

# Overview of Guidelines for Establishing a Face Transplant Program: A Work in Progress

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Since 2005, nine face transplants have been performed in four countries: France, the United States (US), China and Spain. These encouraging short-term outcomes, with the longest survivor approaching 5 years, have led to an increased interest in establishing face transplant programs worldwide. Therefore, the purpose of this article is to facilitate the dissemination of relevant details as per our experience in an effort to assist those medical centers interested in establishing a face transplant program. In this article, we address the logistical challenges involved with face transplantation; including essential program requirements, protocol details, face transplant team assembly, project funding, the organ procurement organization and the corner. It must be emphasized that face transplantation is still *experimental* and its therapeutic value remains to be validated. All surgical teams pursuing this endeavor must dedicate an attention to detail and should accept a responsibility to publish their outcomes in a transparent manner in order to contribute to the international field. However, due to its inherent complexity, facial transplantation should only be performed by university-affiliated medical institutions capable of orchestrating a specialized multidisciplinary team with a long-term commitment to its success.

**Keywords:** Composite tissue transplantation, composite tissue allograft, face transplant, IRB protocol, recovery process, team assembly

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## Background

On November 15, 2004, we were granted the world's first IRB approval for human face transplantation (1). Nearly 1 year later, the first successful face transplant was performed on November 27, 2005, in Amiens, France (2). Currently, a total of nine face transplants have been performed in four countries: France, the United States (US), China and Spain (3–5) (Table 1).

There are undoubtedly many institutions worldwide planning to establish composite tissue allotransplantation (CTA) centers in the near future capable of performing facial transplantation (6,7). Unfortunately, different countries require inconsistent protocols/approvals through an assortment of various government agencies. Therefore, providing a simple, generic recipe for program establishment would be both misleading and simply impossible. In addition, none of the previous publications on facial transplantation effectively describe the optimal sequence, timing and steps required for obtaining an IRB-approved face transplant protocol and/or establishing a program (8,9).

The complexity of establishing the face transplant program goes far beyond performing the actual surgery. In this article, we describe the pretransplant requirements, such as the logistics of organizing a team, essential program requirements, IRB protocol details, project funding, the organ procurement organization (OPO) and the corner. Although this overview may be more applicable to the U.S.-based institutions, we hope that these blueprints for building a program will have worldwide application and be of significant interest to many plastic surgeons pioneering this new transplantation procedure in their respective countries.

## Pretransplant Phase

### Essential program requirements

It is intuitive that any medical institution assembling a facial allotransplant program should undoubtedly consider this project to be a long-term dedication of multiple decades and one that needs significant time, money and manpower prior to seeing fruition. It would be naïve to think that hiring a single staff member familiar with microsurgery and/or interest in CTA simply translates into a successful, blossoming program. More importantly, in the best interest of the patients, a detailed plan should be in place given the unforeseen circumstance a team leader moves or retires.

In our experience, this project should be assessed by months and years, and not by hours and weeks. There are multiple checkpoints of success throughout this process prior to one entering the operating room, which begins with team assembly, IRB-protocol approval, patient evaluations, patient selection and numerous tailored mock cadaver transplants (Table 2).

**Table 1:** Recent timeline of the world's first eight face transplants

Transplant Date	Indication	Place	Team
November 2005	Dog bite	France	Dubernard et al.
April 2006 <sup>1</sup>	Bear attack	China	Zhang et al.
January 2007	Neurofibromatosis	France	Lantieri et al.
December 2008	Gunshot blast	Cleveland, Ohio	Siemionow et al.
March 2009	Gunshot blast	France	Lantieri et al.
April 2009	Burn	Boston, Massachusetts	Lantieri et al.
April 2009 <sup>2,3</sup>	Fall/electrical injury	France	Pohamac et al.
August 2009 <sup>4</sup>	Cancer resection	Spain	Cavadas et al.

<sup>1</sup>Expired June 2008, 2 months posttransplant.<sup>2</sup>Concomitant bilateral hand transplant.<sup>3</sup>Expired July 2009, 2 years posttransplant.<sup>4</sup>Concomitant tongue transplant.

