

# VCA Deceased Donors in the United States

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**Background.** Vascularized composite allograft (VCA) transplants include diverse organ types and are made possible primarily by deceased donors. **Methods.** We used Organ Procurement and Transplantation Network data to characterize VCA deceased donors (n = 66 of 70) in the United States from 1998 to 2017 and compare their characteristics with those of kidney donors in 2017. **Results.** Through December 31, 2017, 20 transplant programs performed 72 deceased-donor VCA transplants, with organs donated by 70 donors, including 30 upper limb (17 unilateral and 13 bilateral) and 11 face donors. Other donors donated both upper limbs and face (n = 2), uterus (n = 4), abdominal wall (n = 19), larynx (n = 2), penis (n = 1), and scalp (n = 1). About a third of VCA donors were female, and the majority (86.4%) were white. Almost half (45.5%) were between the ages 18 and 34 years. Smaller proportions were younger than 18 years (19.7%), 35 to 44 years (15.2%), 45 to 54 years (13.6%), and older than 55 years (6.1%). Median body mass index for all VCA donors was 24.9 and varied widely, especially for upper limb and face donors. There was considerable variation in Kidney Donor Profile Index among VCA donors (median, 27.5; interquartile range, 11–59). Donor causes of death included head trauma (39.4%), cerebrovascular/stroke (25.8%), and anoxia (31.8%). VCA donors also donated solid organs that were transplanted, including 87.1% of kidneys, 93.9% of livers, 40.2% of lungs, and 56.1% of hearts. **Conclusions.** VCA donors are a demographically and clinically diverse group. Understanding this diversity and future trends in VCA donor characteristics is critical in supporting this life-changing field of transplantation.

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Vascularized composite allograft (VCA) transplantation is an evolving field that provides reconstruction of severe tissue defects to restore function and enhance quality of life. VCA transplants include numerous diverse organ types, including upper limb, face, scalp, uterus, abdominal wall, larynx, and penis. Through 2017, there have been 6 living donor uterus transplants performed in the United States, but the majority of VCA transplants have used organs donated by deceased donors.

Although VCA transplants are not considered “lifesaving” transplants, it is undeniable that these transplants have a profoundly life-altering effect on their recipients.<sup>1,2</sup> Depending on the type of VCA organ transplanted, recipients can experience benefits that include improved ability to independently engage in self-care and activities of daily living (upper limb),<sup>3</sup> functional restoration of the ability to chew and swallow, breathe without a tracheostomy, smell, and engage more freely in social life without the fear of stigma associated with disfiguring trauma (face),<sup>4,5</sup> reduced morbidity from recurrent suprapubic catheter infections and ability to experience intimacy (penis),<sup>6</sup> or ability to carry a pregnancy (uterus).<sup>7</sup>

The life-changing field of VCA transplantation began as a local and regional phenomenon, but in March 2008, the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services published a Request for Information in the Federal Register requesting feedback on whether VCAs should be included within the Organ Procurement and Transplantation Network (OPTN) Final Rule’s definition of organs. Modifications to the OPTN Final Rule adding VCA to the definition of “covered human organs” were effective on July 3, 2014. Health Resources and Services Administration subsequently directed the OPTN to establish policies regarding VCA within its existing policy structure, with the goal of instituting a basic framework for VCA transplantation. This framework included healthcare policy for definitions, membership requirements, VCA allocation, and VCA candidate and recipient data collection.

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The OPTN also developed clinical guidance regarding living VCA donation and deceased VCA donation, including deceased VCA donor authorization. The OPTN waiting list began on July 3, 2014, allocating deceased-donor VCA organs in a national system for the first time.<sup>8,9</sup>

Donors and the generosity of their families play a critical role in all transplants, but there are special challenges related to donation of VCA organs. Although public acceptance of organ donation for solid organs such as kidneys and hearts is favorable overall,<sup>10</sup> VCA donation is a newer phenomenon; the public has not had decades of experience with the idea of donating these organs, which in many cases will be visible after transplantation. US residents have indicated lower support for VCA transplants than for solid organ transplants, but survey results suggest there is public support for VCA donation.<sup>10</sup>

Among transplant professionals, an important concern is whether or not VCA organ recovery affects the ability to recover life-saving solid organs, such as kidneys, livers, hearts, and lungs, from donors. Leaders in VCA transplantation have worked closely with solid organ recovery teams to avoid logistical problems in organ recovery. They also ensure that the VCA consent process protects the solid organ transplant process, with consent for VCA donation requested only after the donor's family has agreed to solid organ donation.<sup>2</sup> Analyses of VCA donors who donated facial allografts between 2008 and 2014 found that facial VCA recovery did not appear to negatively affect recovery of solid organs and resulted in good outcomes for recipients of the solid organs,<sup>11</sup> but this is a topic that will require continued attention.

