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# Vascularized Composite Allografts Data and Data collection

**Ryutaro Hirose, MD**

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# Disclosures

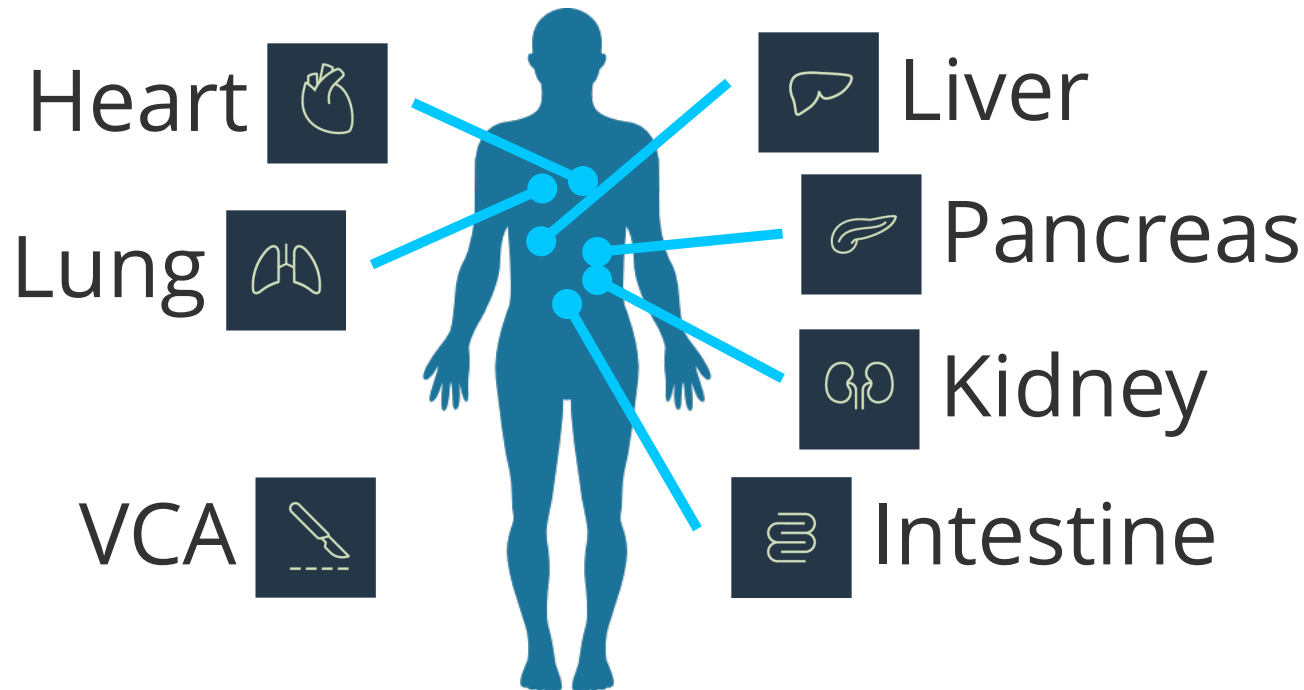
- I serve as the Chief of Transplant Surgery at University of Washington
- I personally perform adult and pediatric kidney, pancreas and liver transplants
- I also serve as Surgical Director of the SRTR\*
- I do not perform VCA transplants personally, so NOT a content expert in the conduct of these particular operations
- I serve as Chair of the AASLD Surgery and Liver Transplant Committee
- I serve as Chair of the ASTS/ACS NSQIP Transplant Task Force
- I am Vice chair of the ASTS DEI Committee

\*This work was supported by HRSA Contract #75R60220C00011. The views expressed do not necessarily reflect the official policies of the U.S. Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

