Total Face, Double Jaw, and Tongue Transplant Research Procurement: An Educational Model

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Background: Transplantation of a facial vascularized composite allograft is a highly complex procedure that requires meticulous planning and affords little room for error. Although cadaveric dissections are an essential preparatory exercise, they cannot simulate the true clinical experience of facial vascularized composite allograft recovery.

Methods: After obtaining institutional review board approval to perform a facial vascularized composite allograft research procurement, a 66-year-old, brain-dead donor was identified. The family graciously consented to donation of a total face, double jaw, and tongue allograft and multiple solid organs.

Results: A craniofacial computed tomographic angiogram was obtained preoperatively to define the vascular anatomy and facilitate virtual computerized surgical planning. The allograft was procured in 10 hours, with an additional 2 hours required for an open tracheostomy and silicone facial impression. The donor was coagulopathic throughout the recovery, resulting in an estimated blood loss of 1500 ml. Fluorescence angiography confirmed adequate perfusion of the entire allograft based on lingual and facial arterial and external jugular and thyrolinguofacial venous pedicles. The solid organ transplant team initiated abdominal organ isolation while the facial allograft procurement was in progress. After completion of allograft recovery, the kidneys and liver were recovered without complication.

Conclusions: Before conducting a clinical face transplant, adequate preparation is critical to maximize vascularized composite allotransplantation outcomes and preserve solid organ allograft function. As more centers begin to perform facial transplantation, research procurement of a facial vascularized composite allograft offers a unique educational opportunity for the surgical and anesthesia teams, the organ procurement organization, and the institution. (*Plast. Reconstr. Surg.* 130: 824, 2012.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, V.

The R Adams Cowley Shock Trauma Center manages over 8000 trauma admissions yearly and has a long history of dedicated expertise treating a large volume of high-energy facial injuries. These injuries are often the result of avulsive, ballistic, or blunt mechanisms requiring multistage reconstructive procedures. Although great success has been achieved treating a majority of these composite high-energy facial injuries, there remains a select group of patients who cannot achieve normalcy. The frustration with this limitation, despite the utility of the most sophisticated techniques, demanded exploration of innovative approaches.

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Facial transplantation has become technically, immunologically, and ethically feasible, with 23 facial vascularized composite allotransplantations performed worldwide.[1,2] This pursuit has resulted in an increasing number of centers receiving institutional review board approval to proceed with facial vascularized composite allotransplantation. Although much has been gained from the experience shared, this is the beginning of a paradigm shift and many questions remain unanswered. Some of the reservations raised by institutions, transplant teams, and organ procurement organizations are related to the fact that facial procurement is patient-specific and exceedingly complex, and demands precise coordination between transplant teams to optimize solid organ recovery.[3,4]

Because "necessity is the mother of invention,"[5] a facial vascularized composite allotransplantation dissection model that included the total face, double jaw, and tongue was designed and rehearsed on 10 donor-recipient cadaveric pairs. The next logical step in this instructional process was to provide "proof of concept" and perform the rehearsed model under real-time conditions. This opportunity would verify technical and operational feasibility and provide valuable information and experience. In this article, we provide specific details of the first reported research facial vascularized composite allograft procurement and concomitant solid organ recovery by means of a comprehensive article and educational video.

MATERIALS AND METHODS

Mock Cadaveric Face Transplantation in the Operating Room

To prepare the operating room staff for a facial vascularized composite allograft research procurement, a mock cadaveric face transplant consisting of the total face, double jaw, and tongue was performed in the main operative theater. A team of surgeons prepared the recipient in one operating room while another team procured the allograft in a second operating room. The procedures were performed using sterile technique and with the assistance of perioperative support staff, to most accurately simulate the planned research procurement (Fig. 1).

Facial Vascularized Composite Allograft Research Procurement

Formal institutional review board approval for a facial vascularized composite allograft research procurement was provided by the Living Legacy Foundation of Maryland in May of 2009. The aim was to educate the anesthesia and surgical teams, the organ procurement organization, and the institution to improve clinical outcomes and minimize the risks to potential face and solid organ transplant recipients. On October 31, 2011, we were alerted by the Living Legacy Foundation that a potential donor had been identified and the family was receptive to a total face, double jaw, and tongue research procurement. On November 2, 2011, our teams were provided the opportunity to proceed through the generous gesture of donation by the donor's family.

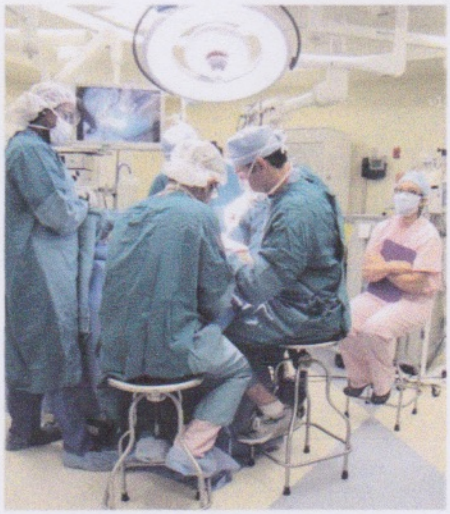


Fig. 1. Mock cadaveric face transplant in the operating room. Note the use of sterile technique and presence of surgical scrub technician.