Transplantation of VCA organs is a developing field, and there are correspondingly few data available about VCA donors. This is in contrast to transplants of solid organs such as hearts, livers, and kidneys, which are now commonplace in the United States. Over 28 000 deceased-donor solid organ transplants were performed in the United States in 2017, and there is a rich body of research on these transplants and the donors who make them possible. The limited published data on VCA donors, however, typically describe small cohorts and focus predominantly on the transplant recipients<sup>4,7,12-20</sup> or organ recovery logistics and procedures.<sup>2,21-26</sup> This paucity of data on VCA transplantation means the field does not

yet have a clear picture of the diverse donors who make VCA transplants possible.

The OPTN began collecting detailed data on VCA transplants in September 2015. This systematic data collection, which includes both demographic and clinical characteristics of candidates, recipients, and donors, allowed the OPTN to create a rich data set that can be used to monitor development of the field and evaluate outcomes of VCA transplants. These data allow us to characterize VCA deceased donors who have donated in the United States to illustrate the diversity of donors who are appropriate for VCA donation.

## MATERIALS AND METHODS

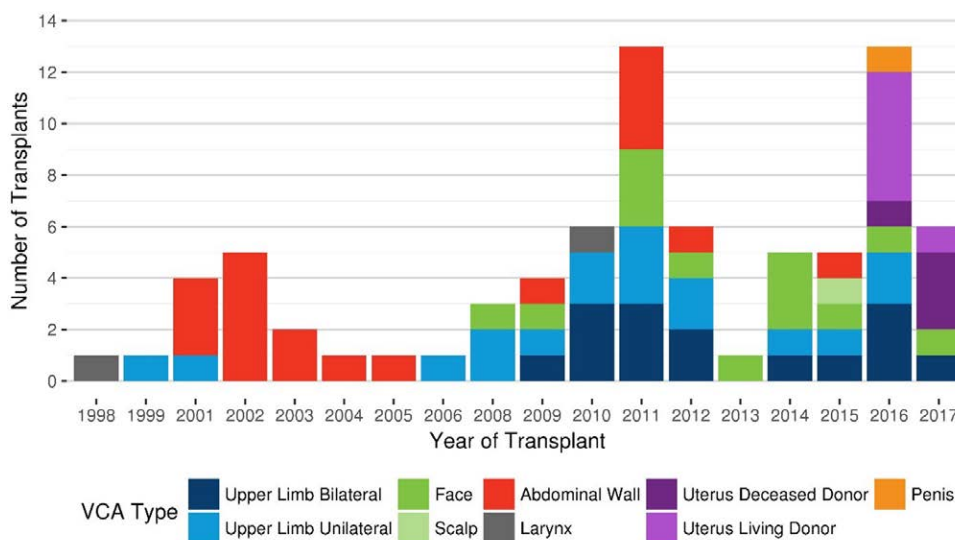
### Data Sources

This study used data from the OPTN, whose data system includes data on all donors, waitlisted candidates, and transplant recipients in the United States, submitted by the members of the OPTN, and has been described elsewhere (<https://optn.transplant.hrsa.gov/data/about-data/>). HRSA, US Department of Health and Human Services, oversees the activities of the OPTN contractor.

Donor data are submitted by Organ Procurement Organizations (OPOs) on the OPTN Deceased Donor Registration form, which is completed for all deceased donors. Institutional review board exemption was obtained from HRSA.

### Cohort

Our primary cohort included VCA deceased donors who donated in the United States with a VCA organ transplanted between January 1, 1998, and December 31, 2017. Donor data were unavailable for 2 larynx transplants and 2 abdominal wall transplants; our final cohort included 66 donors of 70 deceased VCA donors known to the OPTN in this time period. Donors who donated VCA organs before the OPTN began collecting data about VCA transplants were identified with assistance from the transplant programs. Living donor uterus donors were excluded. Our comparison cohort included all deceased kidney donors who donated between January 1, and December 31, 2017.



**FIGURE 1.** VCA transplants in the United State by VCA type and year of transplant 1998–2017. VCA, vascularized composite allograft.