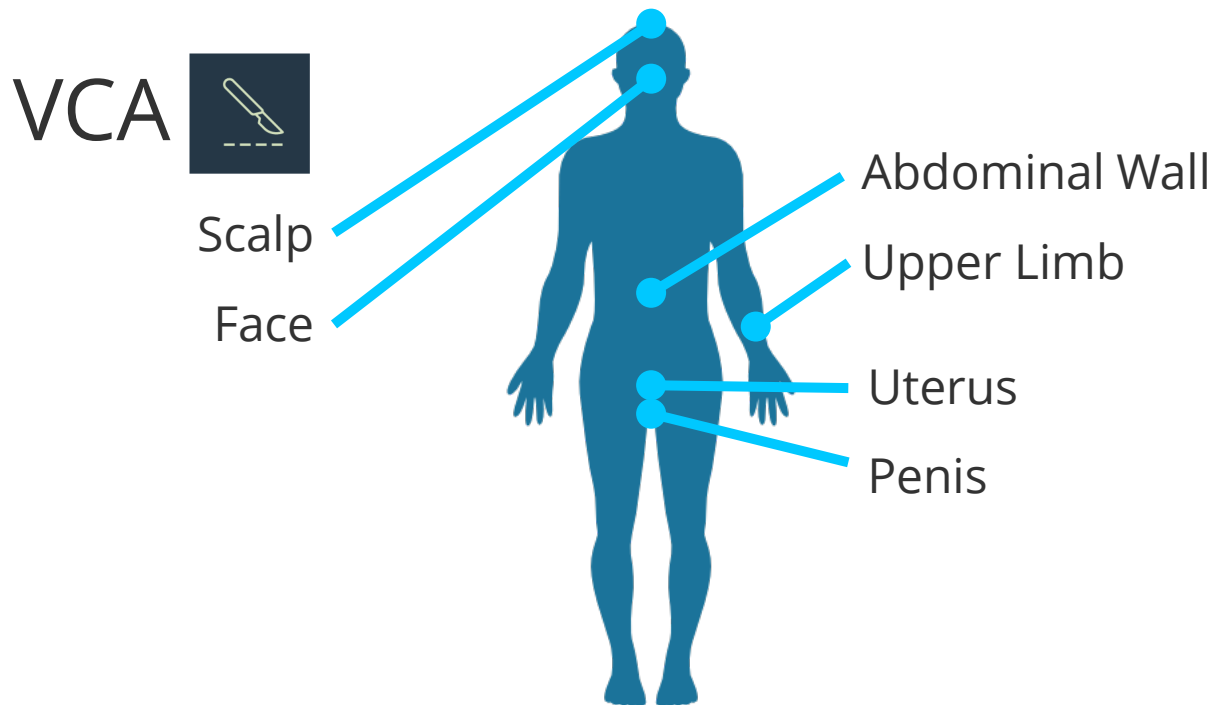
# What is a Vascularized Composite Allograft

Any body part that meets ALL nine criteria and is not otherwise described organ for transplantation, e.g, heart, lung, kidney, liver, pancreas, intestine →

# The Field of Solid Organ Transplantation:



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# VCA criteria

1. Vascularized - requires blood flow by surgical vascular anastomoses to function after transplant
2. Contains 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 – processing that does not alter the original relevant characteristics of the organ
6. For homologous use – replacement/supplementation of recipient's organ that performs the same basic functions in the recipient as in the donor
7. Not combined with another article (device)
8. Susceptible to ischemia
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase ID risk to recipient

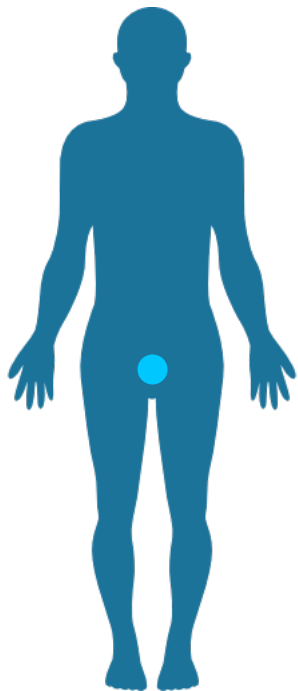
# OPTN Requirements – hospitals to perform VCA transplant and OPO allocation

Submit application materials, receive approval from OPTN to operate a VCA transplant program

Registered candidates in need of graft as a VCA transplant candidate

OPOs ensure that VCA grafts are only allocated to candidates registered on the VCA Candidate list.