RESULTS

Donor

The donor was a 66-year-old woman who was found unresponsive at home and diagnosed with a subarachnoid and right frontotemporal intracerebral hemorrhage as a result of a ruptured right middle cerebral artery aneurysm. Emergent neurosurgical intervention included a right frontotemporoparietal craniectomy, clipping of the right middle cerebral artery aneurysm, and partial hemispherectomy. Unfortunately, the patient's postoperative neurologic status deteriorated, and she was declared brain dead the following day. After discussion and coordination with the Living Legacy Foundation, her family graciously provided

consent for facial vascularized composite allgraft research procurement and multiorgan donation.

Preoperative Preparation

Before proceeding to the operating room, craniofacial computed tomographic angiography scanning was performed (Fig. 2), and computerized surgical planning was performed with Synthes ProPlan CMF (West Chester, Pa.)/Materialise (Leuven, Belgium) (Fig. 3). This information allowed simulated surgical osteotomy placement according to the planned defect of a potential recipient candidate. Concomitantly, our facial vascularized composite allotransplantation research procurement protocol was activated, mobilizing all members of the multidisciplinary surgical, anesthesia, transplant, anaplastology, and operating room support teams. We commenced with an open tracheostomy, and then turned the patient 90 degrees from the anesthesia team to facilitate simultaneous facial and multiorgan recovery.

Facial Impression and Silicone Mask

Before commencing the facial recovery, a silicone facial impression of the donor (Fig. 4) was performed, which allowed the anaplastologist to create a facial silicone mask simultaneously during the course of the procurement (Fig. 5). The impression took 30 minutes to perform, and the finalized mask was completed several hours later. This was ultimately placed on the donor's facial defect, providing a dignified return of the donor's remains to the donor's family, funeral home staff, and any other providers in contact with the donor before final resting placement.

Preoperative Fluorescence Angiography

Baseline perfusion of the proposed facial segment was evaluated by means of fluorescence angiography (LifeCell SPY Elite Imaging System, Bonita Springs, Fla.). After intravenous injection of indocyanine green, excellent perfusion of the entire facial allograft was documented, with the exception of predictable diminished blood flow evident in the area of the right frontotemporoparietal craniectomy incision.

Operation

The entire face, head, neck, chest, abdomen, and thighs were widely prepared and draped to allow for unrestricted access to both facial vascularized composite allotransplantation and solid organ transplant teams. Applying the experience gained from rehearsed cadaveric dissections outlined in another article entitled "Total Face, Double Jaw, and Tongue Transplant Simulation: A Cadaveric Study Employing Computer-Assisted Techniques,"[6] the same strategy was applied toward execution of the research procurement. The details of the research procurement and surgical approach may be found in the supplemental video included with this article. [**See Video, Supplemental Digital Content 1,** which provides details of the research procurement and surgical approach, ***http://links.lww.com/PRS/A537***. (Used with permission from Eduardo D. Rodriguez, M.D., D.D.S.)] A brief, yet complete synopsis of this operative endeavor follows.

Cutaneous markings were outlined taking into account aesthetic subunits and the previous craniectomy incision in attempts to avoid any notable compromised tissues (Fig. 6). Markings