We feel that one of the key requirements for success is that the transplant program be affiliated with a university hospital. This includes collaborating with an active, productive basic science laboratory that accelerates both the institution's facial CTA program, as well as contributes to the overall advancement of the international field (10–17).

Also, each hospital considering this endeavor must be capable of assembling a team available at *all* times 7 days a week. Utilizing a broadly based cross-coverage schedule allows one to incorporate a talented network of reconstructive microsurgeons, craniomaxillofacial surgeons, transplant surgeons, infectious disease specialists, transplant psychiatrists/psychologists and immunologists. Each team member is *equally* valuable and all of those involved should mentally prepare for an extremely large time commitment, since postoperative management will be challenging and unprecedented (18). The team leader should be well familiar with all of the technical, immunological and legal aspects of CTA, along with this specialty's historical developments and future directions (19,20).

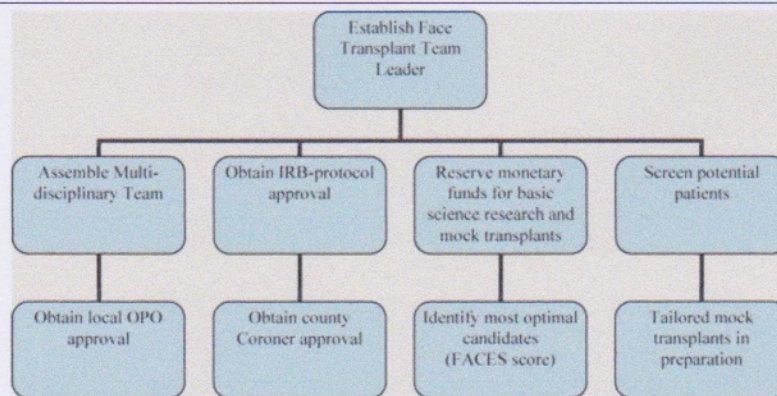
#### **Institutional review board (IRB) protocol**

Obtaining an IRB-approved face transplant protocol is a unique, complex process that can easily and quickly be-

come overwhelming and frustrating. It requires perseverance and a significant time commitment of 1–2 days/week. The principal investigator (PI) of the IRB protocol is most likely to become the FTT team leader and his/her collaborators will need to also reserve 1–2 days of nonclinical time each week to help work on establishing the protocol.

Besides having to detail the three critical phases of face transplantation (pre-, peri- and posttransplant) from start to finish, he/she needs to provide the IRB with acceptable donor and recipient consent processes, which will also be equally challenging. Reason being is that any IRB in the United States needs to be in agreement of two important distinctions. The first is to make sure that the subject's overall risk is 'reasonable' in relation to the anticipated benefit and that the important knowledge gained is 'reasonably expected'. Second, the IRB must be assured that adequate informed consent will be obtained. These are two separate, but tremendously important, requirements (21).

The team leader should expect to attend a multitude of IRB-required meetings, respond timely to the committee members' questions, and provide scientific evidence to

**Table 2:** Proposed checkpoints for establishing a face transplant program

**Table 3:** Modified Gordon CTA classification system based on relative complexity<sup>1</sup>

Type	Complexity	Allografts	Characteristics
I	Low	Flexor tendon Tongue Uterus Vascularized nerve	1. Absent skin 2. Reduced antigenicity
II	Moderate	Abdominal wall Facial subunit (ear) Genitalia (penis) Larynx Scalp Trachea Vascularized joint (knee)	1. Contain skin 2. Absent or less challenging rehabilitation
III	High	Upper extremity (hand) Face	1. Requires multidisciplinary transplant team 2. Complex rehabilitation 3. Significant psychological obstacles 4. Complicated cortical reorganization
IV	Maximum	Concomitant CTA -Face/hand(s) Face/tongue	1. High mortality risk 2. Extremely difficult rehabilitation

<sup>1</sup>(Siemionow M, Zor F, Gordon CR. Face and upper extremity transplantation: Future challenges and potential concerns. *Plast Reconstr Surg* 2009; in press).

justify the protocol details. In the end, an estimation of 1 to 2 years seems to be a safe presumption for how long the start-to-finish time will entail. However, the sole exception being that if your institution already has a current hand or abdominal wall transplant IRB-approved protocol, then your approval process will be somewhat streamlined.