## RESULTS

## VCA Transplant Centers and OPOs

As of December 31, 2017, there were 61 OPTN-approved VCA transplant programs in the United States, located at 27 distinct transplant hospitals. VCA transplants have been performed at 21 transplant programs. Of the 58 federally designated OPOs in the United States, 22 OPOs have coordinated

VCA procurements. The majority of the recoveries and transplants were in the eastern half of the United States.

## VCA Transplant Volume

There were 72 deceased-donor VCA transplants in the United States between 1998 and December 31, 2017 (Figure 1). These transplants were the result of donations

TABLE 1.

VCA deceased donors in the United States 1999 to 2017 and kidney donors in 2017

	Organ donated						Kidney (n = 9401)
	Face <sup>a</sup> (n = 11)	Upper limb <sup>a</sup> (n = 30)	Upper limb and face (n = 2)	Uterus (n = 4)	Abdominal wall <sup>b</sup> (n = 17)	All VCA <sup>c</sup> (n = 66)	
Sex							
Male	8 (72.7)	22 (73.3)	1 (50)	0 (0)	13 (76.5)	46 (69.7)	3714 (39.5)
Female	3 (27.3)	8 (26.7)	1 (50)	4 (100)	4 (23.5)	20 (30.3)	5687 (60.5)
Race							
White	11 (100)	28 (93.3)	2 (100)	2 (50)	12 (70.6)	57 (86.4)	6297 (67)
Hispanic	0 (0)	1 (3.3)	0 (0)	2 (50)	4 (23.5)	7 (10.6)	1340 (14.3)
Black	0 (0)	1 (3.3)	0 (0)	0 (0)	1 (5.9)	2 (3.0)	1350 (14.4)
Asian	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	232 (2.5)
Native American	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	62 (0.7)
Pacific Islander	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	29 (0.3)
Multiracial	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	91 (1)
Age, y							
<18	0 (0)	4 (13.3)	0 (0)	0 (0)	9 (52.9)	13 (19.7)	857 (9.1)
18–34	6 (54.5)	13 (43.3)	1 (50)	3 (75)	5 (29.4)	30 (45.5)	3028 (32.2)
35–44	1 (9.1)	6 (20)	1 (50)	1 (25)	1 (5.9)	10 (15.2)	1627 (17.3)
45–54	2 (18.2)	6 (20)	0 (0)	0 (0)	1 (5.9)	9 (13.6)	1893 (20.1)
55+	2 (18.2)	1 (3.3)	0 (0)	0 (0)	1 (5.9)	4 (6.1)	1996 (21.2)
ABO							
A	6 (54.5)	6 (20)	0 (0)	2 (50)	6 (35.3)	20 (30.3)	3516 (37.4)
B	0 (0)	4 (13.3)	0 (0)	0 (0)	1 (5.9)	6 (9.1)	1058 (11.3)
AB	0 (0)	0 (0)	0 (0)	0 (0)	2 (11.8)	2 (3.0)	323 (3.4)
O	5 (45.5)	20 (66.7)	2 (100)	2 (50)	8 (47.1)	38 (57.6)	4504 (47.9)
Cause of death							
Head trauma	5 (45.5)	11 (36.7)	0 (0)	1 (25)	7 (41.2)	26 (39.4)	2830 (30.1)
Anoxia	3 (27.3)	11 (36.7)	0 (0)	1 (25)	6 (35.3)	21 (31.8)	3890 (41.4)
Cerebrovascular/stroke	3 (27.3)	7 (23.3)	2 (100)	2 (50)	3 (17.6)	17 (25.8)	2414 (25.7)
CNS tumor	0 (0)	0 (0)	0 (0)	0 (0)	1 (5.9)	1 (1.5)	35 (0.4)
Other	0 (0)	1 (3.3)	0 (0)	0 (0)	0 (0)	1 (1.5)	232 (2.5)
Mechanism of death							
Intracranial hemorrhage/stroke	3 (27.3)	8 (26.7)	2 (100)	2 (50)	4 (23.5)	19 (28.8)	2457 (26.1)
Blunt injury	3 (27.3)	5 (16.7)	0 (0)	1 (25)	7 (41.2)	17 (25.8)	1956 (20.8)
Gunshot wound	2 (18.2)	5 (16.7)	0 (0)	0 (0)	1 (5.9)	9 (13.6)	866 (9.2)
Cardiovascular	1 (9.1)	3 (10)	0 (0)	0 (0)	2 (11.8)	6 (9.1)	1625 (17.3)
Drug intoxication	1 (9.1)	5 (16.7)	0 (0)	0 (0)	0 (0)	6 (9.1)	1215 (12.9)
Asphyxiation	0 (0)	2 (6.7)	0 (0)	1 (25)	2 (11.8)	5 (7.6)	597 (6.4)
Drowning	0 (0)	1 (3.3)	0 (0)	0 (0)	1 (5.9)	2 (3.0)	100 (1.1)
Death from natural causes	0 (0)	1 (3.3)	0 (0)	0 (0)	0 (0)	1 (1.5)	278 (3.0)
Other	1 (9.1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.5)	307 (3.3)
Geographic distribution <sup>d</sup>							
Local	11 (100)	19 (63.3)	2 (100)	2 (50)	7 (41.2)	43 (65.2)	10511 (70.9)
Regional	0 (0)	3 (10)	0 (0)	1 (25)	0 (0)	4 (6.1)	2215 (14.9)
National	0 (0)	8 (26.7)	0 (0)	1 (25)	10 (58.8)	19 (28.8)	2101 (14.2)