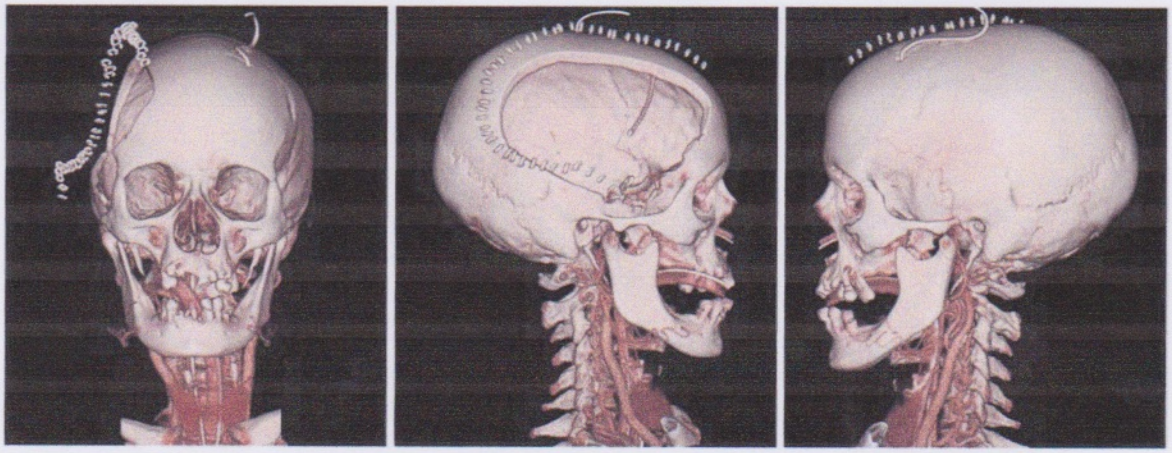


Fig. 2. Preoperative three-dimensional computed tomographic angiograms of the donor illustrating the vascular anatomy and a previous right frontotemporoparietal craniectomy.

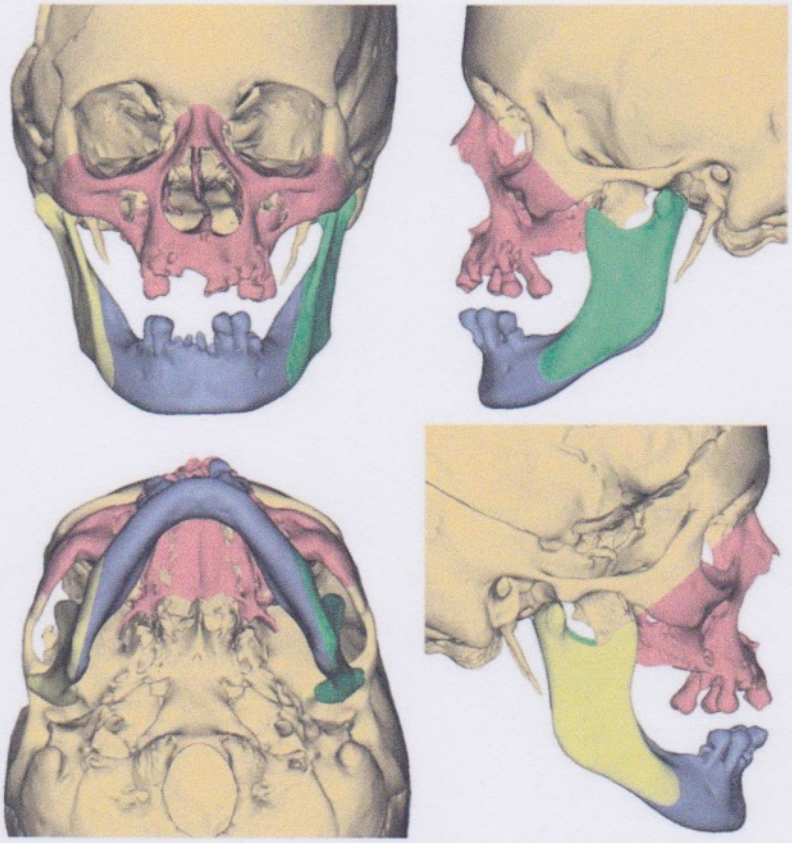


Fig. 3. Preoperative computer surgical planning of donor Le Fort III and mandibular osteotomies.

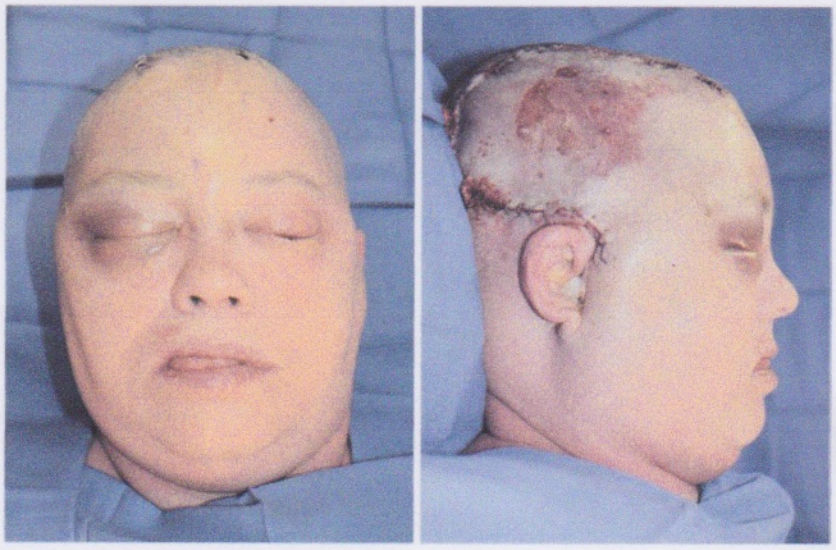


Fig. 4. Preoperative appearance of the donor showing previous craniectomy incision.