### Assembling the team

Once the IRB-protocol has been finalized, the team leader should (1) act as an architect and design a project timeline with a tentative sequence of steps and (2) assemble accordingly an experienced team of experts capable of performing the task at hand. We recommend choosing a team leader established in the field of CTA and one that is devoted to a life-time commitment, since he/she should possess a passion to succeed and the capability to lead and motivate.

As published recently, this innovative, experimental surgery is still in its infancy stage and is extremely complex in relative comparison to other CTA subtypes such as abdominal wall, as defined by our recently modified classification system (22) (Table 3). Therefore, facial transplantation should *not* be simply seen as another challenging reconstruction case. Plastic surgeons must envision this procedure analogous to an organ transplant with distinct indications and contraindications, and not as an additional rung on the reconstructive ladder (23).

We suggest establishing a sizeable, overlapping surgical team in the range of 6 to 10 staff surgeons, whose members are wholeheartedly devoted to the project. A complete combination of craniofacial- and microsurgical-trained

plastic surgeons is ideal, with a potential need for adding an ENT/head and neck surgeon.

In preparation for 'The Big Day', all surgical team members should be required to participate in a series of mock, fresh-cadaver facial transplants (for our team, the early weekend mornings were most accommodating) and practice exercises to ensure all details are complete. These invaluable mock transplants should come with mandatory attendance, since they are crucial for both defining each surgeon's role and for perfecting the team's surgical chemistry in an effort to decrease potential delay and complication (24–27). In the interim, your program's team leader and members should meet and present the protocol to various hospital ICU staff, anesthesiology staff, OR nurse manager(s) and surgical intensivist(s) as a means of perfecting timely execution and understanding of procedure complexity.

**The ancillary staff members:** Unquestionably, a diverse team is needed for an optimal outcome. The world's finest reconstructive transplant surgeons could not perform successful face transplants if it were not for the right ancillary support. A large responsibility is delegated to a wide variety of surgical colleagues and nonsurgical staff, which includes a face transplant coordinator, transplant surgeon, transplant immunologist, transplant infectious disease expert, social worker, ethicist and transplant psychiatrist/psychologist (18).

**Face transplant coordinator:** The team leader needs to select and assign a knowledgeable face transplant coordinator (FTC). This person must be well informed as to the intricacies of face transplantation and should be

either a physician, physician's assistant or registered nurse. The true magnitude of this role cannot be underestimated. Their duties involve pre- and posttransplant coordination, aiding tasks such as candidate screening, coordinating all transplant-related activities, overseeing test results and prescription compliance, and helping to arrange follow-up care (main transplant hospital vs. patient's local hospital).

For the first three posttransplant months, the FTC is on-call '24/7'. A 'back-up' FTC system may be needed in some cases. Responsibilities include monitoring/ presenting daily drug levels and/or lab work since obvious abnormalities are of utmost importance and need to be confirmed by the FTC. Having a central figure in the middle of a large multidisciplinary team will theoretically increase communication efficiency and decrease the chance of miscommunication and/or wasteful duplication. Also, since most face transplant recipients will reside at a far distance from your university hospital, the FTC will arrange posttransplant monitoring via nearby hospital-subsidized housing for the first 2–4 months posttransplant. Scheduling and coordinating periodic follow-up visits are also his/her responsibility.

The FTC should prearrange a 'satellite' medical team for all FT patients living at a significant distance from the hospital. This satellite team, which should obviously be in close proximity to the patient's primary residence, includes a surgeon (preferably a plastic, ENT or transplant surgeon), an internist and a physical therapist. This is of tremendous value to the patient if for some reason the FTT wants to request a tissue biopsy, medical exam and/or alter any specific facial physical therapy (20).

