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BRIEF REPORT

Three Patients with Full Facial Transplantation

Bohdan Pomahac, M.D., Julian Pribaz, M.D., Elof Eriksson, M.D., Ericka M. Bueno, Ph.D., J. Rodrigo Diaz-Siso, M.D., Frank J. Rybicki, M.D., Donald J. Annino, M.D., Dennis Orgill, M.D., Edward J. Caterson, M.D., Stephanie A. Caterson, M.D., Matthew J. Carty, M.D., Yoon S. Chun, M.D., Christian E. Sampson, M.D., Jeffrey E. Janis, M.D., Daniel S. Alam, M.D., Arturo Saavedra, M.D., Joseph A. Molnar, M.D., Thomas Edrich, M.D., Francisco M. Marty, M.D., and Stefan G. Tullius, M.D.

SUMMARY

Unlike conventional reconstruction, facial transplantation seeks to correct severe deformities in a single operation. We report on three patients who received full-face transplants at our institution in 2011 in operations that aimed for functional restoration by coaptation of all main available motor and sensory nerves. We enumerate the technical challenges and postoperative complications and their management, including single episodes of acute rejection in two patients. At 6 months of follow-up, all facial allografts were surviving, facial appearance and function were improved, and glucocorticoids were successfully withdrawn in all patients.

FACIAL TRANSPLANTATION IS A SINGLE, COMPLEX OPERATION INTENDED to transform severely deformed features to near-normal appearance and function with the use of techniques that conventional plastic surgery cannot match.¹ Since 2005, a total of 18 patients have received transplants with promising results.²⁻⁷ Most facial transplantations have been designed to restore partial-face defects; full-face transplantations include the forehead, eyelids, nose, lips, chin, and cheeks,^{8,9} with or without underlying bone. Full-face transplantation has been considered nearly impossible because of the complexity of the blood supply as well as ethical, psychological, and social implications. We report our initial experience in full-face transplantation in three patients.

METHODS

PATIENTS

All patients provided written informed consent to participate in the clinical trial (ClinicalTrials.gov number, NCT01281267) for face transplantation, as approved by the human research committee at Brigham and Women's Hospital and by the Army Medical Research and Materiel Command Human Research Protection Office.

All patients were evaluated by our multidisciplinary team before participation.^{10,11} Their medical histories are summarized in Table 1. Pretransplantation frontal photographs are shown in Figure 1, and pretransplantation profile photo-

From the Department of Surgery, Division of Plastic Surgery (B.P., J.P., E.E., E.M.B., J.R.D.-S., D.O., E.J.C., S.A.C., M.J.C., Y.S.C., C.E.S.), Applied Imaging Science Laboratory, Department of Radiology (F.J.R.), Department of Surgery, Division of Otolaryngology (D.J.A.), Department of Dermatology (A.S.), Department of Anesthesiology, Perioperative and Pain Medicine (T.E.), Department of Medicine, Division of Infectious Disease (F.M.M.), and Department of Surgery, Division of Transplant Surgery (S.G.T.), Brigham and Women's Hospital, Boston; the Department of Plastic Surgery, University of Texas Southwestern Medical Center, Dallas (J.E.J.); the Section of Facial Plastic and Reconstructive Surgery, Head and Neck Institute, Cleveland Clinic, Cleveland (D.S.A.); and the Department of Plastic and Reconstructive Surgery, Wake Forest University School of Medicine, Winston-Salem, NC (J.A.M.). Address reprint requests to Dr. Pomahac at the Department of Surgery, Division of Plastic Surgery, Brigham and Women's Hospital, 75 Francis St., Boston, MA 02115, or at bpomahac@partners.org.

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graphs are shown in Figure 1 in the Supplementary Appendix, available with the full text of this article at NEJM.org.

After extensive discussion of the indications, risks, and benefits, which included input from an ethicist, treatment by full-face transplantation was elected by all three patients in an attempt to enhance function and appearance. The New England Organ Bank identified and obtained consent for organ donation from families of suitable brain-dead donors who were matched with the patients according to sex and skin color. In addition, donors and recipients were matched on the basis of several clinical characteristics (Table 1), including negative T- and B-cell cross-matching. Our surgeons were divided into teams with specific objectives during the operations.

