

# On the Ethics of Facial Transplantation Research

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Transplantation continues to push the frontiers of medicine into domains that summon forth troublesome ethical questions. Looming on the frontier today is human facial transplantation. We develop criteria that, we maintain, must be satisfied in order to ethically undertake this as-yet-untried transplant procedure. We draw on the criteria advanced by Dr. Francis Moore in the late 1980s for introducing innovative procedures in transplant surgery. In addition to these we also insist that human face transplantation must meet all the ethical requirements usually applied to health care research. We summarize the achievements of transplant surgery to date, focusing in particular on the safety and efficacy of immunosuppressive medications. We also emphasize the importance of risk/benefit assessments that take into account the physical, aesthetic, psychological, and social dimensions of facial disfigurement, reconstruction, and transplantation. Finally, we maintain that the time has come to move facial transplantation research into the clinical phase.

## Introduction: Advances in Transplant Surgery and Ethical Criteria

The field of transplantation surgery has always pushed the boundaries of medicine forward. In doing so it has repeatedly raised unprecedented ethical questions. Today, as teams around the world consider performing a human facial transplantation, the frontiers of medical ethics are again being tested. Not long ago the pressing ethical issues in transplantation concerned the scarcity of donated organs and the deaths of potential recipients that resulted from this lamentable scarcity (Veatch 2000). With the relatively recent advent of human hand transplantation, however, ethical reflection has shifted to the need to weigh the risks the patient assumes for the sake of receiving a donated organ that, unlike a heart or liver, is not necessary for his or her survival.

The aim of this essay is to address these ethical issues when they arise for human facial trans-

plantation research. When considering facial transplantation research, the ethical concerns must be based on the scientific, surgical, psychological, and social dimensions of the procedure and its aftermath. Therefore, this article devotes considerable space to discussing these dimensions in so far as they have implications for ethics. The ethical questions that arise here are complex and, as we have indicated, unprecedented. Issues of the psychological hopes, anxieties, and stability of transplant recipients have always caused ethical concerns, but with facial transplantation the psychological and social dimensions loom much larger: what is at stake is a person's self-image, social acceptability, and sense of normalcy as he or she subjectively experiences them. To formulate these broad concerns in the language of medical research ethics, many of the "risks" and "benefits" of the surgery seem unpredictable.

## Keywords

composite tissue  
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procedures  
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As one of the teams preparing to perform human facial transplantation, a key part of our program at the University of Louisville consists of soliciting and incorporating professional discussion into our protocol. The purpose of this essay is to present our reflections on human facial transplantation research to the biomedical ethics community in order to solicit their responses. We view this essay as a component of the “open display and public and professional discussion” required for proceeding in an ethical manner toward the performance of an innovative surgical procedure. As the reader will see below, this is one of the four ethical criteria that Dr. Francis Moore stipulated for undertaking such procedures (Moore 1988, 1989). Our team adopted these criteria and is adhering to them as part our program’s ethical guidelines. Throughout this essay we shall refer to the steps our team at the University of Louisville has taken to meet both Moore’s criteria and the ethical standards applicable to all health care research.

In part I of this article, we sketch the surgical procedures that are presently utilized in treating facial disfigurements.

In part II, we presuppose the guidelines and regulations formulated by *The Nuremberg Code*, the *Declaration of Helsinki*, *The Belmont Report*, and various official documents that form the basis for the ethical evaluation of all health care research performed today, and we examine facial transplantation from this point of view. We accordingly address the permissibility of facial transplantation research in terms of risk/benefit assessment, informed consent, and privacy and confidentiality.

In part III, we address the criteria enunciated by Francis Moore for judging the acceptability of innovative surgery (Moore 1988, 1989; Siegler 1998). Since we believe that Moore’s criteria prompt us to focus on issues not routinely included in the ethics of research, we also deem it important to examine facial transplantation in the light of these requirements.

In part IV, we raise the question, Is it time to perform a facial transplant? Based on parts II and III we summarize eight criteria that, we think, must be satisfied in order to answer this question in the affirmative. We then consider that we have satisfied these criteria at the University of Louisville and that therefore it is justifiable to move forward with performing an experimental facial transplant.