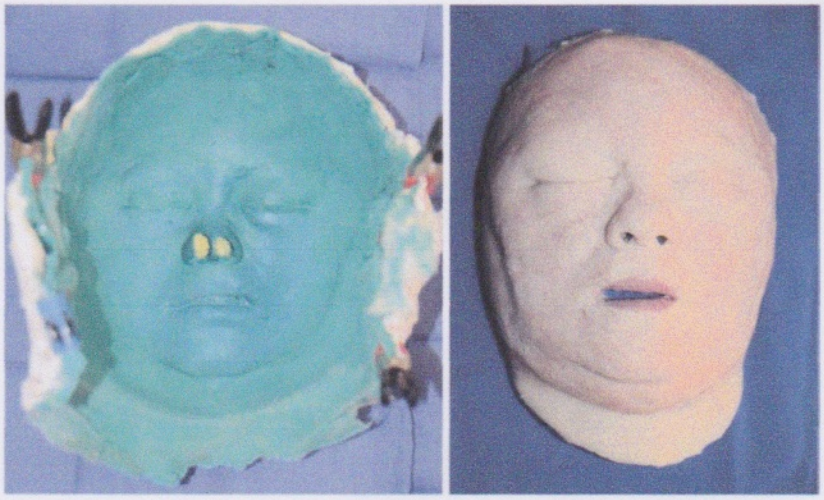
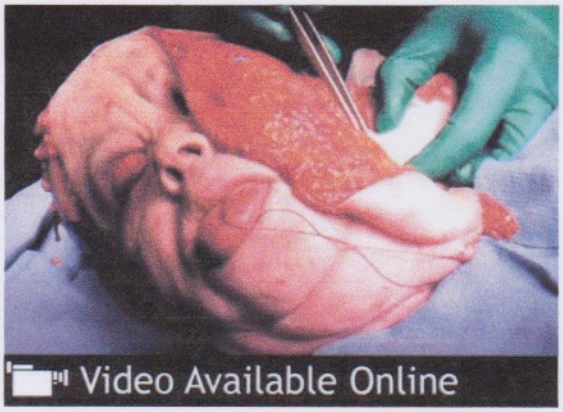


Fig. 5. A silicone impression of the donor face (*left*) was taken and used to make a silicone mask (*right*) for reconstruction of the donor facial defect.



Video 1. Supplemental Digital Content 1 provides details of the research procurement and surgical approach, ***http://links.lww.com/PRS/A537***. (Used with permission from Eduardo D. Rodriguez, M.D., D.D.S.)

along the pretrichial coronal line, preauricular creases extending to the neck and clavicles toward the sternal notch superior to the tracheostomy, and supraciliary and subciliary lines were made as reference. The initial neck incision proceeded laterally to the posterior extent of the sternocleidomastoid muscle, taking care to preserve the external jugular veins. This was then joined by the preauricular incision, allowing for elevation and wide exposure of the neck flap to facilitate sensory nerve branch preservation and access to the major neck vessels. Subsequent dissection of the carotid sheath allowed for more detailed dissection of the external carotid arteries and its branches. The lingual and facial arteries and the thyrolinguofacial venous trunks were identified and preserved.

Facial nerve anatomy was identified by elevation of the preauricular skin flap in a sub–superficial musculoaponeurotic system plane. Dissection was continued deep to the parotidomasseteric fascia, allowing identification of the facial nerve branches as they exited the parotid gland, with special attention taken to identify all divisions using intraoperative nerve stimulation. The identified facial nerve branches were marked individually with color-coded suture ligatures, divided proximally, and elevated with the facial flap.

Continuation of the dissection in a cephalad direction allowed for periorbital dissection by means of supraciliary and subciliary approaches. Periorbital tissue elevation proceeded deep to the orbicularis oculi muscle and arcus marginalis down to the infraorbital rim and then superficial to the levator mechanism to arrive at the supraorbital rim. The infraorbital nerve was liberated from its floor and foramen. Next, the pretrichial coronal flap was elevated in a subperiosteal plane to join the periorbital dissection and liberate the supraorbital nerves from their foramens.

The tongue dissection proceeded at its base with continuation to the previous neck dissection, with care taken to preserve the lingual vascular pedicles. The same approach was completed on the contralateral side. The completion of this dissection provided the requisite preparation for the mandibular bilateral sagittal split osteotomies and Le Fort III midfacial osteotomies (Fig. 7). By means of a combination extraoral and intraoral