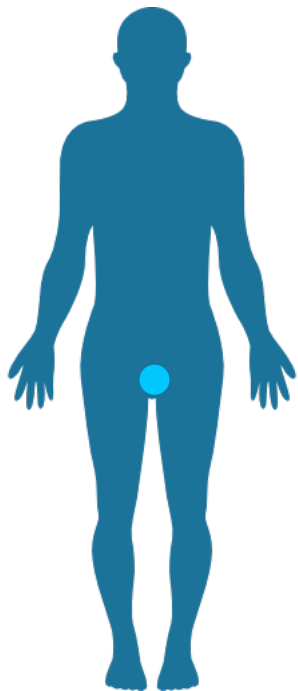
# VCA – UTERINE TRANSPLANTS



DONOR	2016	2017	2018	2019	2020	2021	2022	2023	TO DATE
ALL	6	4	7	12	2	2	5	3	41
Deceased Donor	1	3	1	6	1	0	4	1	17
Living Donor	5	1	6	6	1	2	1	2	24



# VCA – Penile transplant

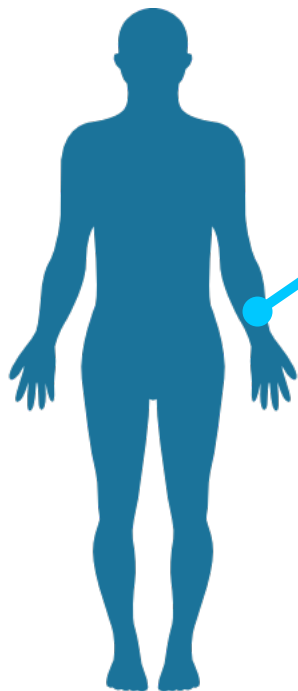


**TO DATE: 2**

2016: 1

2018: 1

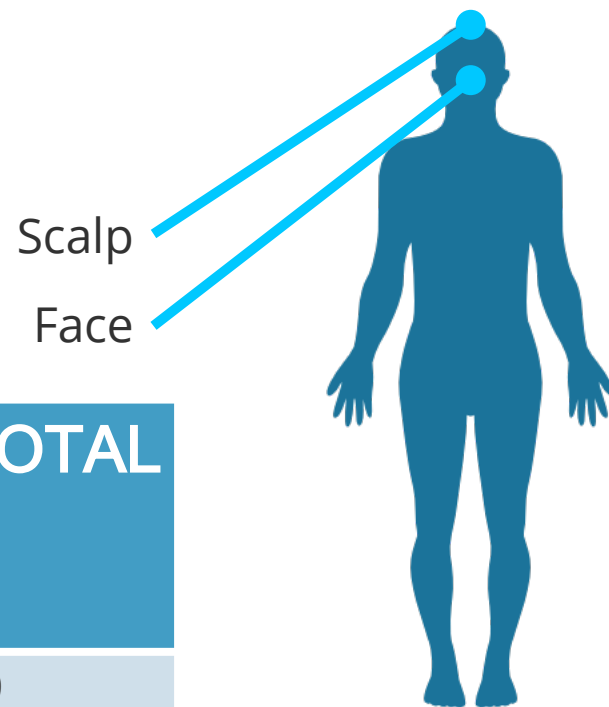
# VCA – Upper Limb (s)