### *1. Present-Day Procedures for Treating Facial Disfigurements*

Facial disfigurement can result from trauma, extirpation of tumors, major burns, severe infections, or

congenital birth defects. Patients with such disfigurements number in the thousands (Lee and Mathes 1999). The most advanced treatments available today consist of reconstructing these defects by surgically reattaching the original tissues (Buncke 1996; Thomas et al. 1998), transferring autologous tissues from another part of the body (Angrigiani and Grilli 1997; Pribaz and Fine 2001), and/or using prosthetic materials to replace the missing tissues (Beumer, Roumanas, and Nishimura 1995). By far the best outcomes are achieved with the first alternative, when the original tissues can be salvaged and used to reconstruct the defect. Unfortunately, in most cases the original tissue cannot be salvaged, either because the trauma or disease causing the loss destroyed it beyond use or because the original tissues never existed in the first place (as in congenital birth defects).

When, as in most cases, the original tissues are not available, autologous tissue and/or prosthetic materials are used to reconstruct large tissue defects of the face. In these situations, complications caused by prosthetic materials (e.g., infection or rejection) are common, donor site morbidity (at the location from which the autologous tissues are taken) is almost always present, and multiple “revision” operations and prolonged rehabilitation are usually required. Moreover, functional and aesthetic recovery is usually poor, and the resulting deformity almost always leads to major psychosocial morbidity. The latter in turn often prompts these patients to retire to a secluded environment, becoming social recluses (Lefebvre and Barclay 1982; MacGregor 1990).

A possible solution to the above scenario is to reconstruct these severe facial deformities with identical tissues transplanted from brain-dead human donors (Composite Tissue Allotransplantation), as is done in solid organ transplantation. Composite Tissue Allotransplantation (CTA) in the form of human hand transplantation has recently received a great deal of attention in scientific circles and in the lay media. In the more than twenty hand transplants performed to date, the fact that the tissues used (human hands from brain-dead donors) were identical in both form and function to those originally lost has resulted in excellent early (five years) functional and aesthetic outcomes.

If facial transplantation were available for clinical application in the above-cited example, one could envision a single operation to replace the burned facial tissues with healthy donor tissues identical to the tissues destroyed in the accident. Following surgery, there would be a few revision

operations giving the patient a normal appearance and nearly normal function, allowing him or her to return to a normal life in a relatively short time.

In spite of these advantages that facial transplantation has over current reconstructive methods, the main disadvantage is that patients receiving facial tissues from a donor would, like solid organ recipients, have to take potentially toxic immunosuppressive drugs for life in order to prevent rejection. The risks posed by these drugs raises the central question concerning facial transplantation: Do the benefits of facial transplantation justify the risks posed by the immunosuppressive drugs?

## II. Official Ethical Codes for Research on Human Subjects

Here we shall address three of the main requirements of the ethics of research using human subjects: (1) risk/benefit assessments, (2) informed consent, and (3) privacy and confidentiality.

### *Risk/benefit assessments*

Ethical codes governing medical and surgical research require careful risk/benefit analyses.

The *Declaration of Helsinki* states:

Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interest of science and society. (Jonsen, Veatch, and Walters 1998)

*The Belmont Report* clarifies the extent of risks and benefits that need to be considered:

Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological, physical, legal, social and economic harm and the corresponding benefits. (Jonsen, Veatch, and Walters 1998)

The extent of risks and benefits may go beyond the individual subject, according to *The Belmont Report*: "Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society)" (Jonsen, Veatch, and Walters 1998).

