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A multidisciplinary protocol for face transplantation at Brigham and Women's Hospital

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Summary Face transplantation introduces an unprecedented potential to restore form and function in patients with severe facial disfigurement. A successful face transplantation programme requires a sound research protocol, a solid infrastructure, expert personnel and adequate funding. There are only a few active face transplant programmes in the world and interest in the development of new such programmes continues to grow. After 2 years of working on the development of the face transplant programme, in 2009 the team at Brigham and Women's Hospital (BWH) performed the 2nd face transplant in the United States. Since then, the team has continued to evaluate several possible face transplant candidates and performed three additional facial transplants. These experiences have helped refine a highly effective multidisciplinary protocol that carries a patient through recruitment, informed consent, screening, preoperative planning, face transplantation surgery and postoperative long-term follow-up. The members of the BWH face transplantation team responsible for carrying out this protocol include a team leader, a programme manager/coordinator, clinical and rehabilitation specialists, social workers, bioethicists, nurses and administrative staff. The roles of each team member during the various stages of the face transplant process are presented here. Additional insight into the interaction between the face transplant team, the Institutional Review Board and the regional Organ Procurement Organization is given. The BWH team's experience has shown that true collaboration, creativity and a unique approach to each candidate translate into the optimal care of the face transplant patient both before and after surgery.

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Face transplantation (FT) has unprecedented potential to restore the most devastating facial defects. Where staged conventional reconstruction has limited success, FT replaces the damaged facial parts with functional and

aesthetic equivalents from a human donor in a single major procedure.

An FT programme requires an Institutional Review Board (IRB)-approved protocol, personnel, equipment and

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funding. Establishing an FT programme in the United States involves successful collaboration between a strong project leader, a managed multidisciplinary team, an IRB and an Organ Processing Organization (OPO).¹ Guidelines for establishing an FT programme have been described by one group.^{2,3} A few FT programmes are active in the United States, and others are under development. Each differs in policy and protocol. The disclosure of these differences and their rationale, along with each centre's experience to the medical and patient communities will promote the safe and timely evolution of clinical FT.

The BWH FT programme

The FT programme at BWH has a project leader who is a plastic and reconstructive surgeon (PRS) with high interest in clinical research, full belief and wholehearted dedication to FT.¹ The team leader must be a strong communicator and motivator and fulfil the responsibilities outlined in Table 1. In addition, he/she is routinely involved in the treatment of patients who may benefit from FT, and thus understands the functional, aesthetic and psychosocial consequences of severe facial disfigurement. The BWH programme also has a full-time project manager who is intimately familiar with and participates in almost all stages of the FT protocol (Figure 1, Table 2). He/she interfaces with the IRB and OPO and works closely with the team leader to liaise all of the different programme components. He/she ensures adherence to protocol, timelines (Figure 2), and smooth progress. A manager can be a very valuable asset for a team leader with a heavy clinical load, as long as there is frequent and effective communication.

In the US, every research project involving human subjects must be overseen by an IRB. The IRB guards the safety, privacy and confidentiality of human research subjects. The FT team must work extensively with the IRB

to develop a safe protocol. The process can be challenging because FT is perceived as having a high level of risk. From the IRB's perspective, the major issues of FT are that it binds patients to the research protocol and to the institution for the remainder of their lives, and they are followed by critics, media, the medical community and the general public. Our FT team worked with the IRB to ensure that the final protocol was in best alignment with the safety and privacy of our patients.

The BWH's administration and leadership is involved in many crucial elements of the FT programme. The administration has assisted the team in securing initial funding, establishing an agreement with the regional OPO, interacting with the media, providing legal counsel, maintaining patient's privacy, security and confidentiality, ensuring third-party coverage of post-transplant follow-up and immunosuppression and assisting out-of-town patients with lodging. The FT programme at BWH is supported by a research contract; the research finance and administration departments help properly allocate and invoice the expenses associated with the programme and provide infrastructural support.