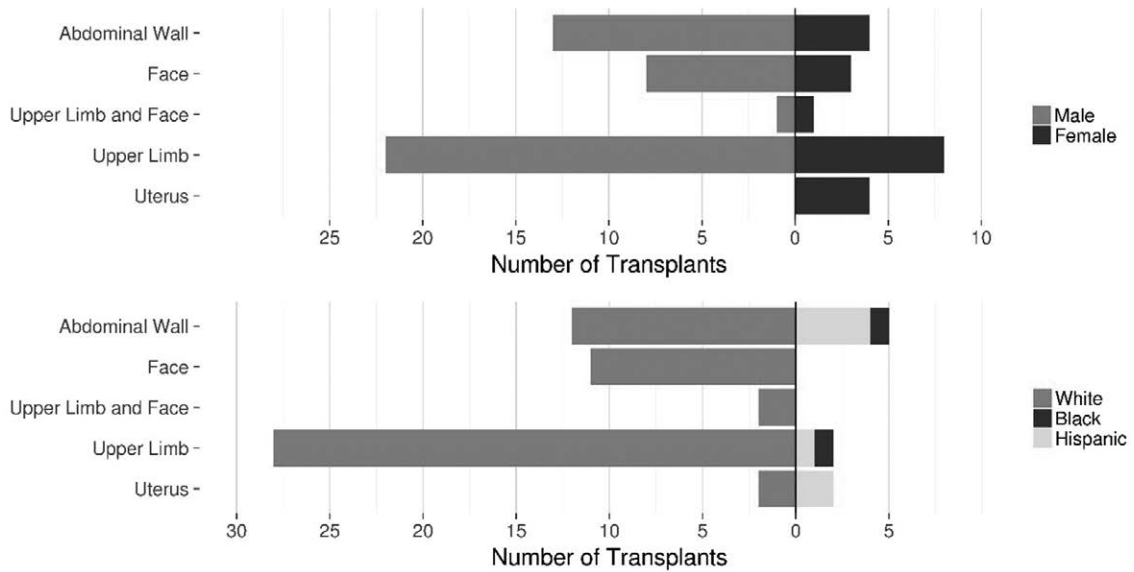
<sup>a</sup>Donors who donated face and upper limb are counted separately.

<sup>b</sup>Includes 17 of 19 known abdominal wall transplants.

<sup>c</sup>Excludes 2 larynx donors and 2 abdominal wall donors.

<sup>d</sup>Kidney transplants between January 1, 2017, and December 31, 2017; n = 14827.

CNS, central nervous system; VCA, vascularized composite allograft.



**FIGURE 2.** Sex and race of VCA deceased donors in the United States 1998–2017. VCA, vascularized composite allograft.

from a total of 70 deceased donors, including 30 upper limb donors (17 unilateral and 13 bilateral) and 11 face donors. Two additional donors donated both bilateral upper limbs and a facial allograft, with 1 donating both to the same recipient, and the other donating bilateral upper limbs to 1 recipient and a facial allograft to a second recipient. There were 4 deceased uterus donors, 19 abdominal wall donors (17 included in these analyses), 2 larynx donors (not included in these analyses), 1 penis donor, and 1 scalp donor.