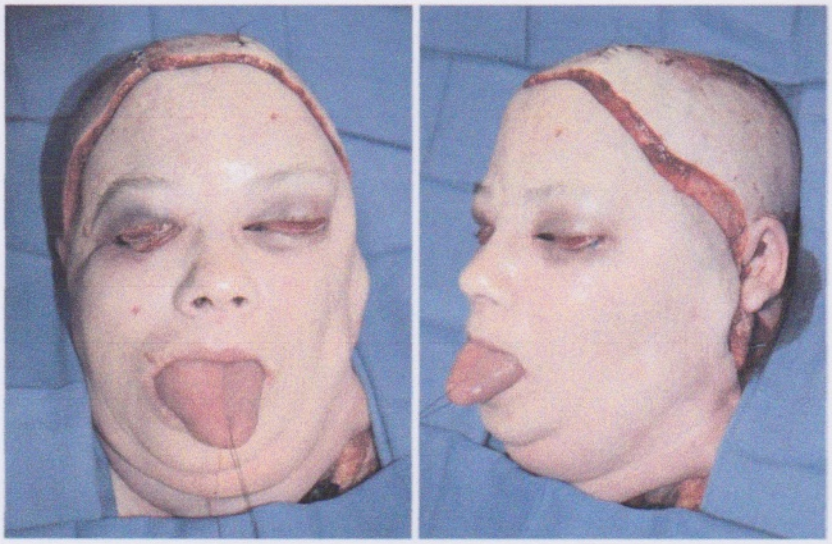


Fig. 6. Coronal, preauricular, neck, and eyelid incisions. Ideally, the coronal incision would have been located more posteriorly, but we were limited by the anterior extent of the previous craniectomy incision.

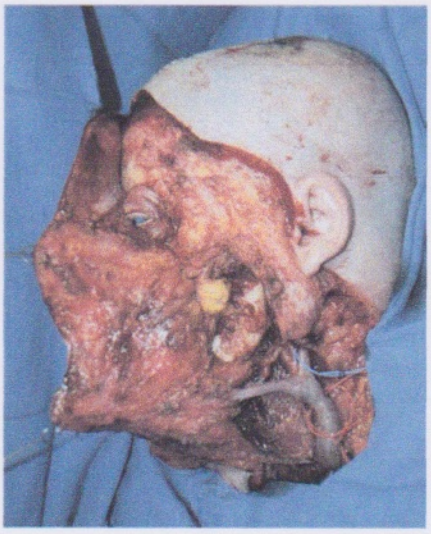


Fig. 7. Facial flap reflected revealing the vascular pedicles. The soft tissue has been elevated off the zygoma and mandible to allow adequate exposure for the Le Fort III and mandibular osteotomies.

approach, bilateral sagittal split osteotomies were performed, with preservation of the inferior alveolar nerves. The Le Fort III osteotomies were then completed, allowing for final division of the nasal septum and mucosal elements. At this point, the entire facial vascularized composite allotransplantation could be elevated based primarily on its vascular pedicles (Fig. 8).

Facial allograft perfusion was once again confirmed by means of fluorescence angiography. First, the right external carotid system was clamped selectively, and complete perfusion of the total face, double jaw, and tongue allograft was demonstrated (Fig. 9). Second, perfusion by means of both external carotid systems was allowed, again validating complete perfusion of the fully dissected and mobilized facial vascularized composite allograft.

Adequate donor urine output (0.7 ml/kg/hour) and oxygenation (arterial partial pressure of oxygen, 192 to 254 mmHg), stable blood pressure (mean arterial pressure, 70.1 ± 8.4 mmHg), and normal blood pH (7.30 to 7.35) were maintained throughout the research procurement. Seven liters of crystalloid, 9 units of packed red blood cells, 6 units of fresh frozen plasma, and 1 pooled unit of platelets were administered by the anesthesia team. An estimated 1500 ml of blood loss was recorded, the majority of which occurred during midface dissection and after the initiation of abdominal organ recovery (Fig. 10); however, hemoglobin concentration was maintained from 6.8 to 9.7 g/dl. Blood loss was exacerbated by a coagulopathy noted throughout the procurement with an international normalized ratio range of 1.7 to 2.2 and an activated partial thromboplastin time range of 36 to 47 seconds. Total facial vascularized composite allograft procurement time was 9 hours 59 minutes.

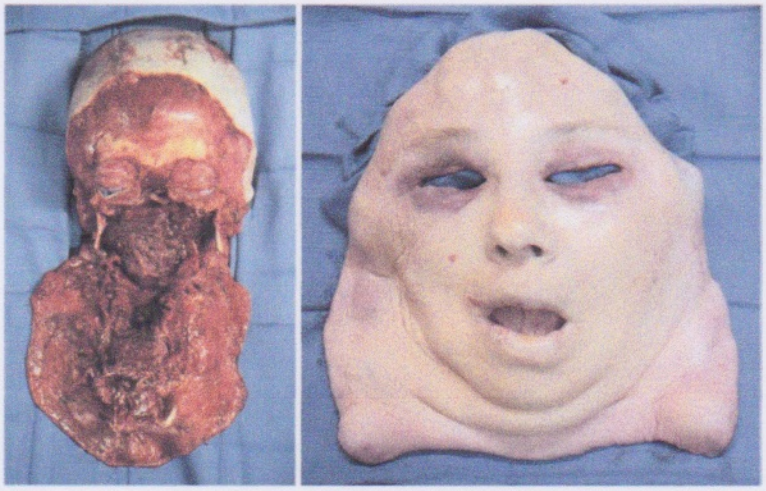


Fig. 8. Total face, double jaw, and tongue vascularized composite allotransplantation elevated before (*left*) and after (*right*) division of the vascular pedicles. Note the healthy appearance of the entire flap before pedicle division and the extent of the donor defect.

