

Donor Facial Composite Allograft Recovery Operation: Cleveland and Boston Experiences

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Background: Complexity of logistic issues related to facial transplantation includes donor tissue recovery, recipient preparation, and operative execution. Limited information is available on the intricate process associated with facial allograft procurement in the United States.

Methods: The face transplant teams at the Cleveland Clinic and Brigham and Women's Hospital have combined their experiences regarding collaboration with organ procurement organizations and institutional review boards, and outlined technical and logistic challenges encountered during the process of facial allograft procurement and compared them with those of solid organ procurement.

Results: In a collaborative effort, both programs have created comprehensive guidelines for all aspects involved in donor facial allograft procurement.

Conclusions: The authors suggest that every face transplant team should develop a thorough understanding of the local and regional legislative issues related to organ and tissue donation and ethical concerns surrounding this procedure. The recovery plan has to be communicated extensively among all members of the team. The Cleveland and Boston teams hope their experiences may help other teams in the process of building new face transplant programs. (*Plast. Reconstr. Surg.* 129: 461e, 2012.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, V.

Few reports focus on the technical and logistic aspects of allograft procurement in face transplantation.¹⁻⁵ Mainly, the literature contains experimental and anatomical studies⁶⁻¹⁴ and clinical reports for five published facial transplantations.¹⁵⁻²²

Before establishing a face transplantation program, an institution must establish an agreement and guidelines for facial allograft donor matching and procurement in collaboration with one or more organ procurement organizations and the institutional review board. The challenges hardly end there: facial allograft procurement is a difficult operation involving complex logistics, extensive patient-specific planning not often seen in solid organ transplantation, and an intimate knowledge of the recipient's defect anatomy. In this article, the Boston (Brigham and Women's Hospital) and Cleveland (Cleveland Clinic) face transplant teams describe their experience and

provide guidelines for donor facial allograft procurement and compare the logistics with those of solid organ procurement. The Cleveland and Boston groups have performed the only face transplantation operations to date in the United States.^{17,21}

DONOR MATCHING CRITERIA

The Cleveland and Boston teams may recover facial allografts from heart-beating (brain-dead) or donation-after-cardiac-death donors, as is done in solid organ allografts. Heart-beating donors are highly preferred because more time is allowed for mobilizing the surgical teams (donor and recipient), the donor's team may work undisturbed in the operating room before the arrival of other procurement teams, and ischemia time can be better controlled because the facial allograft is retrieved under continuous circulation. Furthermore, blood loss following reperfusion is markedly diminished compared with donation-after-cardiac-death dissections under cold ischemia.

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Nonetheless, as in solid organ donation, consideration of donation-after-cardiac-death donors allows enlarging the facial allograft donor pool. Because donation-after-cardiac-death status is not a risk factor in the long-term outcomes of kidney²³ or face transplants,²⁰ this option is acceptable, provided that ischemia time is kept at approximately 4 hours. Logistically, this limited time makes it more complicated to work with a donation-after-cardiac-death donor. In the first Cleveland and Boston cases, donors were heart-beating, and total ischemia times were 2 hours 40 minutes, and 1 hour 15 minutes, respectively.

In general, the Cleveland and Boston teams agree that facial allograft donors are even more scarce than solid organ donors, both because the matching requirements are more strict and because facial allograft donation is more difficult to consent to. The consent process for facial allograft donation may be one of the most difficult discussions the organ bank representative has with a donor family. Clearly, the recovery will disfigure the donor despite reconstruction, and organ procurement organizations must always obtain consent from the next of kin, regardless of the donor designation on various state registries.²⁴

Each potential facial allograft donor must be evaluated thoroughly on a case-by-case basis to better assess the potential perioperative, functional, and aesthetic outcomes of the transplantation. Inclusion criteria for facial allograft donation must include the standard compatibility screen for organ transplantation (ABO typing, negative crossmatch), plus sex and skin color matching. To date, all face transplant operations have used sex-matched donors.^{17,19–21,25} Slight differences in skin color can be masked with makeup, and information on the recipient's skin tone can be provided to the organ procurement organization, using visual aids whenever possible. In general, the Cleveland and Boston teams follow the guidelines in Tables 1 and 2.^{26,27} Although age matching is based on skin texture, the Boston team has estimated the ideal donor's age between 20 years younger and 10 years older than the recipient.²⁶