The FT team at BWH was developed over approximately 2 years. IRB approval was obtained to perform FT in adults with partial facial defects larger than 25% of the facial area and that included important central facial unit(s) such as the nose, lips and eyelids. The first partial FT surgery under the approved protocol took place in April 2009, and in October 2009 we entered into a research contract with the Department of Defense's Biomedical Translational Initiative to perform an outcome-oriented study of 5–10 FTs. Since then, we expanded both the patient population to include patients with full facial defects and the donor pool by including deceased-by-cardiac-death in addition to heart-beating donors and by establishing agreements with additional OPOs. We are actively enrolling patients and recently performed the first three full facial transplantations in the US in March, April and May 2011. Our experience with evaluation of indications for FT has led to an evolved philosophy that strongly emphasises functional deficits and considers candidates on a case-by-case basis. Patients have shown us that in the absence of alternative treatments, they need to be given increased power to decide if they are willing to assume the risks, of which we must ensure they are well informed. We have built a highly effective multidisciplinary team with specific individual roles through the various stages of the FT protocol (Figure 1). Just as in other complex medical problems,^{4–8} a multidisciplinary approach is paramount to the well-being of the FT patient. Although the FT team operates under a standard protocol, constant communication between members allows making patient-specific adjustments.

Patient selection

Candidates for FT are rigorously screened (Table 3) to ensure that the expected benefits outweigh the risks, that a solid plan is available in case of FT failure, that the patients understand the necessity and side effects of post-transplant lifelong immunosuppression, that FT is reasonably safe and that the patients have realistic expectations

Table 1 Responsibilities of the face transplantation multidisciplinary team's leader at BWH.

The team leader

- Assembles the face transplant multidisciplinary team
- Leads the IRB approval effort
- Establishes an agreement with the local OPO for donation of facial allografts^a
- Ensures that perioperative care hospital staff is trained and familiar with the face transplant protocol
- Participates in the donor and recipient surgeries
- Participates in patient evaluation, screening, perioperative and postoperative care
- Is the first person contacted by the OPO when a donor is found
- Heads efforts to secure funding for face transplantation
- Interacts with the media (with guidance from the institution's Public Affairs)
- Actively advocates for face transplantation

^a In the United States, facial allografts are treated as tissues rather than as organs, and their allocation and procurement are not regulated by the Organ Procurement and Transplantation Network (OPTN) or the United Network for Organ Sharing (UNOS).

	Recruitment	Initial consultation	Screening	Transplant waitlist	Donor procurement	Donor surgery	Recipient surgery	Immediate post-op	Long-term
Team Leader	✓	✓	✓	✓		✓	✓	✓	✓
Project Manager / Coordinator	✓		✓	✓				✓	✓
IRB	✓		✓	✓					✓
Plastic and Reconstructive Surgery	✓	✓	✓			✓	✓	✓	✓
Transplant Medicine			✓	✓			✓	✓	✓
Organ Processing Organization				✓	✓	✓			
Psychiatry			✓					✓	✓
Social Work			✓					✓	✓
Radiology			✓						✓
Infectious Disease			✓					✓	✓
Rehabilitation			✓					✓	✓
Nutrition			✓					✓	
Speech/Swallow			✓					✓	
Dentistry			✓						✓
Bioethicist	✓		✓						
Patient Advocate			✓	✓					
Hospital's Administration	✓		✓				✓	✓	✓

All members of the teams are available should they be needed during stages of the protocol where they do not typically participate.

Figure 1 Participation of the various members of the BWH FT multidisciplinary team in each of the various stages of the FT protocol.

Table 2 Responsibilities of the face transplantation program's manager/coordinator at BWH.

The program manager/coordinator

- Interfaces with the IRB
- Maintains detailed patient files and program's documentation
- Ensures that patients complete screening procedures
- Helps ensure coverage of post-transplant follow-up and immune suppression by the patient's medical insurance
- Communicates with the face transplant team
- Coordinates team meetings
- Leads patient recruitment efforts
- Assists with logistics of peri- and postoperative patient transportation and lodging
- Facilitates rapid exchange of information with the OPO
- Ensures that billing for face transplant-related expenses is correctly allocated^a

^a Medical insurance carriers do not currently cover face transplantation pre- and perioperative procedures.

of the outcome. The screening process involves professionals from plastic and reconstructive surgery, transplant immunology, radiology, infectious disease (ID), psychiatry, social work and rehabilitation, among others.

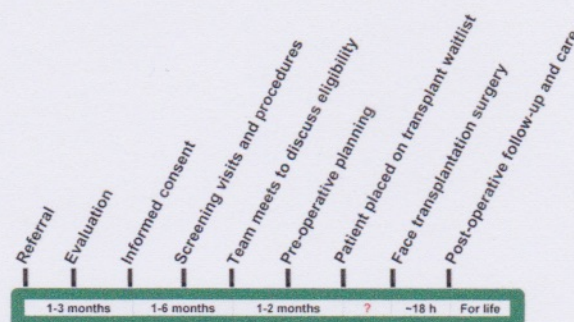


Figure 2 Stages of FT: according to our experience, elapsed time from patient referral to placement on transplant waitlist may total 3–11 months. Time spent on transplant waitlist is unpredictable. Postoperative follow-up will continue until allograft failure or patient's death.