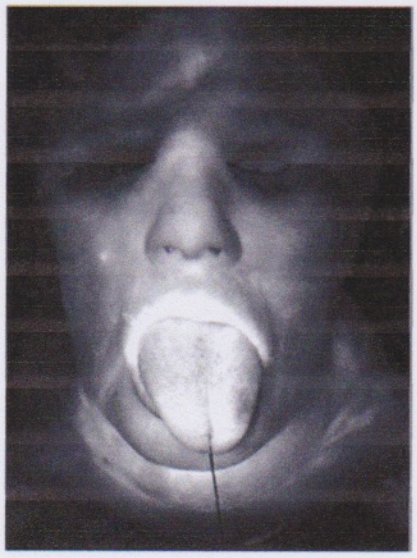


Fig. 9. Fluorescence angiographic image showing full perfusion of the facial vascularized composite allotransplantation segment based only on the left facial and lingual arterial pedicles and venous outflow by means of the left external jugular and thyrolinguofacial veins. Equivalent perfusion was observed based on the bilateral arterial and venous systems (image not shown).

DISCUSSION

Although facial transplantation is now a clinical reality, it is still a highly complex and laborious procedure with reported operative times ranging from 14 to 36 hours.[2,7,8] The complexity of such a procedure is evident by the combination of so many aspects of plastic surgical expertise. Therefore, it is clear that those centers arranging to move forward with such an endeavor must be thoroughly prepared for the challenges that lie ahead. Previous reports detailing the process of cadaveric facial vascularized composite allograft recovery are clearly documented in the literature.[9-11] In preparation for a facial vascularized composite allograft research procurement, 11 mock cadaveric face transplants were performed, with the final transplant being a real-time, two-team, two-operating room dissection performed with the perioperative personnel in the main operating rooms. The experience gained from the cadaveric dissections provided refinement of operative techniques and definition of the relevant anatomy, pertinent equipment, and requisite personnel. However, two critical questions remained unanswered based on cadaveric dissections alone. First, would it be feasible to procure such a large allograft without causing donor compromise or exsanguination before solid organ recovery? Second, would the facial and lingual arteries and venous outflow based on the thyrolinguofacial and external jugular systems be sufficient to provide perfusion of the cadaveric model facial vascularized composite allograft, particularly to the entire forehead, Le Fort III midface segment, and mandible? These specific questions motivated initiation of a research procurement based on the design of the rehearsed facial vascularized composite

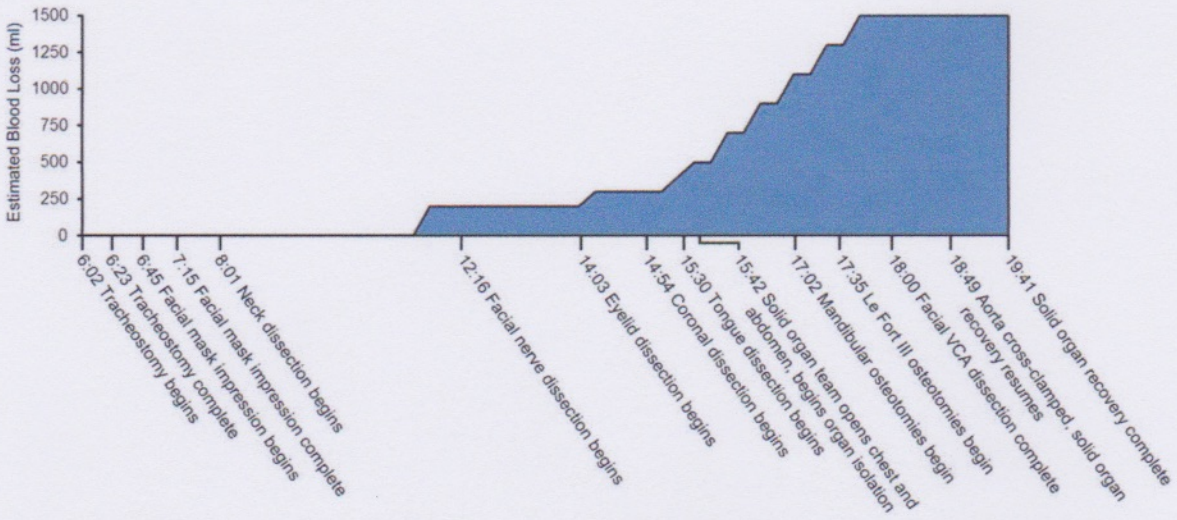


Fig. 10. Schematic showing cumulative blood loss throughout the procedure and critical time points. *VGA*, vascularized composite allograft.

allograft model. In addition, we wanted to closely simulate the procurement operation, including real-time stressors such as active blood loss and the need for coordination between the facial vascularized composite allotransplantation, solid organ transplant, anesthesia, organ procurement organization, and perioperative teams.