The Cleveland Clinic lists "minimal amount of medical/surgical comorbidity before death" as an inclusion criterion to wean out potential donors that over time have proven to provide organs with a shorter graft survival. This is in keeping with the scrutiny that expanded criteria donors (i.e., those with a history of comorbidity factors) receive, and their prescribed use in solid organ transplanta-

Table 1. Facial Allograft Donor Inclusion Criteria at Brigham and Women's Hospital and the Cleveland Clinic*

	Boston	Cleveland
Documented brain death with hemodynamic stability	Yes	Yes
Minimal amount of medical/surgical comorbidity before death	No	Yes
Acceptable craniofacial imaging to identify unknown hardware and/or vascular abnormalities	No	Yes
Acceptable mandible imaging to rule out dental caries	No	Yes
ABO compatibility	Yes	Yes
Suitable HLA typing	Yes	Yes
Negative crossmatch	Yes	Yes
Sex match	Yes	Yes
Skin color match	Yes	Yes
Age match	No	Age matched by skin texture
Location	Maximum 4 hr of commercial flight	Case-by-case

HLA, human leukocyte antigen.

*From Aflaki P, Nelson C, Balas B, Pomahac B. Simulated central face transplantation: Age consideration in matching donors and recipients. *J Plast Reconstr Aesthet Surg*. 2010;63:283–285.

tion. It has been reported that comorbidity factors shorten graft survival.

The Boston team considers each potential donor on a case-by-case basis so as not to write off valuable potential donors. The Cleveland team prefers donors with acceptable craniofacial and dental imaging to rule out various abnormalities and caries because these have a potential detrimental effect on the functional outcomes of the operation and may precipitate infections in the immunosuppressed recipient. The Boston team recognizes the value of these criteria; however, in the majority of cases, this information may not be available in time for facial allograft recovery. Ischemia concerns limit the geographic location of the donor with respect to the face transplant institution. In contrast to solid organs, which have acceptable ischemia times ranging from 4 (heart, lungs) to 24 or more hours (kidney), facial allografts have a significant muscle component that could suffer irreversible ischemic damage if isolated from the body's circulation for significantly more than 4 hours. The Boston team works with an organ procurement organization that covers

Table 2. Facial Allograft Donor Exclusion Criteria at Brigham and Women's Hospital and the Cleveland Clinic

	Boston	Cleveland
Unresolved sepsis	Yes	Yes
HIV/AIDS	Yes	Yes
Cytomegalovirus	Case-by-case	Case-by-case
Epstein-Barr virus	Case-by-case	Case-by-case
Tuberculosis	Yes	Yes
Viral hepatitis	Yes	Yes
High-risk (CDC definition)*	Case-by-case	Case-by-case
Congenital craniofacial disorder	Case-by-case	Case-by-case
Documented connective tissue disorder	No	Case-by-case
Facial nerve palsy	Case-by-case	Yes
History of significant craniofacial or neck trauma and/or surgery	Case-by-case	Yes
History of recent carcinoma (<5 yr)	No	Yes

HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome; CDC, Centers for Disease Control and Prevention.

*From "Guidelines for preventing transmission of human immunodeficiency virus through transplantation of human tissue and organs." Centers for Disease Control and Prevention. *MMWR*. 1994; 43:1-17.

extensive territory within New England and includes only donors whose facial allograft can arrive to Brigham and Women's Hospital within 4 hours of procurement. The Cleveland team is fortunate to have multiple organ procurement organizations within the state of Ohio, plus additional organ procurement organizations within driving distance in the neighboring states, and therefore their team evaluates the geographic location of the donor on a case-by-case basis. Multiple organ procurement organizations gives the Cleveland team the advantages of a large donor pool and increased awareness on facial transplantation within the organ procurement organization community.