Table 3 Screening steps for facial allotransplantation at Brigham and Women's Hospital.

Appointments	Goal(s)
Initial evaluation	Team leader assesses the facial defect and potential of restoration through face transplantation and provides information including alternative treatments.
Plastic surgery	Entire plastic surgery team members continue with the above goals and reach clinical consensus.
Psychiatry	Assesses understanding and expectations of procedure and alternatives, quality of life, emotional state, behavioural trends, support structure, cognitive ability, coping skills, issues of identity and body image and medical compliance.
Social work	Assesses support network, substance abuse, benefits, disability, medication coverage and lodging if applicable.
Transplant medicine	Evaluates immunological history and status and obtains information for donor matching.
Infectious disease	Screens for a variety of infectious diseases and provides immunisation and prophylaxis planning.
CT and angiography	Evaluates the deep structures of the head and neck and visualises vascular anatomy.
MRI ^a	Evaluates the soft tissues of the head and neck.
Functional MRI	Sets a baseline for postoperative evaluation of cortical plasticity.
PT	Discusses post-transplant rehabilitation.
Nutrition ^a	Improves the preoperative nutritional status.
Speech/swallow ^a	Assesses functional problems and provides coping strategies.
Laboratory	Obtains a wide picture of overall health status and addresses issues in need of attention.
Second opinion	A study-independent psychiatrist ensures the patient's best interest and acts as patient's advocate.
Dentistry ^a	Treats existing problems and educates on post-transplant oral hygiene.
Age-appropriate screening ^a	Screens for underlying problems that would compromise safety.
IRB	Gives approval for transplant waitlisting.

^a Not all patients go through this step. This step is carried out on an "as-needed" basis.

Multiple opinions and expert hands are needed during the simultaneous donor and recipient operations. Our FT team includes at least 10 PRSs, most with extensive microsurgical experience. PRSs provide feedback and identify areas in need of attention during screening. They assess the candidate's facial defect and functional limitations and estimate the potential functional and aesthetic benefits of FT. The FT candidates may present with a variety of facial defects and reconstructive history, and it is mainly the potential functional improvement that must be balanced with the risks of lifelong immune suppression.

Transplant physicians then generate the immunological profile of the FT candidate. They examine the patient's immunological history and status and obtain the information necessary for donor matching, such as blood type, human leucocyte antigen (HLA) and previous sensitisation.

Radiologists comprehensively evaluate and recreate the recipient's anatomy. They use computed tomography (CT) to evaluate the deep structures of the head and neck and CT angiography to visualise the vascular anatomy in great detail. The latter is particularly useful in cases of prior surgeries and extensive scarring.⁹ Magnetic resonance imaging (MRI) is used to evaluate the soft tissues.

ID specialists evaluate the candidate for tuberculosis, hepatitis A, B and C, cytomegalovirus (CMV), varicella zoster virus (VZV), syphilis, Epstein-Barr virus (EBV), toxoplasma and human immunodeficiency virus (HIV), among others, with additional tests if the patient has travelled or resided outside the United States. They prescribe the necessary immunisations prior to transplantation.

The team's psychiatrist conducts a thorough evaluation of the FT candidate. FT recipients must be able to

withstand the psychological stress of pre-, peri- and postoperative procedures and media attention as well as to comply with a complex lifelong immunosuppression regime and adapt to a changed appearance.¹⁰ All these are very strict psychological requirements. The psychiatrist evaluates the patient's emotional state, behavioural trends, support structure, cognitive ability, coping skills, issues of identity and body image, understanding of the procedure and likelihood of medical compliance (Table 3).¹¹ Inability to adhere to the postoperative immune suppression regime results in exclusion. The FT candidate must be strongly motivated even after fully understanding the risks of the procedure.¹² The BWH psychiatrist meets with FT candidates as many times as needed prior to the operation.

Social workers play a critical role in the adjustment of FT recipients both pre- and post-transplantation.² They ensure that the candidate has a solid social infrastructure that will support him through the arduous peri- and postoperative phases of FT. The social worker meets with the patient several times during evaluation and works through these different aspects (Table 3).