At the time of writing the clinical face transplant protocol (www.clinicaltrials.gov identifier: NCT01140087), we included a provision that our team would have the opportunity to perform up to three research procurements. Our institution's institutional review board determined that this did not require review; however, institutional review board approval to proceed with this educational endeavor was obtained from the Living Legacy Foundation of Maryland. On notification that a donor had been identified, we examined the face for suitability and obtained a craniofacial computed tomographic angiogram to delineate the relevant skeletal and vascular anatomy. We then coordinated with Synthes ProPlan CMF/Materialise to virtually plan the skeletal osteotomies, to assess the feasibility of computer surgical planning within the limited time span before the recovery. We had also arranged an activation protocol to ensure that necessary multiteam personnel were informed in sufficient time to organize and prepare for the clinical face transplant. This involved direct communication with all relevant team leaders, including perioperative staff, anesthesia, relevant hospital personnel, and facial vascularized composite allotransplantation and solid organ transplant teams. The research procurement provided a real-time opportunity to evaluate and ultimately streamline this process.

During this research procurement, the tracheostomy and facial impression were performed in the operating room. However, this process required nearly 2 hours, and we have therefore modified the process to perform these two procedures at the bedside, before the formal organ recovery. This modification will not only save time but will also consolidate the recovery procedure so that less burden is placed on the system.

At the R Adams Cowley Shock Trauma Center, our team routinely treats patients with severe craniofacial injury, often requiring multiple reconstructive procedures. However, the semielective nature of our procedures means that our typical patients are relatively hemodynamically stable. Conversely, facial vascularized composite allograft recovery often involves a critically ill patient who may be coagulopathic and hemodynamically unstable. The facial vascularized composite allotransplantation surgeon must appreciate the time-sensitive nature of the recovery procedure and recognize that tissues are more prone to bleeding, such that dissection techniques need to be expedited and modified to ensure hemostasis. For example, meticulous use of needle-tip electrocautery dissection should be preferred over sharp dissection to maintain a bloodless field. During the research procurement, the anesthesia team attempted to correct the donor's coagulopathy by means of transfusion of fresh frozen plasma; however, the international normalized ratio was

never fully normalized. Before performing our skeletal osteotomies, the solid organ transplant team was informed that we were about to initiate the portion of the dissection with the potential for greatest blood loss. With this in mind, the solid organ team accessed and isolated the aorta and the visceral organs of interest in preparation for an expeditious subsequent recovery, limiting potential warm ischemia time. At this point, the rate of blood loss began to increase because of diffuse oozing of both the abdominal and facial sites. When recovering a facial vascularized composite allograft concomitantly with solid organs, the surgical and anesthesia teams must be prepared for significant blood loss associated with concurrent dissection at multiple surgical sites in a coagulopathic donor. Despite challenges with blood loss, we were able to complete recovery of a full osteomyocutaneous facial vascularized composite allograft in approximately 10 hours, without donor decompensation or compromise of solid organ function.

Previous descriptions of donor operations for clinical facial transplantation have noted inadequate space at the operating table to allow both facial vascularized composite allotransplantation and solid organ recovery teams to work concurrently.[12] However, our experience has confirmed that such teams can work together simultaneously with a well-coordinated and well-communicated approach (Fig. 11). In fact, several hours before the completion of the facial vascularized composite allograft dissection, our solid organ transplant colleagues were able to begin abdominal organ isolation, allowing our team ample time to complete the procurement in a controlled and safe fashion. In having done this, we preemptively planned for possible clinical deterioration of the donor and ensured that all solid organs could still be recovered quickly without compromising their viability. It is also valuable to note that the facial and solid organ transplant surgeons were understandably skeptical about concomitant recovery. However, after completion of the procurement,

