The Chair asked if the section would include a note on the difference between living uterus recovery and deceased donor VCA recovery. A member replied that it will.

The Vice-Chair asked if the section would address when consent for VCA recovery would be sought, given the challenges of not overwhelming families or potentially losing consent for solid organ donation. The member responded that the section included grief counseling, the resources available at recovery centers, and some notes on best practices for approaching VCA donation. However, some of the information, they felt, could be placed in the donor identification section.

Media/PR

A member noted that the goal for this group was to be less prescriptive about timelines and requirements for sharing information. The group felt that this conversation should be predominantly driven by the donor family's and the recipient's willingness to share, and this conversation needs to occur proactively.

Family Considerations

This section was designed to allow for OPOs to anticipate more of the questions and reactions from donor families.

Members felt that there should be an increase in community education. This would hopefully nurture a connection between a donor family and a transplant hospital to increase the likelihood of VCA transplant. They suggested having a HIPAA-compliant way to share candidate stories with their community such that individuals could understand who their donation was going towards.

Additionally, the use of terms such as "wet run" need to be translated into terms that the public can understand and explained in such a way that a donor family member understands this VCA will not be used as a transplant but will be furthering the field.

A member asked how the section aims to address candidates who have experienced a tragic accident or a suicide attempt and do not wish to share their story with the donor family. Another member replied that it would entirely be up to the recipient how much or how little they would be willing to share.

Next steps:

Staff will review the drafts with Committee Leadership and finalize them into a draft of the guidance document.

3. Penile Transplantation versus Conventional Reconstruction – Decisions and Dilemmas

The Committee heard a presentation from a member on their experience with penile transplantation.

Data summary:

The member's program performed their first penile transplant at their institution. The background, intraoperative procedure, outcome, and next steps were presented on.

The presentation addressed three main areas:

- Current limitations of conventional reconstruction
- Why consider penile transplant?
- Potential future indications for penile transplant?

When considering penile reconstructive surgery, there are four goals:

- An aesthetically acceptable result
- Creation of a neo-urethra that allows for voiding while standing
- A return of tactile and erogenous sensation
- The ability to have successful intercourse with an implant

Current complications for reconstructive surgery are:

- High rates of urethral strictures and fistulas
- No inherent erectile function
- High rate of inherent complications
- Lack of donor tissue

Summary of discussion:

A member asked what the age limit for their IRB agreement was. The presenter replied that their age limit for consideration of penile transplant was 18-65. They also asked if standard reconstruction was being performed on children under the age of 18, to which the presenter responded that they were. The presenter noted that, in the future, age should not be the absolute limiter; if there were candidates that were a good match, who had a good support system, and met all criteria for transplantation, they may consider them. At present, they would be placed in a holding pattern for consideration once they turn

18. The presenter noted that they had hesitation transplanting candidates within the younger age range because it was likely they would need a second graft when they were older.

Another member asked about the outcome for the penis transplants performed in South Africa. The presenter noted that the program has been very open about their outcomes, with one being lost due to sexually transmitted infection.

It was asked if the field is being too conservative by limiting themselves to older candidates. In the member's opinion, the candidates who may most benefit from a penis transplant would be the younger candidates, such as 18-year-olds. The presenter agreed but added that there could be challenges in adequately conveying the risks and outlook to these candidates.

The past-Chair asked if there were any consideration of what the graft life expectancy for penis transplants was. The presenter responded that it was too soon to be able to predict it. They also asked how the need for blood flow was assessed, and whether there was any way to determine if the approach taken was overcautious. The presenter noted that, in their dye studies, 85% of grafts that did not include the pudendal artery did not have adequate perfusion to the shaft skin. However, they pointed out that the transplant performed at Massachusetts General Hospital did not use the additional artery and did not lose shaft skin, so they agreed that they may be overcautious.

