

Facial Transplantation - **ASRM/ASPS Guiding Principles**

The American Society for Reconstructive Microsurgery (ASRM) and the American Society of Plastic Surgeons (ASPS) recognize the innovative and revolutionary prospects of facial transplantation and the hope it offers to those who suffer from severe facial disfigurement for an improved quality of life. As remarkable as the potential possibilities are for facial transplant recipients, we acknowledge the controversy and the many questions associated with the procedure. The ethics of facial transplantation go beyond the life and death issues common to most transplant procedures and raise other issues that heretofore have not influenced medical decision making processes.

Human transplantation utilizing composite tissue allotransplantation (CTA) is experimental and presents many technical and medical challenges. While there have been many scholarly papers published and scientific research performed, there remain many unanswered questions regarding facial transplantation and its consequences.

Background

Immunosuppression

The complications associated with immunosuppressants are well known and include increased incidence of opportunistic infections, increased risk of malignancies, and end-organ toxicity. Hand transplantation is considered to be the CTA procedure most similar to facial transplantation, and the immunosuppressive regimen required for hand transplantation has been remarkably similar to those for other solid-organ transplants. It is not entirely clear if the anti-rejection immunosuppressive drug regimens for hand transplant patients are applicable to facial transplant patients.

Transplant Rejection

Long-term graft survival for facial transplantation cannot be reliably determined at this time but if the rejection rate is similar to hand transplant, it is estimated that 10 percent of facial transplant recipients will experience an episode of rejection within the first year, with a thirty to fifty percent rate in the second to fifth year.³ While an episode of rejection might possibly be treated by increasing the dosage of immunosuppressive drugs, surgical removal of the transplanted tissue could well be necessary. Removing a rejected facial transplant would require additional surgeries, and at best, return the patient to preoperative levels of disfiguration with possible further facial scarring.

Technical Issues

The technical issues surrounding total facial transplantation are complex. Preparation of the recipient site and donor tissues are critical with the potential for considerable blood loss. Blood supply of the transplanted tissue will likely require at least two arteries and veins from the donor's face. In order to restore sensation and muscle function, numerous nerve repairs will be required. The resultant quality of restored facial animation is as yet unknown but the restoration of sensation can be expected to be relatively good. In some cases a partial facial transplantation may be an appropriate reconstructive option that minimizes the risks of whole face transplantation. The partial facial transplantation may utilize a combination of skin, soft tissue, muscle and/or bone. Therefore, what occurs in one patient may not be completely applicable to others.

Psychological Aspects

Our face helps us understand who we are, provides information about our age, gender, and ethnicity, and is central to communication and our recognition by others. Individuals that fall outside of appearance norms due to severe facial deformity or disfigurement often experience psychological suffering and social isolation. The degree of distress is often dependent upon a combination of the attitudes and reactions of others, as well as the individual's own coping skills. While not minimizing the burden of facial deformity, facial transplantation has its own set of psychological stressors.²

Psychological issues facing all transplant patients

- Difficulty coping with the burden of complying with strict postoperative medical regimes
- Understanding complicated issues associated with the many side effects and risks from immunosuppression
- Swings in emotion including gratitude and guilt in relation to the donor and his/her family
- Stress of self perceived responsibility for success or failure of transplantation operations

Psychological issues unique to facial transplant patients

- Difficulties integrating the facial transplant into existing body image and identity
- Deficits of nonverbal communication and possible lack of improvement in facial animation
- Dealing with the reactions of friends and family members to a different appearance
- Fear associated with graft failure that may result in ongoing anxiety and hyper vigilance for signs of rejection
- Anxiety that appearance will return to preoperative levels of disfiguration, or worse, if the graft fails.

Guiding Principles

These guiding principles are meant to assist plastic surgeons who may choose to participate in facial transplantation procedures. ASPS and ASRM urge these surgeons to consider the following principles before undertaking such a step:

1. Facial transplantation should only be utilized for patients with severe facial deformities who cannot be helped through traditional reconstructive surgical measures.
2. Facial transplantation should only be undertaken in institutions with appropriate Institutional Review Boards familiar with the many intricacies for approval and application of new clinical procedures and protocols.
3. Facial transplantation should be conducted in the context of a transplant team having appropriate institutional resources and commitment to the project. The team should be ideally composed of specialists representing the disciplines of plastic surgery, immunology/ transplant, medical ethics, psychology, infectious disease, oncology, medico-legal, physical therapy, pharmacology, and patient advocacy.
4. Appropriate patient selection criteria should be established and a complete risk/benefit ratio must be considered for each patient on a case-by-case basis.
5. To facilitate informed consent:
 - a. The physician must provide the patient with the latest and complete information on the risks associated with facial transplant.
 - b. The preoperative evaluation of potential donors may involve additional considerations as more experience is gained. At this time the results of facial transplantation are unknown. If early results are less than optimal, potential patients should be informed of any newly identified limitation of the procedure.

- c. Patients must demonstrate a thorough understanding of all the known risks and benefits.
 - d. The physician should regard the facial transplantation procedure as experimental and it should be subjected to the evaluation of an independent research ethics committee. This committee should subject the transplant and informed consent proposal to the rigors of valid consent for treatment in the context of surgical research.
 - e. The informed consent should include an alternative and acceptable solution for management of the recipients' face in the event of transplant failure.
6. Candidates for facial transplant should undergo a complete psychological evaluation as well as an evaluation of their psycho-social support system.
 7. Patients with known psychological or psychiatric diagnoses, poor coping skills, or a poor support system are poor candidates for facial transplantation.
 8. As with any new medical/surgical innovation, incremental steps are necessary to ensure its appropriate application.
 9. Peer review of the results of facial transplantation is mandatory to assure compliance with medical standards of care and objective assessments of outcome.
 10. The ethics of performing an experimental procedure with a potentially fatal or deforming outcome for the purposes of advancing science must be carefully weighed against the few potential benefits for a small group of patients, and society in general.

References

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