Risk/benefit assessments must be carried out by three different parties. The individual subjects themselves must make such comparisons. The investigative team must make them. And the Institutional Review Board (IRB) reviewing the research

proposal must perform them. Regarding the IRB's duties, the U.S. Department of Health, Education and Welfare's Institutional Guide, *On the Protection of Human Subjects*, states:

The committee should carefully weigh the known or foreseeable risks to be encountered by subjects, the probable benefits that may accrue to them, and the probable benefits to humanity that may result from the subject's participation in the project or activity. If it seems probable that participation will confer substantial benefits on the subjects, the committee may be justified in permitting them to accept commensurate or lesser risks. (Jonsen, Veatch, and Walters 1998)

### *Risk/benefit assessment in facial transplantation*

In the light of these codes we must seek to develop a clear understanding of the risks to which a patient treated with a facial transplant would be exposed in comparison with the possible benefits. The main risks are those related to the surgical transplant procedure and the lifelong immunosuppression medications that patients would have to take in order to prevent the transplanted tissue from being rejected. The expected benefits primarily would be improvements in quality of life in the form of restored function and aesthetic appearance and the concomitant improvement in the recipient's body image and sense of self. These benefits would probably also increase the recipient's ease and ability in social interactions with other people. While using transplanted tissues to reconstruct facial deformities would significantly improve a patient's quality of life, in most cases these procedures would not be life-saving in the strict sense of the word. This situation stands in contrast to life-saving treatments, like heart and liver transplants, in which the risk/benefit ratio is more readily conceptualized.

Below we discuss the risks and the benefits of facial transplantation and apply them to the "risk and benefit" lessons learned in solid organ transplants and the recent hand transplants.

### *General Risks of Organ Transplantation Compared to Face Transplantation*

*Risks Related to Surgery.* While facial transplantation is a complex procedure, it does not pose more risks than conventional reconstructive procedures in which the patient's own tissue is used to repair the defects. In a 1998 multicenter study, Dupont et al. (1998) estimated this mortality to be no higher than 0.0567%, which was a figure far higher than that reported in most studies. In addition, compared to

conventional reconstructive procedures, facial transplant procedures would utilize tissues taken from a donor rather than from the patient's own body and would thus obviate the complications associated with donor site morbidity. Also, conventional reconstructive methods can require over 100 revision surgeries over many years whereas, if successful, facial transplantation would require only a few surgeries. Since each surgical procedure carries with it inherent risks, it could be argued that conventional reconstructive methods are associated with more risks than facial transplants.

#### *Risks related to immunosuppression*

The immunosuppression-related risks in facial transplantation are also expected to be the same as those experienced by the solid organ and hand transplant recipients, who receive the same drug regimens. The most common complications associated with the use of immunosuppressants include increased incidence of: (1) infections, (2) malignancies, and (3) end-organ toxicity. In rare instances malignancies associated with immunosuppressive therapy can result in death. The incidences of these complications, in the particular case of tacrolimus and mycophenolate mofetil/prednisone combination therapy (the drug regimen that would most likely be used in facial transplants), are as follows:

*Infections:* The incidence of opportunistic infections (bacterial, fungal, and viral, including CMV) reported in kidney transplant recipients using tacrolimus and mycophenolate mofetil (MMF) range from 8.4% to 31% (Daoud et al. 1998; Stratta 1997). When this complication occurs, the initial treatment usually consists of the appropriate antibiotic, antifungal, or antiviral agent. In rare cases it is necessary to lower the level of immunosuppression, or even to halt immunosuppressive drugs altogether.

*Malignancies:* In transplant recipients, there exists a 1.2% incidence of posttransplant lymphoproliferative disease (PTLD) and an 11.1% incidence of nonmelanoma skin carcinoma (reported over a three-year period of follow-up) (Mathew 1998). When malignancies occur in heart, lung, or liver transplant patients, immunosuppression must be continued because of the life-saving nature of the transplanted organ.

However, in facial transplantation, as in kidney transplantation, immunosuppression could be halted so that the patient's immune responsive-

ness against the tumor might be strengthened. Here, the recipient's life would not be put at risk by discontinuation of immunosuppression even though the consequence would be loss of the transplanted tissue.