Rehabilitation therapists must prepare a thorough plan for extensive post-transplant rehabilitation and discuss it with the FT candidate, specifically addressing modalities, frequency, goals and expectations (Table 3). The candidate must be fully committed to complying with the rehabilitation plan, as physical therapy is critical to restore facial function after FT.

FT patients with impaired ability to chew, swallow and/or breathe may have compromised nutrition status. Therefore, the team's nutritionist strives to improve their preoperative nutritional status (Table 3). In addition,

because so many of the candidates present with compromised speech-and-swallow functions, a speech-and-swallow therapist conducts a pre-transplant evaluation to assess these functional problems, provide coping strategies and determine the baseline status to be compared with postoperative functional gains (Table 3).

FT sometimes involves the total or partial transplant of the maxilla and/or mandible with teeth from the donor to the recipient. Dental hygiene is important as dental infections can lead to systemic infections that compromise the survival of the transplanted allograft and/or the health of the immunosuppressed recipient. FT candidates should undergo pre-transplant dental check-up and work-up, with special emphasis on reinforcing good dental hygiene (Table 3).

The FT candidate undergoing screening is encouraged to choose a friend, family member, attorney or study-independent health-care provider (such as a study-independent psychiatrist) to act as his/her advocate. The advocate ensures that the candidate understands the FT protocol and that his/her interests are prioritised. The candidate may also grant the advocate a 'power of attorney' (POA), and if needed, the advocate may make decisions on behalf of the patient within the scope of the POA.² The advocate remains available throughout the screening, peri-operative and postoperative processes. The FT candidate may change the advocate at any time, as desired.

The inclusion of a bioethicist in the BWH's FT team has proved very beneficial. Two main ethical issues are associated with FT. The first is the transfer of facial appearance and identity from the donor to the recipient. This was initially thought to potentially have negative psychological effects on the recipient and on the bereaved family of the donor. The degree of this identity transfer has been investigated and found to be low.¹³⁻¹⁵ The second ethical issue is the justification of lifelong immunosuppression for a non-life-saving therapy. Immunosuppression likely shortens life by as many as 10 years and introduces several complications, such as increased risk for cancers and infections.¹⁶ The BWH bioethicists help ensure that the patient understands both of these issues and can properly assess the risk/benefit ratio. The bioethicist is also the person to consult regarding the ethics of the intervention. For example, while some centres regard blindness as absolute contraindication for FT,³ our institution's bioethicists advised not to exclude a patient on account of blindness, as this could constitute discrimination. Concerns when including a blind patient in a face transplant protocol are related to rehabilitation and post-transplant care.

In the early stage, sighted patients are forced to rely on visual feedback, as the allograft is initially insensate. Over time however, with evolution of sensation and proprioception, blind patients can participate in customised therapy. As the sensation and proprioception typically return first, motor recovery can be adequately guided. Blind patients will depend their family or social network to monitor the allograft for signs of rejection and for complying with the medication regimen, though it appears that even blind patients can feel changes associated with rejection (such as new onset of swelling) very well. Screening should ensure that adequate and dedicated support is present. Ethically, the principle of

justice demands that blind patients should have equal access to treatment. Refusal to provide treatment to blind patients based on their disability is hence ethically unacceptable. Blind patients with severe facial deformity suffer the same social withdrawal and exclusion and present the same functional limitations as sighted individuals with similar defects. We evaluate the medical need of sighted and blind patients alike and determine eligibility based on functional benefit to the patient and change in quality of life.

Preoperative planning

An FT candidate is deemed eligible or ineligible for FT by at least 50% of the team's members during a full team meeting. If eligible, the candidate is placed in the transplant waiting list to initiate the effort of finding a compatible donor. The entire FT team is informed of the candidate's placement in the transplant waitlist. PRSs carry preoperative planning, which includes extensive anatomical discussion and mock dissections. The radiological evaluations obtained during screening are extremely valuable in guiding both the recovery of the donor allograft and the preparation of the recipient's facial bed. At this stage, it is also extremely important to formulate a concrete plan for candidate mobilisation to BWH, especially in the case of out-of-town candidates. The candidates must be able to arrive to BWH within a 4-12-h time window after being notified that a donor has become available. The project manager oversees the planning for this mobilisation and shares them with the team and the candidate in writing.