The Chair asked what the rehabilitation process for penile grafts was. The presenter replied that there was no rehabilitation required beyond conventional and routine usage. They also inquired if there were urologic considerations that were needed for children with bladder exstrophy. The presenter responded that for children that cannot urinate through their penis, it is very difficult if not impossible to reattach the urethra through the penis. However, for children that do have a conventional urethra extending to the phallus area, it is much easier to incorporate into the reconstruction.

The Vice-Chair inquired what type of monitoring would be developed for these transplants and whether there was any innovation being done in assessing rejection given the multifaceted areas in which it could occur. The presenter agreed that it was certainly a complicated area to monitor but added that they had had great compliance from the recipient in monitoring for rejection. They noted that likelihood of compliance was a factor considered when evaluating VCA candidates for this type of transplant. In addition, their program was working to develop a non-invasive urine test to assess rejection, but this was not functional at present.

The Vice-Chair also asked if the only exit strategy for conventional reconstructive grafts and transplants was an abdominal flap. The presenter replied that it was, adding that, especially for gender affirming surgery, the vascular demands of a transplant would not be met in the event a reconstruction failed.

A member of the OPO who had participated in this transplant lauded the communication between the transplant program and the OPO. Given the need for abdominal wall when recovering the graft, the OPO prepared several aesthetic prostheses in advance for the donor's funeral. The member felt that this had been very well planned out and communicated prior to the operation.

Staff asked how this coordination had taken place. The member replied that their OPO knew of the specific needs for this candidate because they had been updated by the transplant hospital. This spoke to the need for early and clear communication of candidate-specific needs; it allowed for early evaluation of the donor for VCA transplant.

<u>Next steps:</u>

Staff thanked the member for their presentation.

4. New Projects

The Committee reviewed their existing project ideas and offered suggestions for new ones.

Summary of discussion:

The Chair asked if there were any project ideas surrounding penis transplant. Staff replied that there was not. They also asked if a brief description of project types could be given, which staff provided.

The past-Chair wondered if project ideas could be complied once VCA was incorporated into the OPTN Computer System. Staff agreed this would be a good approach, but the Committee should have a project to focus on prior to VCA's implementation in the OPTN Computer System.

A member asked what was being done to prepare members for the implementation of VCA in the OPTN Computer System. Staff responded that there were multiple methods of communication being distributed to OPTN members; these included targeted letters, educational courses, and webinars to prepare for its implementation. A second member suggested including specific recommendations such as ensuring programs had access to the OPTN Donor Data and Matching System.

It was suggested that a data field be included to track whether VCA donation was considered for each donor. Multiple members supported this project idea. The Vice-Chair asked if there was a way to track why each donor was not considered for VCA donation. Staff replied that this could result in incomplete data collection, given that only donors that are approved for other organs but not VCA would be tracked in this manner.

A member suggested a guidance document on improving VCA donation rates from donor groups that are traditionally underrepresented. The past-Chair endorsed this suggestion, noting that VCA among all other organs tends to require very specific donor and recipient matching; this necessitates donor representation from all races and ethnicities.

Next steps:

Staff will compile the list of project ideas for the Committee.

Upcoming Meeting

- May 24, 2023

Attendance

- **Committee Members**
  - Sandra Amaral
  - Vijay Gorantla
  - Bo Pomahac
  - Liza Johannesson
  - Anji Wall
  - Debbi McRann
  - Lawrence Gottlieb
  - Christina Kaufmann
  - Elizabeth Shipman
  - Donald Rickleman
  - Stefan Tullius
  - Max Hendrix
  - Debra Priebe
  - Lori Ewoldt
  - Amir Dorafschar
  - Brian Berthiaume
  - Rick Redett
  - Amanda Gruendell
  - Charlie Thomas
  - Bruce Gelb
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kelley Poff
  - Isaac Hager
  - Lauren Mauk
  - Debra Vicars
  - Jesse Howell
  - Kristina Hogan
  - Catherine Parton
  - Krissy Laurie
  - Laura Schmitt
  - Roger Brown
  - Tina Rhoades