TRANSPLANTATION PROCEDURES

In each instance, one team performed facial allograft recovery that isolated all major motor and sensory nerves and arterial and venous components (Table 1 in the Supplementary Appendix). Another team recovered radial forearm flaps to act as sentinel tissue from Donors 1 and 2. Another two teams recovered the upper limbs from Donor 3. All recovered allografts were perfused with University of Wisconsin solution and transported in an ice-water slurry.

In synchronization with the donor operation, another team removed the skin, contoured the facial tissue remnants, and isolated bilateral motor- and sensory-nerve branches and neck vessels of the recipient. The residual functioning portions of the recipients' faces were preserved to allow them to return to their pretransplantation level of function in the event of transplant failure.¹¹ All facial-nerve branches and sensory nerves were anastomosed unless they were not present because of injury (Table 1 in the Supplementary Appendix). Donor skin was tailored to the recipients' defects for optimal contour. All facial allografts had complete perfusion after implantation.

A third team transplanted the sentinel skin flaps to an inconspicuous area (in Patient 1) and to a hand contracture (in Patient 2); Patient 3 underwent simultaneous bilateral transplantation of the upper limbs, a procedure that is not described in detail in this report. The patients were initially treated in the intensive care unit

and were subsequently transferred to the surgical ward until discharge (Table 2).

IMMUNOSUPPRESSION

All patients received mycophenolate mofetil, methylprednisolone, and rabbit antithymocyte globulin before allograft reperfusion. Maintenance immunosuppression consisted of mycophenolate mofetil, tacrolimus, and prednisone taper (Table 2, and Fig. 2 in the Supplementary Appendix). We obtained skin-biopsy samples from facial and sentinel allografts periodically and during suspected rejection (Table 2). Biopsy samples were graded according to the Banff 2007 scale.¹² Immunosuppression was adjusted on the basis of clinical judgment, biopsy results, and tacrolimus trough levels (Table 2). Perioperative antibacterial prophylaxis consisted of vancomycin and cefazolin and was modified according to perioperative findings; Patients 2 and 3 also received perioperative antifungal prophylaxis with micafungin. All patients received trimethoprim-sulfamethoxazole and valganciclovir prophylaxis against *Pneumocystis jirovecii* and cytomegalovirus, respectively, for at least 6 months.

Postoperatively, all patients had tracheotomies placed; these were removed within 3 months in all cases. All patients had access to continuous counseling from psychiatrists and social workers.

RESULTS

PATIENT 1

Patient 1 received 24 units of packed erythrocytes and 17 units of blood obtained by intraoperative cell salvage (Cell Saver, Haemonetics) during the operation, a volume of blood that was greater than anticipated. On day 3, the patient reported that his olfaction was restored. On day 8, secretion from a suture line grew *Candida albicans* and *Pseudomonas aeruginosa*. Treatment with micafungin and cefepime was initiated. On day 13, drainage of a recurrent submental collection was identified as sterile saliva. Botulinum toxin was injected into each of the donor's submandibular glands to decrease saliva production, and fluconazole and amoxicillin-clavulanic acid were prescribed for further antimicrobial treatment. The submental lymph nodes of the allograft became markedly enlarged (Fig. 3 in the Supplementary Appendix), and reactive changes were noted in biopsy sam-

Table 1. Selected Characteristics of the Donors and Patients.*

Characteristic	Patient 1	Patient 2	Patient 3
Age (yr)			
Donor	48	31	42
Recipient	25	30	57
Initial injury and year	Electrical burn, 2008	Electrical burn, 2001	Animal attack, 2009
Missing facial structures	All facial soft tissues, eyelids, left eye, nose, lips, teeth, large portion of left temporoparietal scalp	Skin over the forehead, cheeks, and eyelids; soft tissues of the nose and upper and lower lips	Nose, eyelids, both eyes, maxilla, and lips, with extensive scarring of the remaining face
Functional limitations	No breathing through the nose, no facial expression, inability to close mouth, impaired speech	No lip closure, impaired speech, no facial expression, inability to close mouth	No breathing through the nose, impaired speech, no facial expression, inability to close mouth
Total allograft ischemia (hr)	4	2	2
Sentinel flap	Donor radial-forearm graft to recipient's inguinal area	Donor radial-forearm graft to recipient's right hand	Donor bilateral upper limbs to recipient
Blood type			
Donor	O, Rh-positive	A, Rh-positive	O, Rh-positive
Recipient	A, Rh-positive	A, Rh-positive	B, Rh-negative
Panel reactive antibodies (%)	68	0	0
Cytomegalovirus IgG			
Donor	Positive	Positive	Positive
Recipient	Positive	Negative	Positive
Other interventions	Implantation of eye spacers	Eyelids, skin only	Implantation of eye spacers, positioning of transplanted maxilla
Duration of operation (hr)	17	14	19
Blood loss (liters)†	3.0–4.0	0.5	2.5–3.0
Units of packed red cells transfused (no.)	24	2	20
Units of fresh-frozen plasma administered (no.)	13	0	16
Units of platelets transfused (no.)	1	0	0
Days in intensive care unit (no.)	4	4	18
Days of initial hospitalization (no.)	13	10	38