Organ procurement

The FT team must establish an agreement for facial allograft procurement with an OPO. Because of ischaemia-time considerations, facial allografts may only be procured by OPOs located within a certain travel distance. The primary concern of any OPO is the safe allocation, procurement and recovery of 'life-saving organs'. Non-life-saving facial allografts understandably take a back seat, and their recovery cannot compromise life-saving organ procurement. OPO leaders assume the challenging task of developing consent forms for the donation of facial tissues. With unwavering professionalism and integrity, they approach the surviving next-of-kin at a time of terrible loss and bereavement to request donation of the facial allograft. Educational meetings between BWH and the OPO are frequent. Once an agreement is established, the OPO is constantly kept informed regarding patients who are soon to be placed or are already placed on the transplant waitlist. Once a donor is found, the OPO notifies the team leader. The FT team must recover the facial allograft from the donor. PRSs divide into donor and recipient teams that communicate extensively to allow real-time adjustments. The OPO coordinator works alongside the FT team through the donor recovery process. The facial allograft is recovered prior to the solid organs, unless the donor becomes unstable, in which case life-saving organs are given priority.

Donor surgery

The donor team travels to the donor's location to recover the facial allograft; travel is coordinated by the OPO. The BWH team consists of three surgeons and one to two assistants, and travels with an anaplastologist who takes an impression of the donor's face, and prepares a restorative mask on site. The mask is placed over the facial defect left after the recovery, to preserve the donor's dignity. The donor hospital's operating room (OR) provides the nursing team. The recovery of the facial allograft, radial forearm sentinel flap and the preparation of the recipient start simultaneously, unless there are special considerations. Once fully recovered, the allograft is perfused with University of Wisconsin solution, packaged on ice and transported back to the recipient's OR as quickly as possible. The anaplastologist remains behind to secure the restorative mask in place.

Recipient surgery

Coordination with OR management is paramount for FT surgery to proceed smoothly. Nurse managers must be engaged in preoperative planning of OR selection, set-up, equipment and personnel. Each nursing team contains staff with considerable experience in microsurgical

reconstruction/replantation and craniofacial surgery that can handle and operate the specialised instrumentation and equipment. Three surgeons and multiple assistants are available for the operation. One team prepares the corresponding facial structures, while the other prepares the recipient's site for the sentinel flap, which in the past has been designed as a functional flap. Each team has a full set of instruments and is supported by nursing staff. The four teams (two at the donor and two at the recipient site) converge into two upon arrival of the donor's tissue to the recipient's OR. Surgeons who are not needed are released for breaks and changes during the inset part of the operation.

Immunosuppression and rejection

Induction immunosuppression is coordinated by the transplant physician. At BWH, it is achieved with anti-thymocyte globulin at $1.5 \text{ mg kg}^{-1} \text{ day}^{-1}$ for 4 days, as well as steroid taper. Maintenance immunosuppression involves a regime of tacrolimus, mycophenolate mofetil and prednisone, and must be closely followed up for the duration of the patient's or allograft's life (Table 4). Over-immunosuppression leads to undesirable side effects, such as infections, while under-immunosuppression leads to rejection of the allograft. Blood levels of immunosuppression medications need to be

Table 4 Postoperative monitoring regimen for facial allotransplantation patients at Brigham and Women's Hospital.

Appointments	Goal(s)	Inpatient frequency	Frequency after discharge
Plastic surgery ^a	Monitoring healing and rejection, performing biopsies and revisions as needed.	Daily	2× per week for the 1st month, 1× per month for 3 months and every 6 months/as needed after.
Transplant medicine ^a	Monitoring immunosuppression and rejection.	Daily	Same as Plastic surgery.
Psychiatry ^a	Providing support coping with stress, changed appearance and media attention.	Daily	Weekly for 3 months, every 3 months until 18 months and as needed after.
Social work	Providing support as needed.	Daily	As needed.
Infectious disease ^a	Monitoring and treating infectious complications.	Daily	2× per week for the 1st month, as needed after.
CT and angiography ^a	Evaluating integration of the facial allograft tissues.	N/A	At 6 months.
MRI ^a		N/A	At 6 months.
Functional MRI	Evaluating cortical reintegration of the transplanted parts.	N/A	At 3, 6, 9, 12, 18 months.
PT	Rehabilitating the transplanted allograft.	Twice a day	2–5× per week for 3 months/as needed after.
Nutrition	Ensuring proper nutrition according to diet limitations.	As needed	As needed.
Speech/swallow	Providing feeding and speaking strategies while the allograft regains function and sensation.	As needed	As needed.
Laboratory	Monitoring overall health status and levels of immune suppression.	As needed	As needed.
Dentistry	Monitoring post-transplant oral health.	N/A	As needed.