The Cleveland and Boston teams strongly agree that exclusion criteria for facial allograft (as for solid organ) donors include unresolved infections/conditions that may compromise the health of the immunosuppressed recipient and craniofacial anatomical abnormalities (Table 2). Both teams consider high-risk donors²⁷ on a case-by-case basis and present them to the recipient, who can accept or reject them. In solid organ transplants, the decision to accept or reject high-risk donors is based on the urgency of the transplant to preserve life. Congenital craniofacial malformations are obviously criteria for exclusion in both face transplantation programs. The Boston program will consider donors with a history of craniofacial and neck trauma or surgery and those

with facial nerve palsy on a case-by-case basis. This is because a recipient's defect is so unique that until the surgeon can assess how these historical findings in a potential donor will impact the outcome of a specific recipient, a valuable potential donor must not be written off. The Cleveland program lists these historical findings as exclusion criteria for facial allograft donation because of their potential detrimental effect to the aesthetic and functional outcomes of the allograft transplantation.²⁸ The Boston team will consider donors with a history of recent (<5 years) carcinoma on a case-by-case basis, and the Cleveland team excludes them.^{29,30} As in solid organ transplantation, the Cleveland, and Boston programs agree that donors with intracranial tumors that are not assumed to have crossed the blood barrier may be discussed controversially. Nonetheless, in tandem with the Boston philosophy, the Cleveland team has carried an experience-based revision of their original donor inclusion/exclusion criteria published in 2010,²⁸ to allow broader acceptance of potential calls from the organ procurement organization. Donors with no apparent exclusion criteria may be excluded after lead surgeon review of medical/social history.

A significant difference in exclusion criteria between face and organ donation, although not listed in Table 2, is the planning for open-casket funerals. Donors whose families wish for open-casket funerals are excluded because the donor's facial defect, even when restored with a mask, is not suitable for viewing, whereas after organ donation, the abdominal/thoracic cavity can be closed, leaving no visible defect.

LOGISTICS OF DONOR OPERATION

The logistics of surgical facial allograft procurement are more complex than those of solid organ procurement. The main concern is allograft ischemia time. Therefore, face transplant institutions must work with the organ procurement organization(s) covering the face transplant institution's geographic area. In the United States, facial allografts are not yet designated to a specific group of organs or tissues; therefore, allocation and procurement are not regulated by the Organ Procurement and Transplantation Network or the United Network for Organ Sharing. These institutions manage a centralized national up-to-date database, which matches donors and recipients of solid organ transplantation across the country. In contrast, the face transplant institution must develop its own agreement with the regional organ procurement organization(s) for facial allograft

procurement. The organ procurement organization holds the same types of responsibilities as in solid organ procurement but also has to fulfill the responsibility of allocation. This has not been a problem to date because of the low number of face transplantation candidates on the transplant waiting list at a given time. The organ procurement organization finds compatible donors, notifies the face transplant surgeon, and assists with donor evaluation and logistics of the recovery operation. In addition, the organ procurement organization has to obtain specific consent for facial allograft donation from the donor's family. The face transplant institution, in turn, is responsible for adhering to the organ procurement organization's regulations, supplying the organ procurement organization with up-to-date information about patients on the waitlist, reimbursing the organ procurement organization for costs associated with the search and procurement, and quickly assembling a traveling team for allograft recovery. Both the face transplant institution and the organ procurement organization must strive to maintain the identities of donors and recipients confidential, perhaps even to a higher degree than in solid organ donation, although this may be impossible as a result of the high level of public interest in face transplantation. The organ procurement organizations in both Cleveland and Boston prepared the donor families for the likelihood of seeing the recipients on several media outlets.