**Medical management:** During the first year, between months 3 and 12, face transplant patients are to be followed closely by the team leader in line with each institution's approved treatment protocol. Postoperative care should include consultations to transplant immunology, infectious disease and transplant psychiatry/psychology at the main hospital where the allotransplant was performed. During months 13 to 24, visits should be held quarterly and then every 6 months starting in the third year, unless there are intermittent signs of rejection and/or other transplant-related health problems. In addition, the PI will orchestrate all nonsurgical visits and medical exams as needed. Routine visits to the patient's primary physician are also encouraged and close relation should be developed with the PI of the IRB protocol to coordinate patient care (9).

**Social worker:** A transplant social worker is also assigned to the FTT. Their involvement is critical for the patient's social adjustment pre- and posttransplant. Their responsibilities include: evaluating the patient's social/family support, current health insurance coverage, occupational status, potential for return to work after transplant or need for job change/re-education. In addition, the social worker may

help to facilitate contact with a lawyer if any legal issues arise either before, during or after surgery (18).

**Patient advocate:** It is strongly recommended that all potential candidate(s) assign either a family member or trustworthy friend/lawyer to act as their 'patient advocate'. Their role is similar to a 'power of attorney', and involves deciding the patient's needs in certain instances during the entire process of facial transplantation. Of interest, the Royal College of Surgeons' guidelines also suggest that each candidate meet with other patients successfully managed by nontransplant, modern-day, facial reconstructive technique, which may be most relevant for pan-facial burn patients (19).

**Medical ethics:** An ethics committee is consulted for all related ethical questions, as they may pertain to pre- and postfacial transplantation. The role of the team bioethicist is to assess, identify, and investigate the patient's motivation and understanding of the procedure, discuss his/her perception of the risk-versus-benefit ratio of transplantation in exchange for life-long immunosuppression with its unavoidable side effects. The ethicist should also discuss the experimental aspect of the face transplantation and emphasize the fact that the final outcome cannot be fully predicted (28).

**Transplant psychiatry/psychology:** A transplant psychiatrist/psychologist is assigned to the FTT. His/her responsibilities include performing pre- and postoperative assessments of the candidates and as required, oversee and provide treatments including psycho-pharmacological therapy, psychotherapy and/or chemical dependency treatment. Beginning with their initial interview, the potential candidate undergoes emotional/cognitive evaluation for transplant potential, assessment of his/her decision-making capacity, and Thematic Apperception testing. Family support in combination with the candidate's socioeconomic status is investigated in order to identify their entire social support system, which may play a crucial role as to the transplant's success. Of significant concern, is their medical compliance history, which includes degree of motivation, realistic expectation, potential for psychological regression, perceived body-image adaptation and anticipated comfort with donated facial allotransplant (18,29).

Prophylactic social/family/marital interventions should be planned and an introductory transplant education should be provided. Psychological assessment of self-esteem, quality of life and body image should be performed using standard 'quality-of-life' measures. The inclusion of an experienced transplant psychiatrist/psychologist will minimize potential psychiatric morbidity throughout the entire process, by aiding the recipient in reintegrating their 'new' face both physically and psychologically. Psychosocial postoperative assessment is mandatory and should be conducted daily for the first 2–3 months, followed by a monthly rotation for the completion of the first

posttransplant year. For the second year, the rotation may be decreased to a minimum of every 3 months and then biannually thereafter. The importance of diagnosing post-transplant depression cannot be understated, and should raise great cautionary measures since failure to comply with immunosuppression and/or rehabilitation will inevitably lead to failure, as witnessed with the world's first-hand transplant and second face transplant patients (3,18).

**Physical therapy and rehabilitation:** Physical therapy and speech therapy to perfect facial muscle reeducation are essential for obtaining optimal functional outcomes. A designated physical therapist and speech therapist should be heavily involved with the patient's cortical reeducation process from day 1 after transplant. It is essential that the patient be religiously compliant with his/her facial muscle exercises and speech therapy based on their individualized regimens. Access to a private gym, treadmill and stationary bike will motivate the patient to continue physical therapy and may ultimately speed up the posttransplant recovery (9).