**VCA Transplant Time Trends**

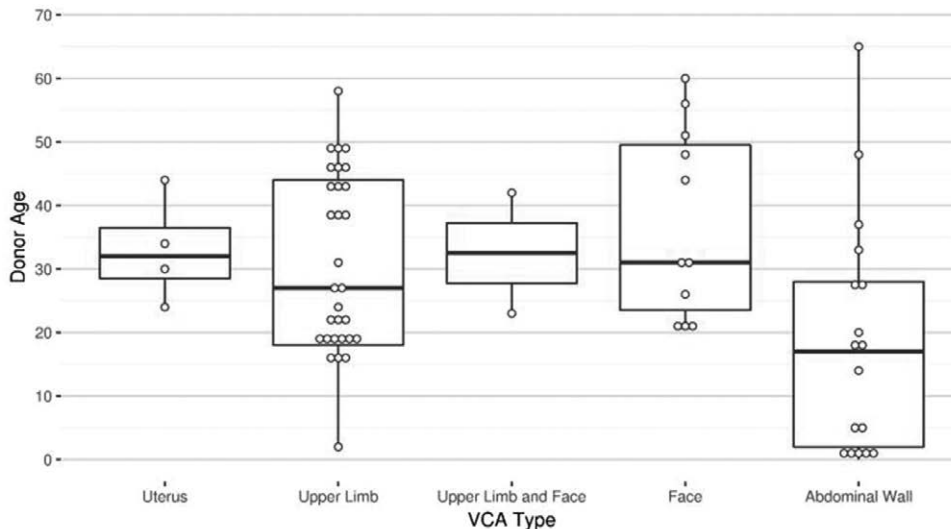
The field of VCA transplantation proceeded slowly before 2008, at which point there was an increase in both the number of VCA transplants and the types of VCA organs transplanted. There has been considerable variation in VCA transplant volume from year to year, but in recent years, up to 6 upper limb transplants have occurred per year. The first face transplant in the United States occurred

in 2008, and 1 to 3 face transplants have occurred most years since then. There have been 4 deceased-donor uterus transplants, with the first in 2016. Abdominal wall transplants occurred at a small number of programs between 2001 and 2012, and there has been a single abdominal wall transplant since implementation of the OPTN VCA waiting list in July 2014.

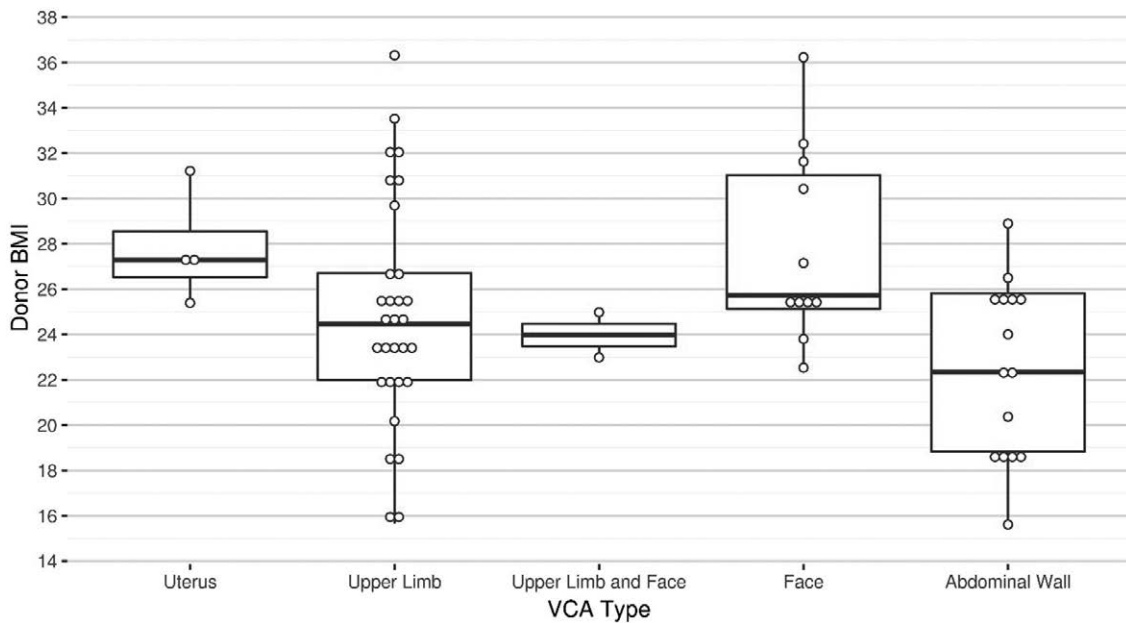
**Donor Demographic Characteristics**

Compared with kidney donors (39.5% female), 30.3% of VCA donors were female, with just over a quarter of face (27.3%), upper limb (26.7%), and abdominal wall (23.5%) donors being female (Table 1; Figure 2). Most VCA recipients received a transplant from a donor of the same sex, but 2 upper limb recipients and 8 abdominal wall recipients received an organ from a different-sex donor.