^a Stated frequency is in the absence of complications. If there are complications, frequency may be increased.

monitored, especially calcineurin inhibitors which are associated with significant nephrotoxicity, and dosages must be adjusted constantly to prevent deleterious side effects, while maintaining drug efficacy. Transplant specialists manage episodes of acute rejection which occur frequently in the months following FT and have been treated successfully to date with temporary increase in immunosuppression. With time after FT, transplant specialists strive to gradually reduce the doses of immunosuppressants, while avoiding allograft rejection.

Postoperative care

Postoperative care starts with the patient's transfer to the intensive care unit (ICU). Patients typically spend from 3 to 4 days in the ICU, after which they are transferred to the regular floor.

Aside from their crucial role in assisting with surgical preparation and during the surgery itself (Figure 1), nurses will be in closest proximity to the patient's bedside during the acute postoperative period. Nurses will be in charge of all the patient's needs, maintain communication with all parties involved and provide precious emotional support to the patient and his/her family. The recipient is closely followed up by the FT team not only during the acute postoperative period, but also for as long as the allograft remains functional (Table 4).

Perioperatively, ID specialists have a crucial role in tailoring antibiotics to the results of surveillance cultures from both the donor and the recipient. PRSs participate in all aspects of wound healing, evaluation of outcomes and revisions (Figure 1). Postoperative MRI and CT are used to assess healing, rejection, and fusion between the donor's and recipient's anatomical structures, typically 6 months postoperatively.

Proper levels of immunosuppression should minimise the risks of opportunistic infectious complications. The most severe infections occur during times of over-immunosuppression, such as the induction phase or management of acute rejection. CMV, EBV and cutaneous herpes simplex infections have been reported.¹⁷ CMV can trigger rejection that can be challenging to control¹⁸; therefore, ganciclovir must be administered based on donor and recipient data. ID specialists work with the immunosuppressed FT recipient with a high index of suspicion, liberal use of laboratory tests and early, focused treatment.

Social workers provide postoperative support on an as-needed basis (Table 4). They typically meet with the patient every 1–2 days during the acute postoperative period. The team's psychiatrist meets daily with the FT recipient during his/her perioperative hospitalisation. After discharge, the psychiatrist meets weekly with the recipient, or on an as-needed basis.

Rehabilitation is crucial to the attainment of maximum motor recovery during the postoperative period. The rehabilitation protocol is created and adjusted for each patient (Table 4). Rehabilitation starts as early as possible and may last 18–24 months. The initial focus is on mobility and airway clearance, and soon after, therapeutic exercise.

The FT patient remains on a 'nil per os' regimen for at least 24 h after surgery, after which periodic speech-and-swallow evaluations are performed with the goals of safe

oral feeding and speech education (Table 4). The diet is modified towards optimal nutrition as the ability to handle a wider variety of foods improves along with allograft functional recovery (Table 4). Nutritional management is also important to assure proper digestion of immunosuppressive medications, to achieve stable levels, and manage adverse effects (diarrhoea).

Complications

Close communication between team members is achieved by members of the team holding daily morning rounds and following them with written communications to the team regarding the patient's status and goals of care. The team leader is the point of contact regarding all patient encounters and the transplant surgeon is in sole charge of all orders related to immune suppression. If complications arise, team meetings are scheduled on short notice to discuss the event, its possible causes, immediate solutions and protocol improvements for future prevention. These meetings and the recorded minutes include the entire co-investigative team as well as anyone and everyone involved in the patient's postoperative care.

Conclusions

We have shared the experience of the BWH multidisciplinary FT team here. Each FT patient presents a unique set of problems and challenges and therefore a multidisciplinary approach is critical for the success of the FT programme. Every member of the FT team at BWH has a clearly defined role (Figure 1) and the knowledge and expertise to fulfil it. We have observed that challenges identified by one team member may affect the entire team. In the right setting, where true collaboration and creativity are encouraged and maintained, a well-led team composed of experts from diverse professional backgrounds is able to find the most effective strategies to tackle these challenges to benefit the face transplant patient.

Conflict of interest statement

The authors of this article have no conflicts of interest to disclose.

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