* A more comprehensive description of additional aspects of the procedures is provided in Table 1 in the Supplementary Appendix.

† Blood loss was estimated by the surgeon.



ples, although skin-biopsy samples did not suggest rejection. On day 116, redundant neck skin was partially resected (Table 2).

At 4 months, sensation had returned on the right side of the transplant, along with movement

of right-sided muscle groups and restoration of facial aesthetics (Fig. 1, and Fig. 9 in the Supplementary Appendix; and video 1, available at NEJM.org). Sensation had not returned on the left side, where sensory nerves were not connected.



Videos are available at NEJM.org

PATIENT 2

Patient 2 received 2 units of packed erythrocytes. On day 4, he was able to talk, eat, and drink. On day 20, erythema and increased swelling of the facial allograft and sentinel flap (Fig. 4 in the Supplementary Appendix) prompted a diagnosis of acute rejection, which was confirmed on face and sentinel-graft biopsies (grade 2 rejection) (Fig. 5 in the Supplementary Appendix). The episode was successfully treated with pulse doses of methylprednisolone. For the first 3 months, the patient recovered well, aside from several episodes of unexplained fever. At 4 months, he was admitted for treatment of polymicrobial bacteremia, attributed to either his long-term peripherally inserted central catheter or periodontal infection. He was treated with vancomycin, levofloxacin, and the extraction of two teeth (Table 2).

At 3 months, Patient 2 had a return of sensation in the forehead and chin and a return of gross lip motion, along with restoration of facial aesthetics (Fig. 1, and Fig. 10 in the Supplementary Appendix; and video 2, available at NEJM.org).

PATIENT 3

Patient 3 received 20 units of packed erythrocytes. This blood loss was expected because of the extent of the combined operation. On day 2, aspiration pneumonia complicated by septic shock developed, which caused irreversible ischemic changes and gradual thrombosis of both transplanted upper limbs. Despite salvage attempts with dobutamine, anticoagulation, and brachial plexus blocks, the upper-limb allografts were removed on day 5, preserving the patient's own right thumb. On day 30, the patient underwent maxillofacial computed tomography to assess lymphadenopathy. Craniofacial three-dimensional reconstruction was performed to assess maxillo-mandibular occlusion (Fig. 6 in the Supplementary Appendix). On day 54, erythema and swelling prompted a diagnosis of acute rejection (Fig. 7 in the Supplementary Appendix), which was confirmed on biopsy (grade 2 rejection) (Fig. 8 in the Supplementary Appendix). The episode was successfully treated with pulsed methylprednisolone at a dose of 500 mg per day for 3 days. At 2 months, the patient was able to breathe through her nose and mouth (Table 2).

At 3 months, there was a return of sensation in the transplant, along with restoration of facial aesthetics (Fig. 1, and Fig. 11 in the Supplemen-

tary Appendix). There was no return of motor function at this time.

DISCUSSION

Full-face transplantation presents unique surgical, immunologic, and ethical challenges. Our operative strategy uses all major motor and sensory nerves to provide gradual proprioceptive feedback as the graft recovers, facilitating cortical integration of the new face. Our efforts to perform motor neurotizations as close as possible to the effector muscle appeared to result in targeted reinnervation.