Most (86.4%) VCA donors were white, a much higher proportion than kidney donors (67.0%). All 11



**FIGURE 3.** Age of VCA deceased donors in the United States 1998–2017. VCA, vascularized composite allograft.



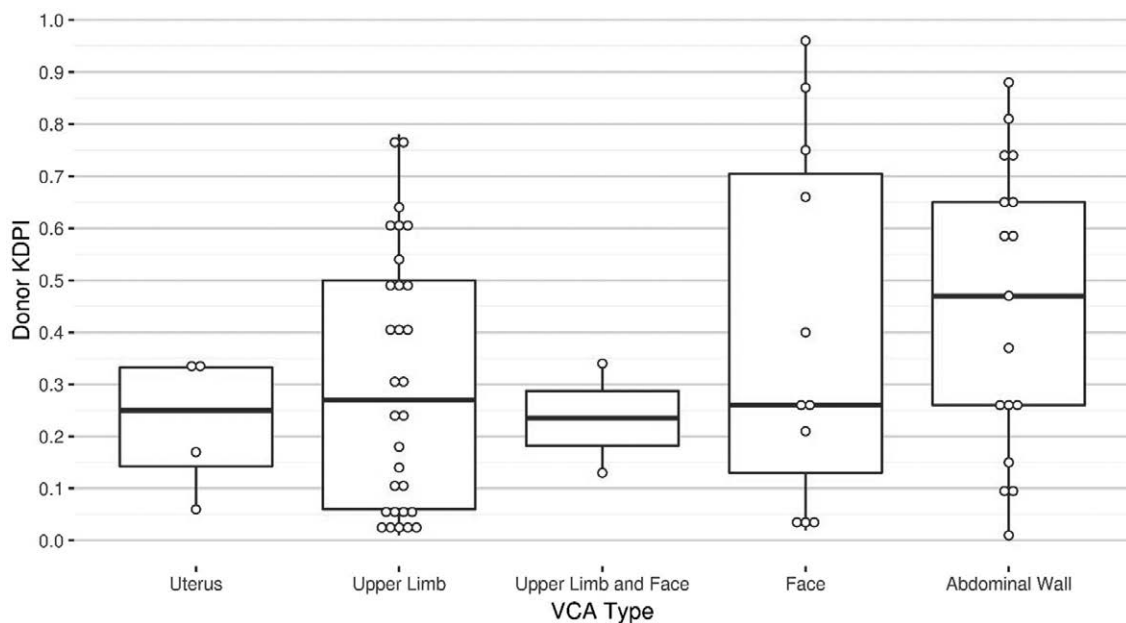
**FIGURE 4.** BMI of VCA deceased donors in the United States 1998–2017. BMI, body mass index; VCA, vascularized composite allograft.

face donors were white, as were 93.1% of upper limb donors (3.3% black and 3.3% Hispanic) and 70.6% of abdominal wall donors (23.5% Hispanic and 5.9% black).