*End-organ toxicity:* In solid organ recipients, tacrolimus has been reported to be associated with end-organ toxicity and presents itself in the form of post-transplant diabetes mellitus in 7 to 11.9% of recipients. Of these, approximately two-thirds are able to discontinue insulin within twelve months after transplant (Johnson et al. 2000; Miller 1999). Tacrolimus is also nephrotoxic, as evidenced by increased blood creatinine levels in approximately 20% of the recipients using this drug. Since organ toxicity is relatively drug-specific, substitution with different drugs often offers a solution in these cases. Combining tacrolimus with MMF makes it possible to reduce the tacrolimus doses and thus diminishes nephrotoxicity while maintaining adequate immunosuppression (de Mattos, Olyaei, and Bennett 2000).

In the case of end-organ toxicity, it could be argued that recipients of transplanted facial tissues have an advantage over solid organ recipients. This is due to the fact that facial tissue recipients could be potentially less susceptible to immunosuppression-related end-organ toxicity than solid organ recipients. This stems from the fact that by the time solid organ recipients receive their donor organ, they have often already experienced multiple organ problems from their underlying chronic disease. Once they receive their transplanted organ, the immunosuppressive drugs they must take often further damage their already debilitated organs. In the case of facial tissue recipients, serious underlying chronic disease would exclude the patient from transplantation, and consequently their organs should be healthy (Cendales and Hardy 2000). Therefore, it is reasonable to expect less end-organ toxicity with the immunosuppressive drugs in facial tissue recipients when compared with solid organ recipients.

*Psychological Risks.* The psychological risks that facial transplant recipients will confront will be similar to those experienced by solid organ transplant recipients, for example, a desperation that creates unrealistic hopes, fears that his or her body will reject the transplant, guilt feelings about the death of the donor, difficulty conforming to the treatment

regimen and its side-effects, and a sense of personal responsibility for the success of the procedure (Zdichavsky et al. 1999).

Moreover, the recipient of a new face must deal with a new appearance, but to some extent this resembles the risk of receiving a new hand, which also reshapes one's sense of one's appearance. What is unique to facial transplantation, however, is that facial appearance is intimately and profoundly associated with one's sense of personal and social identity. Therefore, the recipient of a face must adapt to his or her own responses to this new "identity" as well as to other people's responses to it. It is expected that such adaptations will not occur once and for all; rather, they will repeatedly occur and undergo modifications over time. Moreover, it will be impossible for the recipient of a transplanted face to escape a bright public spotlight, and such publicity will be invasive and long-term. Such risks might be mitigated by careful patient selection, ongoing monitoring, and psychiatric intervention, as indicated.

*Social Risks.* As in cases of solid organ and hand transplantation, the family of the recipient of a face will be responsible for care-giving and social and psychological support. The recipient and his or her family will also be subjected inevitably to intrusive publicity and media coverage. In addition to these risks to the family of the recipient, there are other risks that we might imagine affecting the larger society. For example, a successful facial transplant might be interpreted as conveying the message that a good quality of life cannot be achieved by people with disfiguring conditions. There also exists the possibility that the public may develop unrealistic expectations for the outcomes of such surgery, perhaps to the point of creating an inappropriate demand for its use in less worthy cases, such as cosmetic enhancement for the aging rich or for criminal identity concealment. The facial transplant research team cannot prevent these or other misconceptions. What the team can do is provide accurate information in order, it is hoped, to shape public opinions in a responsible manner.

#### *General Benefits of Organ Transplantation Compared to Face Transplantation*

Benefits associated with facial transplantation can be separated into three categories: functional benefits, aesthetic/psychological benefits, and social benefits. The relative value of these three types of benefits is important when assessing the risk/benefit

equation for a transplant candidate and developing a triage strategy. For example, a hand transplant provides predominantly functional and, to a lesser degree, aesthetic benefits. The combination of these two benefits contributes to the psychological benefit derived from this procedure. A transplanted hand takes the place of the lost/missing hand in the spatial resolution of the patient. This has important psychological implications and is a great benefit of this procedure. This was clear in the repeated statements by Louisville's first hand transplant recipient, in which he asserted that his transplanted hand gave him a sense of being "whole" and "complete" (Klapheke 1999).

*Functional Benefits.* Functional recovery of the facial tissues offers several important benefits. Depending on the extent of the original deformity, the anticipated benefits include restoration of blinking for eye protection, improved oral continence, and restoration of facial expression and sensory function.