It was thought that facial vessels alone could not perfuse the entire face and anterior scalp and that superficial temporal vessels must be included in full-face allografts,¹³⁻¹⁵ complicating and prolonging allograft recovery in a major way. In addition, it was recommended to recover parotid glands to avoid facial-nerve injury, at the expense of excessive bulk at the sides of the face,⁷ unless superficial parotidectomy was performed in the recipient.¹⁶ We carried out full-face allograft recovery by a planned, simplified vascular supply guided by precise vascular mapping in the recipient.^{17,18} Facial recovery was performed in under 4 hours in all three cases. Although superficial temporal vessels may be needed to sustain allograft ears, we speculate that many patients would benefit from the approach we describe.

All patients had postoperative infections of differing severity, and they all recovered. Single episodes of rejection in Patients 2 and 3 were successfully managed.

One of the unique features of full-face transplantation is the large area of direct contact between allograft and recipient tissues. This may result in substantial growth of new vessels, which should lead to secondary revascularization. Such direct angiogenesis may constitute an alternative source of allograft blood supply and would require further investigation to confirm.

The sentinel flap was planned as an alternative site by which to monitor rejection. Sentinel flaps were preferably positioned in sites needing functional improvement. In two of our four face-transplant recipients (the first one was described previously⁵), the sentinel flap indicated rejection more accurately than the facial allograft because it was less prone to confounding facial-skin con-

Table 2. Timing of Selected Interventions and Events after Full-Face Transplantation.*

Timing and Event	Patient 1	Patient 2	Patient 3
Day 0 (surgery)			
Immunologic event	Administration of mycophenolate mofetil (1 g), antithymocyte globulin (1.5 mg/kg/day), methylprednisolone (500 mg)	Administration of mycophenolate mofetil (1 g), antithymocyte globulin (1.5 mg/kg/day), methylprednisolone (500 mg)	Administration of mycophenolate mofetil (1 g), antithymocyte globulin (1.5 mg/kg/day), methylprednisolone (500 mg)
Complication	Substantial intraoperative bleeding	NA	Substantial intraoperative bleeding
Week 1 (days 1–7)†			
Immunologic event	Administration of mycophenolate mofetil, tacrolimus,‡ and prednisone taper; days 1–3: antithymocyte globulin (1.5 mg/kg/day); face biopsy: grade 0; sentinel-graft biopsy: grade 0	Administration of mycophenolate mofetil, tacrolimus,‡ and prednisone taper; days 1–3: antithymocyte globulin (1.5 mg/kg/day); face biopsy: grade 1; sentinel-graft biopsy: grade 0	Administration of mycophenolate mofetil, tacrolimus,‡ and prednisone taper; days 1–3: antithymocyte globulin (1.5 mg/kg/day); face biopsy: not done
Infectious event	NA	Day 2: pneumonia with <i>Haemophilus influenzae</i>	Day 2: pneumonia with <i>Pseudomonas aeruginosa</i> and <i>Acinetobacter baumannii</i>
Complication	NA	NA	Day 2: Septic shock; acute renal failure, continuous venovenous hemofiltration; day 5: bilateral allograft ischemia in both transplanted upper limbs; removal of limbs
Functional outcome	Day 3: restoration of olfaction; day 4: discharge from ICU	Day 4: eating, drinking, and seeing new face; discharge from ICU	NA
Week 2 (days 8–14)			
Immunologic event	Maintenance of immunosuppression; face biopsy: grade 1; sentinel-graft biopsy: grade 0	Maintenance of immunosuppression	Maintenance of immunosuppression
Infectious event	Submental and parotid area collections, hematoma (growth of <i>Candida albicans</i>), drainage	NA	NA
Complication	Submental sialocele, 10 units of botulinum toxin injected into allograft salivary glands	NA	NA
Functional outcome	Day 13: discharge	Day 10: discharge	NA
Week 3 (days 15–21)			
Immunologic event	Face biopsy: grade 1; sentinel-graft biopsy: grade 0	Day 20: acute rejection; hospital admission, methylprednisolone pulse treatment (500 mg/day for 3 days); face biopsy: grade 2; sentinel graft biopsy: grade 2	Face biopsy: grade 1
Infectious event	NA	Low-grade fever	NA
Complication	Allograft lymphadenopathy	NA	NA
Functional outcome	NA	NA	Day 18: discharge from ICU
Week 4 (days 22–28)			
Immunologic event	Face biopsy: grade 1; sentinel-graft biopsy: grade 1	Face biopsy: grade 1; sentinel-graft biopsy: grade 1	Face biopsy: grade 1
Infectious event	Admitted with fever; no source identified	NA	NA
Complication	NA	Headache	Allograft lymphadenopathy
Functional outcome	NA	NA	Craniofacial computed tomography