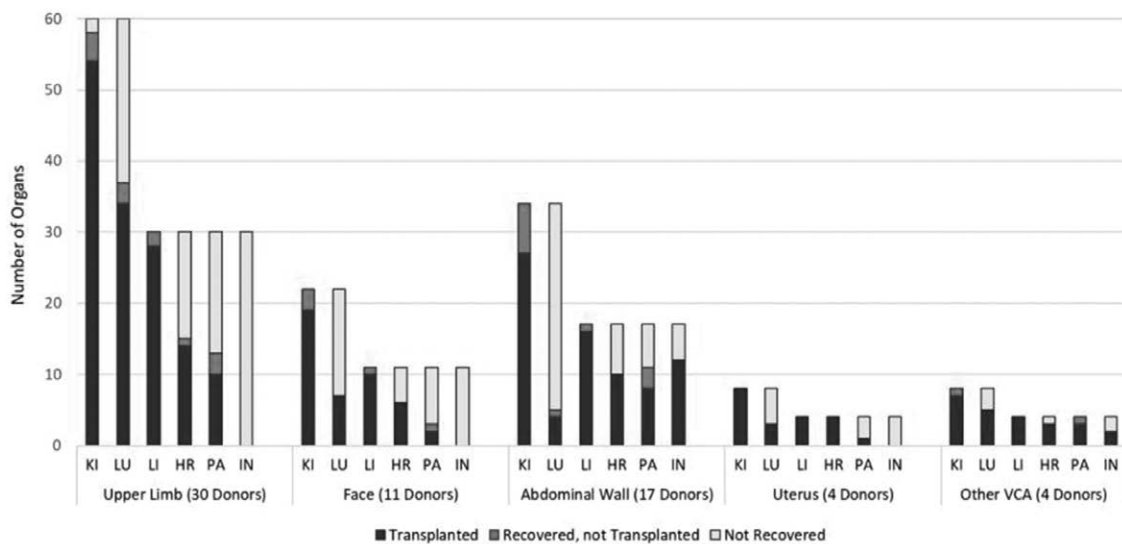
There is considerable variation among VCA organ types in donor age (Figure 3), but most VCA donors were between the ages 18 and 54 years (all VCA, 74.2%; face, 81.8%; upper limb, 83.3%; kidney, 69.7%). Almost half of VCA donors (45.5%) were between the age of 18 and 34 years, a much greater proportion than seen among kidney donors (32.2%). Smaller proportions of VCA donors were younger than 18 years (19.7%), between 35 and 44 years (15.2%), 45 and 54 years (13.6%), and older than

55 years (6.1%). Nine of the 13 VCA donors who were younger than 18 years were abdominal wall donors and 4 were upper limb donors.

Overall, 65.2% of VCA donors had organs recovered by the transplant program’s local OPO, including 100% of face donors, 63.3% of upper limb donors, 41.2% of abdominal wall donors, and 50.0% of uterus donors. Organs of 4 (6.1%) VCA donors were transplanted within the OPO’s OPTN region (face, 0.0%; upper limb, 10.0%; abdominal wall, 0.0%; uterus, 25.0%), and Organs of 19 (28.8%) VCA donors were transplanted nationally (face, 0.0%; upper limb, 26.7%; abdominal wall, 58.8%; uterus, 25.0%). Excluding abdominal walls, which are usually allocated as part of a



**FIGURE 5.** KDPI of VCA deceased donors in the United States 1998–2017. KDPI, Kidney Donor Profile Index; VCA, vascularized composite allograft.



**FIGURE 6.** VCA deceased-donor solid organ use in the United States January 1998 to December 2017. VCA, vascularized composite allograft.

multiorgan transplant, 86.0% of organs traveled <200 nautical miles and 52.0% traveled 50 miles or less.

### Donor Clinical Characteristics

Median body mass index (BMI) for all VCA donors was 24.9 (interquartile range [IQR], 21.9–26.8), slightly lower than the median BMI (26.9; IQR, 23.0–31.5) for kidney donors. BMI varied widely, however, especially for upper limb donors (range, 15.7–36.3) and for face donors (range, 22.5–36.2; Figure 4). The VCA donors' blood type generally followed the same pattern seen among kidney donors, but the VCA donors were more likely to be type O (VCA, 57.6%; kidney, 47.9%), with smaller differences for type A (VCA, 30.3%; kidney, 37.4%), type B (VCA, 9.1%; kidney, 11.3%), and type AB (VCA, 3.0%; kidney, 3.4%).

Kidney Donor Profile Index (KDPI), a measure of the length of time a donated kidney is expected to function that is often used as a proxy for organ quality, was considerably lower (better) for VCA donors (median, 27.5; IQR, 11.0–59.0) than for kidney donors (median, 51.0; IQR, 26.0–76.0). There was considerable variation in KDPI among VCA donors and among donors of different types of VCA organs (Figure 5). KDPI ranged from 2.0 to 96.0 for face donors, from 1.0 to 78.0 for upper limb donors, from 1.0 to 88.0 for abdominal wall donors, and from 6.0 to 34.0 for uterus donors. None of the VCA donors were donation after circulatory death donors, and 2 were Public Health Service increased risk donors.

No single cause of death predominated among the various types of VCA donors. Donor causes of death included head trauma (VCA, 39.4%; kidney, 30.1%), cerebrovascular/stroke (VCA, 25.8%; kidney, 25.7%), and anoxia (VCA, 31.8%; kidney, 41.4%). Head trauma was a common cause of death for all types of VCA organ donors; 45.5% of face donors and 41.2% of abdominal wall donors died from head trauma. Mechanism of donor death showed substantial variation between VCA and kidney donors, likely because of the small numbers for the VCA donors. Notable differences included drowning (VCA, 3.0%; kidney, 1.1%), cardiovascular-related deaths (VCA, 9.1%; kidney, 17.3%),

blunt injuries (VCA, 25.8%; kidney, 20.8%), drug intoxication (VCA, 9.1%; kidney, 12.9%), and gunshot wounds (VCA, 13.6%; kidney, 9.2%).