*Aesthetic and Psychological Benefits.* The human face is unquestionably the most important aesthetic anatomical feature of the human body. Much of how other people react to us depends upon our aesthetic appearance. Moreover, the appearance of our face is the predominant anatomical feature by which we identify and differentiate ourselves from others. In a large number of cases facial disfigurement leads to depression, social isolation, and even the risk of suicide (Robinson, Rumsey, and Partridge 1996; Ye 1998). By replacing the disfigured face with a "normal" appearing/functioning face, facial transplantation would provide important psychological benefits.

*Social Benefits.* Closely related to functional, aesthetic, and psychological benefits is the enhanced social capacity of the subject. Although a period of adaptation will be required for both the subject and others involved, the subject's willingness and ease in engaging in social interactions should improve. Restoring the abilities to make facial expressions, enjoy an aesthetically acceptable appearance, and interact comfortably with others lends significant weight to the benefit side of the risk/benefit equation.

#### *Informed consent*

Ever since *The Nuremberg Code* (Jonsen, Veatch, and Walters 1998), informed consent has been fundamental to any research performed with human subjects. *The Belmont Report* grounds this requirement in the basic ethical principle of respect for persons

(Jonsen, Veatch, and Walters 1998). The *Report* states:

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied (Jonsen, Veatch, and Walters 1998).

*On the Protection of Human Subjects: U.S. Department of Health, Education and Welfare's Institutional Guide* specifies the main items to be covered by informed consent:

The basic elements of informed consent are:

A fair explanation of the procedures to be followed, including an identification of those which are experimental;

A description of the attendant discomforts and risks; A description of the benefits to be expected;

A disclosure of appropriate alternative procedures that would be advantageous for the subject;

An offer to answer any inquiries concerning the procedures;

An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activity at any time. (Jonsen, Veatch, and Walters 1998)

All prospective candidates being considered for facial transplantation in our program will be presented with an informed consent in both oral and written form. Investigators who will be involved in performing the transplant will discuss with the prospective subject all elements of the informed consent and will address any concerns or questions that the subject may have. Prospective subjects will in no way be coerced or manipulated regarding any part of the informed consent process.

To assure that the prospective candidate receives an objective perspective during and after the informed consent process, he or she will be encouraged to select a subject advocate who will assist him or her in understanding and deliberating about the various components of the procedure.

Here we shall not summarize the many items included in this informed consent process. However, we would like to note that item 6 in the *On the Protection of Human Subjects: U.S. Department of Health, Education and Welfare's Institutional Guide* cited above cannot be followed strictly in facial transplantation: the subject must conform to the research-treatment regimen as long as he or she has the transplanted facial tissue.

### *Privacy and confidentiality*

The *Declaration of Helsinki* states:

The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject. (Jonsen, Veatch, and Walters 1998)

In the case of transplantation research, there are two groups of persons whose privacy and confidentiality should be respected. The first is the donor and his or her family, and the second is the recipient and his or her family.

#### *Facial Tissue Donor*

The privacy and confidentiality of the donor and his or her family ought to be respected to the extent permitted by law. All reasonable efforts should be made to protect the donor's anonymity. Identifying information ought not to be publicly revealed. The donor's family must be informed, however, that the research team cannot prevent someone (e.g., a member or friend of the donor's family) who knows about the case from publicizing information on his or her own.

#### *Facial Tissue Recipient*

In the case of an innovative therapeutic procedure like facial transplantation, there are two reasons for concern about the confidentiality and privacy of the recipient and his or her family:

1. The full scientific reporting and discussion of this procedure and its results may be restricted too greatly by efforts to maintain the privacy of the subject. For example, in the publication of the outcomes of the operation it may be highly desirable, from a scientific point of view, to provide unaltered photographs of the face of the recipient. Also, in conference presentations it might be very helpful, again from a scientific point of view, to hear the recipient him- or herself speak about his or her experience and to respond to questions. Hence the mandate to respect privacy and confidentiality may conflict with scientific requirements.
2. The prospect of a facial transplant has already attracted significant media attention, and as the likelihood—and then the reality—of such a phenomenon develops, the interest of the media in it will inevitably become greater. It is difficult to

imagine, then, how the media can be kept from discovering the identity and much other information about the recipient and his or her family. Indeed, for the recipient, “privacy” may not be possible.