Month 2 (days 29–60)	
Immunologic event	Face biopsy: grade 0; sentinel-graft biopsy: grade 0; day 55: prednisone discontinued
Complication	Day 37: overnight hospital admission due to elevated creatinine level (1.5 mg/dl) and dehydration; resolved
Functional outcome	NA
Month 3 (days 61–90)	
Immunologic event	Face biopsy: grade 1; sentinel-graft biopsy: grade 1
Complication	NA
Functional outcome	NA
Later events (after day 91)	
Immunologic event	Day 118: mycophenolate mofetil (750 mg twice daily), tacrolimus
Infectious event	Discontinuation of fluconazole and amoxicillin-clavulanic acid
Complication	NA
Functional outcome	Return of sensation on right side of face; two-point discrimination: 15 mm, 10 mm, and 5 mm in 46%, 23%, and 21% of the face, respectively; movement of right-sided muscle groups; removal of excess skin; restoration of aesthetics
Immunologic event	Face biopsy: grade 1; sentinel-graft biopsy: grade 0; day 48: prednisone discontinued
Complication	Day 54: acute rejection; hospital admission, methylprednisolone pulse treatment (500 mg/day for 3 days); face biopsy: grade 2
Functional outcome	Day 54: insulin supplementation
Immunologic event	Face biopsy: grade 1; sentinel-graft biopsy: grade 0
Complication	Day 38: discharge; day 54: decannulation of tracheostomy
Functional outcome	Day 84: mycophenolate mofetil–induced diarrhea indicated, switched back to Myfortic [‡] ; face biopsy: grade 1
Complication	Insulin (NPH and regular) administered; day 79: deep-vein thrombosis in left leg; anticoagulation started; day 81: warfarin started
Functional outcome	Restoration of facial aesthetics
Immunologic event	Day 116: discharged while taking oral antibacterials, mycophenolate mofetil (750 mg twice daily), tacrolimus
Infectious event	Day 110: admission for polymicrobial bacteremia (<i>Enterobacter cloacae</i> , <i>Streptococcus viridans</i> , and coagulase-negative staphylococcus); day 114: extraction of two teeth
Complication	Day 115: elevated creatinine (2 mg/dl); resolved
Functional outcome	Return of sensation in forehead and chin; two-point discrimination: 15 mm, 10 mm, and 5 mm in 46%, 40%, and 28% of the face, respectively; return of gross lip motion
Immunologic event	Days 100–104: hospital admission for <i>Clostridium difficile</i> colitis
Complication	Day 92: rosacea or seborrheic dermatitis of the facial allograft; topical ketoconazole
Functional outcome	Return of sensation; 15 mm, 10 mm, and 5 mm in 38%, 31%, and 28% of the face, respectively; no motor function

* ICU denotes intensive care unit; NA not applicable, and NPH neutral protamine Hagedorn.

† All patients started antimicrobial prophylaxis with trimethoprim-sulfamethoxazole and valganciclovir.

‡ Tacrolimus was administered to achieve target levels of 10 to 15 ng per milliliter.

§ Myfortic is a delayed-release formulation of mycophenolate sodium.

ditions, since a facial allograft may show erythema and local inflammation from environmental exposure or from conditions such as rosacea or dermatitis.¹⁹

We expected major immediate and gradual changes in facial appearance in these patients. We anticipated that the underlying skeleton and facial volume would shape the final facial appearance, making resemblance to the donors unlikely. It is our subjective opinion, as well as that of two of the donor families, that the patients do not look like their donors (the remaining donor family has chosen to remain unknown).

In conclusion, on the basis of our experience with three patients who had severe facial deformities resulting from various injuries, we have shown that it is feasible to perform face transplantation with the use of a consistent, complex protocol. Despite important adverse events and a short follow-up, this study provides further sup-

port for the concept that full-face transplantation is able to restore functional defects and to resurface major deficits with the use of conventional immunosuppression and early glucocorticoid withdrawal. We will continue to assess functional reintegration, as measured by standardized restoration of motor and sensory function, over time.

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