### VCA Donor Solid Organ Donation

All VCA donors also donated solid organs. One hundred thirty (98.5%) of 132 kidneys were recovered, and 115 (87.1%) were transplanted. All of the 66 livers were recovered, and 62 (93.9%) were transplanted. Smaller proportions of lungs (43.2% recovered; 40.2% transplanted), hearts (57.6% recovered; 56.1% transplanted), and pancreata (48.5% recovered; 36.4% transplanted) were recovered or transplanted. As expected, a small number of intestines were donated (21.2% recovered; 21.2% transplanted).

When solid organ donation is analyzed by VCA type donated, few differences are seen for kidney and liver donation (Figure 6). Most kidneys and livers were transplanted, regardless of VCA type donated. Lungs and hearts were donated for a higher proportion of upper limb and other (penis, scalp, and upper limb/face) donors than for face and abdominal wall donors. A higher proportion of pancreata and intestines were donated by abdominal wall donors, with those organs usually received by the same patient who received the abdominal wall transplant.

### DISCUSSION

VCA transplantation is possible because of the gifts of demographically and clinically diverse deceased donors. These donors vary widely in age, BMI, KDPI, and cause of death. They are less diverse in race and sex, with donors of some VCA types more heterogeneous than others. Despite the diversity of VCA donors, they differ as a group from kidney donors in several important ways, including being more likely to be male and white than kidney donors. On average, they also had slightly lower BMI and notably lower (better) KDPI.

The diversity of VCA donors reflects the need for donors of some VCA types (eg, face and upper limb) to

be similar to their recipients in physical appearance. As a result, homogeneity in some characteristics, such as sex and race, is not surprising. In most cases, the race of VCA donors (86.4% white overall; 80.3% white when excluding nonvisible uterus transplants) will match the race of their recipients, and factors, such as access to health care,<sup>27</sup> likely affect which candidates are listed for VCA transplant. The larger proportion of male recipients (and therefore male VCA donors) is likely related to higher rates of traumatic accidents among men.<sup>28</sup> The wide range of ages seen among VCA donors illustrates that this is not a limiting factor for who can become a VCA donor.

Similarly, the wide range of clinical factors among VCA donors indicates that a wide variety of deceased donors have the potential to become VCA donors. Donors with relatively high BMI or KDPI have successfully become VCA donors. This finding, along with the diversity of causes of death among VCA donors and the somewhat surprising finding that 5 of 11 face donors died from head trauma, suggests that OPOs should not make assumptions about a donor's suitability for VCA donation before carefully considering the history and physical exam, medical-social history, and cause and manner of death of the potential donor. Guidance for VCA authorization and recovery can be found on the OPTN website.

As the first effort to characterize all VCA deceased donors in the United States, this study has several important strengths. We include 66 of 70 VCA deceased donors in the time period—excluding only 2 larynx and 2 abdominal wall donors and giving the most complete analysis to date of the donors who have made VCA transplantation possible. The OPTN data submitted by OPOs allow us to provide a comprehensive view of these donors' demographic and clinical characteristics.

Despite these advantages, the field of VCA transplantation is in a period of transition, and changes in the composition of the waiting list and transplant volume are hard to predict at this time.<sup>29</sup> It is important to be aware of the current situation to understand the future possibilities for VCA donation. It is critical, however, to remember that future trends may diverge from what has occurred in the field to date. Growth in newer types of VCA transplantation, such as uterus and penis transplants, has the potential to change the landscape for VCA deceased donation in the future.

Along with these caveats, we acknowledge the need for additional research on VCA donors' solid organ donation. This descriptive analysis of organ usage provides reassurance that VCA donors' solid organs are being transplanted successfully. We need more extensive analyses, however, to ensure that the use of solid organs from VCA donors has not been compromised by recovery of VCA organs from those donors.

VCA transplantation is a rapidly changing field that is possible because of the generosity of deceased donors and their families. VCA donors are a demographically and clinically diverse group that largely reflects the characteristics of the VCA candidates waiting for a transplants. Understanding this diversity and any future trends in VCA donor characteristics is critical to support this life-changing emerging field of transplantation.

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