Unlike in solid organ transplantation, the intensive care unit and operating room staff at the face transplant institution must undergo special training specific to face transplantation in preparation for donor and recipient procedures. Training for the donor procurement begins with the surgical team identifying the very specific components to be recovered for the particular recipient, in contrast to solid organ transplantation, where only minor specific needs are identified. For example, a liver transplant team may need to recover additional blood vessels, but the recovery is essentially the same for all donors. Facial allograft recovery may be vastly different for each case, ranging from a midface recovery including the nose, lips, or eyelids, to a total face recovery that may include much of the intraoral cavity as well. This difference in recovery needs affects the list of necessary instrumentation and equipment, assembly of the graft procurement travel kit, operating room equipment availability planning and efficient layout, determination of staffing requirements, and operating room setup designing/drawing. Operating room staff are also trained on

full body preparation and draping for multiple organ procurement procedure. Nursing teams generally consist of two scrub personnel and two resident nurse circulators. The Boston team has a standard operating protocol for face transplantation that includes donor and recipient procedure modules and is distributed among the appropriately skilled intensive care unit and operating room staff. The Cleveland program selected and previously trained a team of experienced operating room and intensive care unit nurses, anesthesia staff, and Certified Registered Nurse Anesthetists to take part in the donor and recipient operations.

When the organ procurement organization identifies a potential donor based on standard compatibility requirements, organ procurement organization representatives evaluate other inclusion/exclusion criteria (e.g., Tables 1 and 2). If these match and the donor's family appears approachable, organ procurement organization representatives request the gift of the facial allograft. If the family consents, the organ procurement organization contacts the face transplant institution surgeon and provides donor information, including a photograph or an onsite evaluation if possible. Donors at the face transplant institution may be personally evaluated by the lead surgeon. The lead surgeon then mobilizes the face transplant team. The logistics of what occurs next depend on whether or not the donor is at the face transplant institution.

The best scenario is when the donor is at the face transplant institution. If contiguous operating rooms can be arranged, surgeons can walk back and forth between the donor and recipient rooms to communicate, visualize, and make real-time adjustments. All necessary microsurgical equipment is available at the face transplant institution. Nursing and operating room staff are trained and familiar with donor and recipient procedures. Ischemia time is minimized because the facial allograft can be walked across rooms and reconnected to the recipient circulation before any other connections. Costs of ground and air transportation and chances of contamination are reduced.

If the donor is at another hospital, a recovery team of two to four surgeons must travel to the donor's hospital as is typically done for solid organs. Travel is arranged by the organ procurement organization. The recovery team must bring a surgical kit with all necessary instruments for the procedure, which are not always available at every hospital, where solid organ recovery uses standard surgical instrumentation or kits provided by the

organ procurement organization. The organ procurement organization and donor's hospital may provide all other materials and supplies, including packaging for the facial allograft. However, bringing packaging for the facial allograft is advisable. The costs of materials and supplies are stipulated in the agreement between the face transplant institution and the organ procurement organization. At the donor's hospital, the facial allograft recovery team must work with the hospital staff and the solid organ teams. An anaplastology team takes an impression of the donor's face and fabricates the prosthesis for the donor's facial restoration. This aspect is very different from solid organ donation, which requires no restoration beyond suturing.

The donor may be transferred from his or her own hospital to the face transplant institution for the recovery. In this case, the logistics of medical transportation of the heart-beating donor to the face transplant institution should be previously planned with the local coroner's office.³¹ The Cleveland team established a protocol with the coroner's office for interhospital brain-dead donor transport for deaths that fall under that office's jurisdiction. Such protocols may vary with health system, county, and state policies and laws. In Cleveland, transport of the donor across the state border required consultation with legal counsel and the coroner's office with jurisdiction over the donor.

Lastly, regardless of where the recovery operation is performed, solid organ recovery teams will most likely be involved, and safe procurement of life-saving organs takes priority over recovery of non-life-saving facial allografts. As heart-beating donors are typically hemodynamically stable, procurement of the facial allograft (which takes longer than any solid organ) starts first, but in donation-after-cardiac-death donors, conversations with the organ procurement organization's solid organ teams suggest that the facial allograft should be recovered after or simultaneous with solid organs. The organ procurement organization coordinator remains in the room during facial allograft recovery to monitor the donor's stability, and the abdominal recovery teams are on standby.

