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Brian M. Shepard
Executive Director & CEO

Memorandum

To: Transplant Program Administrators
Transplant Program Primary Surgeons and Physicians
OPO Executive Directors
OPO Medical Directors

From: James B. Alcorn, Esq., Director of Policy

Date: January 13, 2015

Re: Use of VCA Grafts to Reconstruct the Abdominal Wall

On July 3, 2014, the OPTN Final Rule (42 CFR part 121) was amended to add vascularized composite allografts (VCAs) as a covered human organ. Oversight of VCA recovery and transplantation has thus come under the auspices of the OPTN.

The OPTN Final Rule (42 CFR §121.2) outlines the criteria that must be met in order for an anatomical structure to be considered a VCA:

A vascularized composite allograft is defined as any body part that meets *ALL* nine of the following criteria and is not an otherwise described organ for transplantation (such as a kidney, heart, etc.):

1) that is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
2) containing multiple tissue types;
3) recovered from a human donor as an anatomical/structural unit;
4) transplanted into a human recipient as an anatomical/structural unit;
5) minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement);
6) for homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);

7) not combined with another article such as a device;
8) susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and
9) susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

In the clinical practice of Plastic and Reconstructive Surgery, vascularized composite tissue transfers in a single individual, such as free flap procedures, have been done for years and are part of standard practice. When such procedures are done between a donor and a recipient, the possibility of allograft rejection and the need for immunosuppressive medication results in these procedures being considered VCA transplants. Occasionally, such a VCA transplant may be done in conjunction with a traditional solid organ transplant as part of abdominal wall reconstruction. The VCA Committee was concerned that surgeons performing these types of procedures may be unaware of the regulatory changes or unaware that a VCA transplant program approval would be required before they perform such procedures going forward.

The Committee collaborated with colleagues at the Division of Transplantation at the Health Resources and Services Administration (HRSA) to clarify the use of VCAs from organ donors in the surgical repair of the abdominal wall. Any vascularized multiple tissue transfer (soft tissues and/or bone) used to reconstruct an abdominal wall should be considered a VCA. The most commonly used procedure that fits the VCA definition is an anterolateral thigh flap which includes fascia and muscle and requires a vascular anastomosis. The use of a posterior rectus sheath flap that consists of fascia only and is transplanted along with the liver does not require a separate vascular anastomosis and does not meet the VCA definition. Donor fascia, donor de-epithelialized skin, and AlloDerm are other materials used to reconstruct the abdominal wall, and not VCAs.

Additionally, any vascularized multiple tissue transfer between a donor and a recipient (soft tissues and/or bone) used to repair other structural defects in a recipient or transplanted to monitor rejection (e.g. vascularized composite transfer as sentinel graft) meets the criteria for a VCA organ. Tissues not requiring a vascular anastomosis (e.g., tendon, ligament, muscle, nerve, bone, other) do not meet the criteria for VCA.

Before a surgeon can use a vascularized composite allograft from a donor to reconstruct the abdominal wall or another structure, the hospital must have:

1) submitted the required application materials and received approval from the OPTN to operate a VCA transplant program
2) registered the patient in need of such a graft as a VCA transplant candidate with the OPTN

Transplant Hospitals

Please share this information with surgical colleagues at your institution. If you have questions about the application process for a VCA transplant program, please contact

Jacqueline O'Keefe, UNOS Assistant Director, Member Quality (804-782-4857 or jacqueline.okeefe@unos.org).

Approved VCA transplant programs needing assistance adding a VCA candidate to the waiting list can contact the UNOS Organ Center (800-292-9537 or vca@unos.org).

OPOs

OPOs must ensure that VCA grafts are only allocated to candidates on the OPTN VCA Candidate List. If any hospital requests a graft that meets all nine criteria for a VCA for use in other surgical procedures for a patient who is not on the OPTN VCA Candidate List, do not allocate a VCA to that patient.