In a recent article entitled “High-Profile Research and the Media: The Case of the AbioCor Artificial Heart,” E.H. Morreim carefully examined the issue of disclosure of information to the public (Morreim 2004). She pointed out that, from a scientific point of view, the ideal way to provide information to the public is through publications in refereed professional journals. Peer-reviewed publications are better able to provide accurate scientific information than are press releases that occur as the research project progresses. Nonetheless, she noted that high-profile research cannot enjoy such luxury in a society that prides itself on its “freedom of the press.” She sought, then, to sort out the competing obligations to disclose information to the public, to maintain the research subject’s privacy and confidentiality, and to publish the procedures and results of medical/surgical research in professional journals.

Morreim (2004) pointed out that in our society we must recognize “the right of free press” and the public’s “desire to know” about health care innovations. Freedom of the press, she asserted, “does not mean that anyone is required, in the first place, to provide a reporter with whatever information he wants” (Morreim 2004). Similarly with the public’s “desire to know” some kind of information: it does not entail that anyone has the duty to produce the information (Morreim 2004).

Nevertheless, in keeping with our established policy of “open display and professional and public discussion and evaluation,” we believe we are obligated to release to the press basic clinical and surgical information about facial transplants. This obligation, however, must be balanced against the research subject’s right to privacy and confidentiality. Morreim (2004) seems to have concluded that “materially significant trends in the progress of the trial” should be disclosed to the public, and “Patients should not be permitted to veto the disclosure of such information” (Morreim 2004). Affirming the patient’s right to privacy, however, she added,

Patients should be able to control some kinds of information. Clearly, purely personal details such as marital status, education, occupation, and the like should be governed by the patient (Morreim 2004).

And, she continued,

Additionally, patients and families should have the opportunity to review press releases in advance to correct errors, delete unsuitable personal information, and influence the tone of the report. (Morreim 2004)

These suggestions will guide our approach to press releases and to protecting the subject’s privacy and confidentiality. Accordingly, we shall inform the subject and his or her family that we shall need to publish in professional journals some identifying information about the subject. We shall seek, however, to restrict such information to solely what is necessary for scientific purposes. In addition, we shall inform the subject at the outset that we shall provide press releases. As press releases are prepared, the general nature of the information that will be released will be disclosed to the subject and the subject’s family, and they will be given the opportunity to review the information and offer suggestions. We shall also inform the subject that extensive media attention is likely to be forthcoming and that we cannot guarantee that their identities and other personal information will not be discovered and published by the media. As the press releases are prepared, we shall provide subjects and their families the opportunity to review them in advance and offer suggestions. Subjects and their families will remain at liberty to control personal information in so far as this can be done in the light of the intense media spotlight.

### *III. Francis Moore’s Criteria for Innovative Surgical Procedures*

In our facial transplantation program at the University of Louisville, in addition to the above ethical requirements, we have also adopted and are following criteria recommended by Dr. Francis Moore (1988, 1989). In 1988 article, Moore offered four criteria for determining whether it is ethically acceptable to employ an innovative surgical technique. His criteria were: (1) the scientific background of the innovation, (2) the skill and experience of the team (“field strength”), (3) the ethical climate of the institution, and (4) open display and public and professional discussion and evaluation (Moore 1988).

#### *The scientific background of the innovation*

This criterion requires that the scientific preparation for proceeding to carry out an innovative surgical procedure must have been carefully and fully developed. The scientific preparation for facial

transplantation is derived primarily from solid organ and hand transplantation research. In addition, unique to hand and facial transplantation, the risk vs. benefit equation in these non-life-saving procedures is being studied (Cunningham et al. 2004).