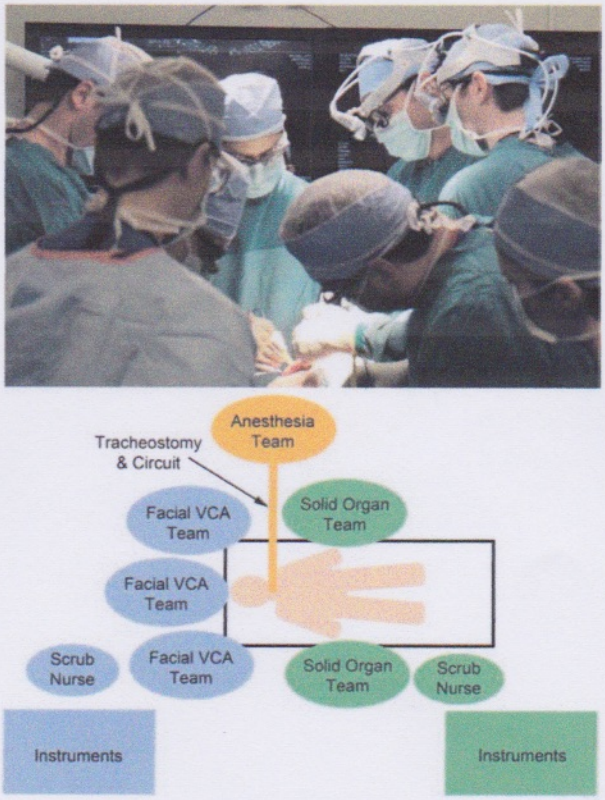


Fig. 11. Intraoperative view of facial vascularized composite allotransplantation and solid organ transplant teams (*above*) operating concurrently and schematic outline of operating room setup (*below*).

we were pleased to note that the solid organ team was satisfied with the outcome and also inquisitive and supportive. Such support from our solid organ transplant colleagues was not only critical for the realization and ultimate success of the research procurement but also the future success of all facial vascularized composite allograft procurements.

Our facial vascularized composite allotransplantation model is intended to reconstruct a typical central demolition pattern of ballistic facial injury, representing one of the most extensive facial segments described to date. Based on prior cadaveric dissections delineating the maxillary blood supply, our team and others previously believed that the maxillary artery was required for perfusion of a full Le Fort III maxillary segment.[9,11] However, a rich anastomotic system exists between branches of the facial and maxillary arteries, allowing the entire Le Fort III midface segment to survive based on the facial arteries alone.[13] This concept was confirmed by fluorescence angiography, showing adequate perfusion of the maxillary bone and palatal tissues based only on facial arterial pedicles. Beyond this, there has been no clinical evidence to prove that a full osteomyocutaneous facial allograft, such as the one described in our research procurement, can be perfused by a single facial artery.[1] During the research procurement, the right facial and lingual arteries were temporarily occluded, leaving the facial vascularized composite allograft perfused by means of the left facial and lingual arteries alone. Complete perfusion of the allograft was then confirmed with fluorescence angiography. Although our vascularized composite allograft also included the lingual arteries required for tongue perfusion, this clinical evidence suggests that sufficient perfusion of a full osteomyocutaneous facial vascularized composite allograft can be maintained based on a unilateral arterial pedicle.

The estimated cost of a clinical face transplant has been quoted in the literature to be approximately $350,000.[14] This becomes important as one considers the cost of a research procurement. Such costs should be accounted for by the centers establishing facial vascularized composite allotransplantation programs or by the institutions supporting such endeavors. Although this is not insignificant, lessons learned from such an exercise may ultimately prove valuable, provide improved clinical outcomes, and reduce overall costs.

Moore has used the terms "field strength" and "institutional climate" in discussion of centers performing innovative surgical procedures.[15] At the R Adams Cowley Shock Trauma Center and University of Maryland School of Medicine, we have proven success in treating a high volume of patients with severe craniofacial injury. This is the type of "field strength" that is required before establishing a clinical face transplant program. In performing a facial vascularized composite allograft research procurement, we were able to strengthen our "institutional climate" by having all necessary multidisciplinary teams on board to proceed with clinical face transplantation. We believe that similar research procurements may assist other institutions hoping to establish facial vascularized composite allotransplantation programs to improve their own institutional climates.

CONCLUSIONS

The insight gained from a facial vascularized composite allograft research procurement will offer dedicated centers the ability to optimize facial vascularized composite allotransplantation outcomes, preserve solid organ allograft function, and avoid potential graft compromise during recovery. The long-term success of this burgeoning process is dependent on the dedicated commitment to create reproducible and reliable educational programs.

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PATIENT CONSENT

The patient provided written consent for the use of her images.

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Plastic Surgery Level of Evidence Rating Scale—Diagnostic Studies

Level of Evidence	Qualifying Studies
I	Highest-quality, multicentered or single-centered, cohort study validating a diagnostic test (with "gold" standard as reference) in a series of consecutive patients; or a systematic review of these studies
II	Exploratory cohort study developing diagnostic criteria (with "gold" standard as reference) in a series of consecutive patient; or a systematic review of these studies
III	Diagnostic study in nonconsecutive patients (without consistently applied "gold" standard as reference); or a systematic review of these studies
IV	Case-control study; or any of the above diagnostic studies in the absence of a universally accepted "gold" standard
V	Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or "first principles"

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