SURGICAL PRINCIPLES OF DONOR OPERATION

The donor recovery operations of the five published face transplant cases have been described recently.⁵ Because the principal goal of face transplantation should be the restoration of sensory and motor function, facial allograft procurement

should be planned with emphasis on the functional integration of sensory and motor nerves, which is not a consideration in solid organ transplantation. The role of sentinel, monitoring flaps is not clear yet, but the Boston team is currently implementing a separate—and whenever possible, functional—monitoring fasciocutaneous flap for the recipient.

Donor's Facial Restoration

In solid organ procurement, removal of the organs from the abdominal or thoracic cavity does not result in visible deformity on the donor. Facial allograft procurement, in contrast, inflicts a most striking deformity on the donor. For this reason, most face transplant institution protocols require restoration of the donor's facial defect after allograft recovery. Restoration preserves the donor's dignity and helps make face transplantation more acceptable to the donor's family, society, and the individuals that handle the body. Silicone facial prostheses carefully detailed by a professional can be prepared relatively fast and inexpensively and provide a satisfactory match to the original face, including features such as eyebrows or eyelashes.³² Resin masks provide acceptable cosmetic results and fitting.² In any case, the results are not optimal and most likely not suitable for open-casket funerals. In the Boston protocol, a restoration team takes an impression of the donor's face and creates a silicone mask that covers the facial defect after recovery. In the Cleveland case, the donor's facial defect was covered with dressing, and a non-removable plaster cast was applied in preparation for cremation according to the family's request.

Standard of Care versus Experimental Transplantation

With all new transplant procedures, donor hospitals must learn to work with the recovery/transplant teams and will require additional education to understand the need and process for that particular transplant. In this case, face transplantation is similar to other organ transplant procedures introduced in the 1980s throughout the United States.

Organ procurement and transplantation are considered standard of care; thus, both the Centers for Medicare & Medicaid Services and the Joint Commission on the Accreditation of Healthcare Organizations have outlined the standards that must be met by transplant centers offering these services. Face transplantation waiting lists may never see the volume of potential recipients

as high as on the ever-increasing national organ transplant waiting list. Medical professionals may need recurrent education to maintain a skill level and knowledge base for the procedure. There are yet no recovery or transplant standards developed for face transplantation or other vascularized composite allograft transplants.

Comparison to World Experience

Five European teams and one Chinese team have performed face transplantations.^{20,25,33,34} These teams selected donors based on ABO compatibility, skin color, and sex. However, the Paris and Barcelona teams added anthropometrics as a selection criterion for the donors of their full face transplants.^{4,34} Differences in the facial allograft recovery protocols of these published cases are summarized in the recent report by Bueno et al. on multiorgan recovery, including facial allograft.³⁴

CONCLUSIONS

The authors hope that sharing the Cleveland and Boston⁵ experiences in facial allograft recovery and how they may differ from well-established solid organ recovery protocols will help developing face transplant institution teams around the world. Developing face transplant teams are encouraged to pay close attention to regional and legislative details that may apply to their own institutions. Establishment of an agreement with the regional organ procurement organization(s) in collaboration with the institutional review board is the first, lengthy step toward facial allograft recovery. Many issues must be properly considered and addressed with regard to the donor, such as inclusion/exclusion criteria, logistics of search and allocation, family consent, timing of facial allograft and solid-organ recovery, interhospital transport, and facial restoration. The face transplant team must plan rigorously for the anatomical and technical details of the recovery surgery, be prepared to travel to the donor's hospital on short notice and with a full recovery kit, and train the operating room and intensive care unit staff for the surgical procedure. The technical and anatomical aspects of facial allograft recovery were similar for the Cleveland and Boston face transplant operations performed in December of 2008 and April of 2009, respectively. Differences were based mainly on the extent of the recipient's needs and the original facial defect. The authors were pleased to join efforts and share their experiences with facial allograft recovery.

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