Upper Limb

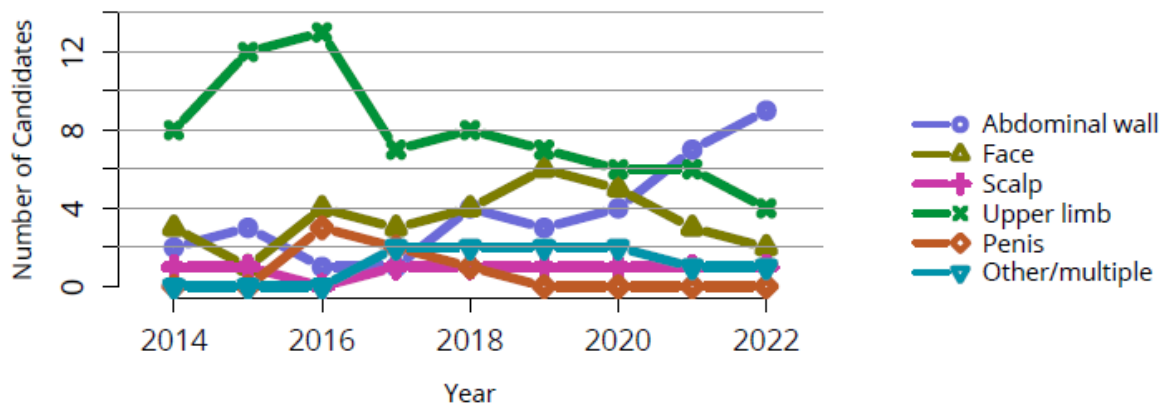
	1 9 9	2 0 1	2 0 6	2 0 8	2 0 9	2 0 0	2 0 1	2 0 2	2 0 3	2 0 4	2 0 5	2 0 6	2 0 7	2 0 8	2 0 9	2 0 0	2 0 1	2 0 2	2 0 3	TOTAL TO DATE
Unilateral	1	1	1	2	1	2	3	2	0	1	1	2	0	0	1	0	0	0	0	18
Bilateral	0	0	0	0	1	3	3	2	0	1	1	3	1	1	1	1	1	0	0	19
TOTAL	1	1	1	2	2	5	6	4	0	2	2	5	1	1	1	1	1	0	0	37

# VCA – Craniofacial



	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	TOTAL
Transplants	1	3	1	1	1	3	1	1	1	2	1	2	1	19

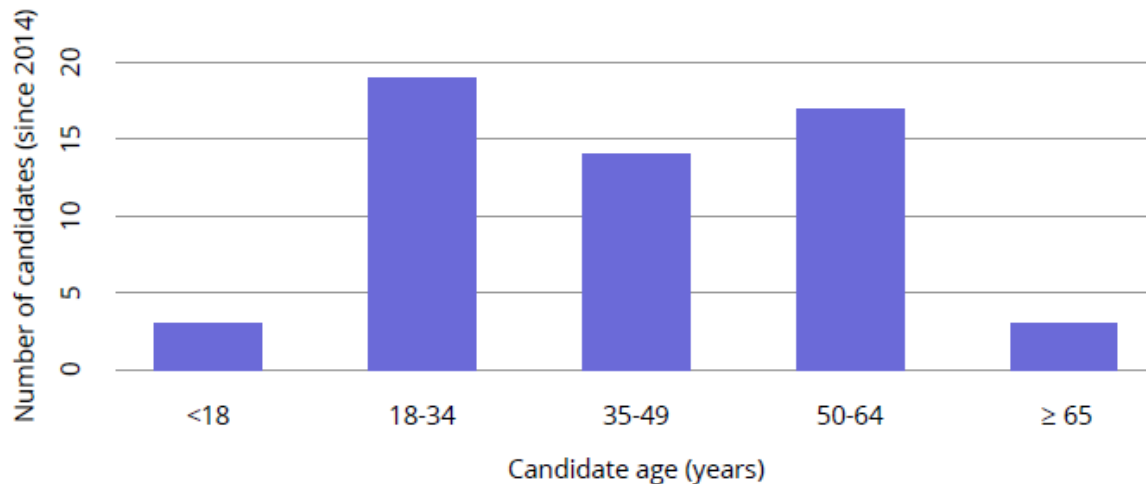
# Candidates for nonuterine VCA



OPTN/SRTR 2022 Annual Data Report

**Figure VCA 13: Number of prevalent nonuterus VCA candidates by organ.** Candidates listed at multiple centers are counted once per listing. Includes active and inactive candidates on the list any time during the year. The other/multiple category includes larynx transplant or transplants that involve multiple VCA organs.