**Institutional media:** All interactions with the media are a collaborative effort between the FTT and a designated representative from the institution's Public Relations department. For patient safety and confidentiality, a media representative should meet with patient before and after transplant to discuss his/her level of willingness to disclose or conceal personal details during interactions with public media. In the early posttransplant period (<1 year), every effort should be made to conceal the patient's identity. For some programs, it may be prudent to admit face transplant candidates to the hospital using an alias, in order to allow full adherence to current privacy (i.e. HIPPA) regulations and to provide optimal protection from the press.

In our experience, an early meeting held between the FTT and the hospital's Public Relations (PR) office at the time of recipient identification is prudent for many reasons. This allows a team-designated PR individual (preferably one at the senior level with significant experience) to help schedule and attend all press conferences, personnel interviews and any other public media sessions. It should be well explained to the patient, as well as to the public media, that all photographs and videos relating to face transplantation are the property of the institution, and that they *must* receive written approval from both the FTT and the hospital prior to any public release (especially since FT will be confined to the ethics of your institution's IRB protocol). It should also be clear that *no* financial commitments with any outside agencies can be made for any transplant-related materials (9).

**Security:** During the immediate posttransplant time period, all patients should be provided with private rooms isolated from the mainstream hospital access. In our experience, providing 24-h security at the front entrance of

the patient's room provides an additional layer of privacy protection.

### **Funding**

The overall cost attributed to face transplantation is dependent on a variety of factors, such as the geographic location for which the surgery is performed (i.e. county, state or country). When compared to hand transplantation, for example, its overall cost-per-patient is slightly greater, and may in fact range from \$250,000 up to \$1,500,000 (20). This gross estimation includes the complete cost of surgery (each surgeon's time and billing), an average stay of 2–3 weeks in the ICU, an entire hospital stay of 2–4 months, hotel room expenses thereafter (approximately 3–6 months), all related transplant medications, pertinent monitoring labs/biopsies and rehabilitation therapy.

At this time, since this surgery is still considered 'experimental', the inpatient bill will be, for the most part, *not* covered by the insurance company and therefore all costs are absorbed by the hospital. This financial deficit can, however, be offset by a combination of endowments, research grants and/or departmental funds. Periodic and all unexpected posttransplant procedures during the first-year posttransplant, such as skin biopsies, lab tests and rejection therapies, are usually covered by insurance since they fall under 'medical necessity'. As for mandatory rehabilitation therapy, an adjusted cost schedule is provided to the recipient after 90–180 days depending on his/her medical insurance coverage and financial status. We recommend applying for, depending on your state's individual legislation, full medical coverage of the patient's posttransplant care since many states provide unlimited 'transplant' benefits (i.e. kidney and liver transplant patients). Additionally, it may be prudent to contact the pharmaceutical companies to see if they will provide immunosuppression cost-free by way of an industry-sponsored grant (20). More importantly, it would be unethical to perform such a procedure unless future provisions for postoperative rehabilitation and immunosuppression were allocated.

### **Organ procurement organization**

The support of your institution's local OPO is essential for success, however, the entire process of obtaining OPO approval is lengthy and may be quite challenging. Under the federal system, OPOs are designated to a specific geographic region and must be 501C3 charitable nonprofit organizations. Each hospital is assigned to work with one particular OPO thereby limiting the options of a new face transplant program. Furthermore, donation/transplantation of 'organs' involves a complex process overseen and coordinated by multiple organizations established through the direction of the U.S. government; including the U.S. Department of Health and Human Services, the Organ Procurement and Transplantation Network, the United Network of Organ Sharing, the Health Resources Services Administration and the Centers for Medicare Services (30).

## Guidelines for Establishing Face Transplant Program

The main role of the OPO is to oversee and coordinate the allotment of all donated organs, and therefore it is essential that any hospital entertaining face transplantation consult their OPO early on in the process as we did 2 years prior to IRB approval. Once the IRB protocol for face transplantation is approved by your hospital, it creates a basis for filling specific research protocol requests with your hospital-affiliated OPO. The PI or team leader is responsible for protocol presentation and if requested, an oral presentation at the OPO's Medical Board meeting may be quite valuable. Numerous meetings between the PI and the OPO's director/staff will be necessary for pertinent education about the logistical timeline during the day of surgery, as well as overall goals in identifying and recovering a facial allotransplant (9).