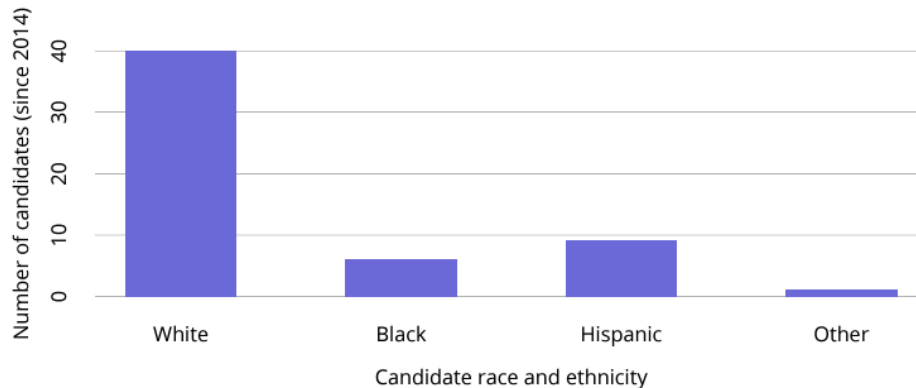
# Candidates for nonuterine VCA by age



*OPTN/SRTR 2022 Annual Data Report*

**Figure VCA 15: Number of nonuterus VCA candidates by age, 2014-2022.** Candidates listed at multiple centers are counted once per listing. Includes active and inactive candidates on the list any time.

# Candidates - nonuterine VCA by race/ethnicity



OPTN/SRTR 2022 Annual Data Report

**Figure VCA 16: Number of nonuterus VCA candidates by race and ethnicity, 2014-2022.** Candidates listed at multiple centers are counted once per listing. Includes active and inactive candidates on the list any time. Other race and ethnicity includes Asian, American Indian/Alaska Native, Native Hawaiian/Pacific Islander, and Multiracial.

# Access by State

**Table VCA 3: Number of nonuterus VCA transplants by state where transplant program is located, 2014-2022.** Nonuterus VCA transplants, including adult and pediatric, retransplant, and multiorgan recipients.

State	Transplant Count
State	
California	2
Florida	2
Kentucky	2
Massachusetts	7
Maryland	3
Minnesota	2
North Carolina	4
New York	5
Ohio	2
Pennsylvania	3
Texas	2

# VCA data submission – 9/2015

Transplant Candidate Registration (TCR)

Transplant Recipient Registration (TRR)

Transplant Recipient Followup (TRF)



# Outcomes

OPTN/SRTR ADR 2022

2014-2022: 8 failed uterus grafts, 1 failed non-uterus grafts

Definition of graft failure?

Define successful graft vs. unsuccessful graft

# Outcomes

Graft survival

Patient survival

What is a 'successful' transplant

Uterine – successful term pregnancy?

Expectation may be eventual graft excision

Limb transplant

how much function is success?

no motor function no sensation but the recipient would like to keep the graft?

# Successful outcomes must be determined and defined

Quality of life

Patient satisfaction

Graft function

# Validated tools to measure outcomes

Patient reported outcomes

- Graft function

- Patient satisfaction with graft

Quality of life tools – general e.g. SF-36

# Registry

Crisp, robust definitions for each variable collected

Enough data and procedures to allow for risk stratification?

VCA is a field in evolution

- Competing technologies

- Prosthetics

- Patient reported outcomes

# Observations

The number of VCA transplants is not steadily increasing

Barriers:

- indications/candidates

- alternative treatments

- Limited funding

- Resources for low volume highly complex procedures

Needs: standardized definitions

- data collection

- outcomes

- validated tools of function/QOL



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# Questions/Discussion