Each OPO-employed transplant coordinator should use a CTA-tailored algorithm when approaching all potential donor families for facial organ donation. In summary, the vital organs such as the liver, kidneys, pancreas, heart and lungs are discussed early on in the process so that facial tissue donation does not interfere with requesting life-saving organs and tissues (31).

Interestingly, in some particular instances, the living recipient is a human subject and falls under the federal IRB regulations, but the donor, however, is not. Therefore, the IRB may or may not be approving the consent form based on the legal requirements of the institution or country. This also raises important logistic steps since the donor may or may not be deceased at the hospital where the protocol is approved, and therefore donor transfer needs to be prearranged accordingly. This may limit a programs' donor pool unless one has a large health system analogous to the Cleveland Clinic Health System (includes nine community hospitals).

Once supported by your local OPO, concise guidelines for the transplant coordinators working at affiliated hospitals should be established. Educational gatherings and presentations by various FTT members are then scheduled to facilitate full understanding of the complexity of the surgical procedure and for presentation of eligible candidates pursuing facial transplantation. We found it valuable to provide a short personal description (one paragraph) of the listed recipient (while at the same time limiting exact details so as to protect the recipient's identity) and how the donated facial organ would conceivably aid his/her reintegration into society. In retrospect, this seemed to greatly aid the transplant coordinator in his/her quest to obtain facial organ donor consent, given the large amount of public uncertainty related to facial transplantation.

### **Role of coroner**

The county coroner in your area (or medical examiner in some instances) is responsible for overseeing all deceased human bodies. If foul play is suspected as to the etiology of death or if the patient is a minor (<18 years old), the body

is immediately placed into the possession of the county coroner until an official autopsy has been completed. Otherwise, an accelerated process is undertaken and the body is placed into the custody of either the funeral home and/or the hospital morgue.

In our experience, multiple meetings at the coroner's office were necessary for the establishment of a protocol for interhospital brain-dead donor transport. Each protocol will differ if perhaps donor transport is within the county or if donor consent is obtained at a community hospital within the same health system. Finally, different approvals are required when donor transport crosses a state border, which entails the local coroner office having to contact the coroner's office of the state where donor consent was originally signed. Full logistical understanding beforehand will expedite this complicated process.

Exact details should also be preestablished for medical transportation (i.e. ground vs. airplane). An ICU physician should be preselected to serve as the accepting staff for the transfer of the beating-heart, brain-dead facial organ donor (preferably admitted to a neurosurgical ICU). We recommend using a different primary attending and separate surgical ICU for the recipient's direct admission, so that the two families (donor and recipient) are not coinciding prematurely. By having both patients in the same locale, concomitant recovery of the donor's facial organ along with the recipient's preparation for transplantation can be done efficiently in neighboring operating rooms. Obviously, this is of tremendous value, since many times preparation of the recipient's craniofacial defect overlaps with the time needed to recover the donor alloflap. This particular process can be quite intricate in detail and adjustments to your original surgical plan may be required (24,25). Therefore, having the option of various surgeons walking between the two operating rooms for the purpose of observing each other's simultaneous progress is invaluable.

## Conclusion

Face transplantation has progressed tremendously since the first partial allotransplant was performed by Dubernard et al. in 2005 (2). A total of nine patients have since followed and the results have been relatively successful. Early postoperative reports regarding aesthetic and functional outcomes are promising (3). However, two recent face transplant-related deaths highlight the importance of patient selection and compliance with regards to immunosuppression, extreme psychological stability/social support, aggressive rehabilitation therapy and constant patient motivation to succeed (8,9,32). Complete evaluation of the current face transplant outcomes and further research pertaining to face transplantation, in areas such as bioethics and immunology, are undoubtedly warranted prior to anyone considering this surgical procedure as *nonexperimental*.

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