The vast majority of solid organ transplantation research that bears relevance to facial transplantation has focused on identifying and developing new immunosuppressive drugs and drug combinations that effectively suppress rejection while also causing minimal side effects. The relevant literature is full of basic science and clinical research describing the development and evaluation of these drugs (Gorantla et al. 2000). In 1997, experiments conducted in our laboratory in a large animal model (Ren et al. 2000) demonstrated that one of these new drug combinations (tacrolimus/MMF/prednisone) successfully prevented rejection of transplanted skin, muscle, bone, and other tissues making up the hand while causing minimal systemic toxicity (Jones et al. 1999; Shirbacheh et al. 1998). Based on these experiments, teams in Lyon (France), Louisville (USA), and Guangzhou (China) performed in 1998 and 1999 the first four human hand transplants using this same drug regimen (Dubernard et al. 1999; Francois et al. 2000; Jones et al. 2000).

From an immunological standpoint, since the face contains mostly the same tissues as the hand, it is reasonable to assume that the same immunosuppressive drug regimen found to be effective in the animal research that preceded human hand transplants and in the human hand transplants that followed should also be effective in facial transplantation.

In addition to this animal research, the scientific preparation for facial transplantation must include empirical studies that address the critical ethical questions that such procedures pose. We are therefore in the process of carrying out several studies that aim to answer the central question, "Do the benefits of facial transplantation justify the risks posed by the immunosuppressive drugs required to prevent rejection?" While the risks of immunosuppression are generally accepted for "life-saving" organ transplantation procedures, these same risks are questioned when it comes to "non-life-saving" or "quality-of-life improving" procedures like facial transplantation. To address this issue we designed a questionnaire-based study (Cunningham et al. 2004) to assess the amount of risk individuals are willing to accept to receive the benefits of facial transplantation. Our initial findings from over 250 individuals in four populations questioned (healthy

normal subjects, upper extremity amputees, organ transplant recipients, and individuals with facial disfigurements) indicate that they would accept significantly more risk to receive a facial transplant than a single hand, double hand, larynx, foot, or even a kidney transplant (Banis et al. 2002). The last point is intriguing since kidney transplantation is a universally accepted treatment for which the risk vs. benefit ratio goes largely unquestioned.

Siegler (1998) has claimed that central to the ethical concerns with respect to these procedures is the question of whether "the equipoise consideration has been satisfied." He defined equipoise as "a situation of uncertainty in which the clinical investigator regards the potential outcome of an experiment or clinical trial as truly balanced between its potential for benefiting the patient or for causing unintended harms" (Siegler 1998). The key term here is "uncertainty." At stake is an uncertainty that remains at the point at which we have gained as much knowledge as we can through scientific studies; and therefore, additional knowledge can be attained only by actually performing the experimental procedure and following the outcome. We believe that facial transplantation has reached a position of equipoise because we are destined to remain uncertain about whether the benefits will outweigh the harms (or vice versa) until we perform the procedure and observe the actual results.

### *The Skill and Experience of the Team ("Field Strength")*

Moore (1998, 1999) emphasized that the skill and experience of the team undertaking the innovative procedure is crucial. Obviously, such a procedure can be truly "tested" for its safety and efficacy only if the skills and experience of the team performing the procedure are unlikely to be the cause of failure. Moreover, the "field strength" of the team must be assured in order to protect the subjects from harm. *The Nuremberg Code* enunciates this ethical concern for beneficence:

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment. (Jonsen, Veatch, and Walters 1998)

The team at the University of Louisville is composed of experts who have extensive experience in the scientific, clinical, surgical, and psychological areas pertinent to facial transplantation. This

includes specialists in reconstructive surgery, head and neck surgery, transplant surgery, immunology, psychology, psychiatry, ethics, Institutional Review Board participation, and organ procurement. The reconstructive and head and neck surgeons on our team are familiar with and regularly employ the latest techniques described above to remove, transfer, and reconfigure autologous tissues to reconstruct facial deformities. Indeed, members of the team have pioneered many of the techniques used today for reconstructing complex facial deformities (Banis and Acland 1984). In addition, the team has acquired relevant skills and experience through having established a program for and performed successful human hand transplants. It is such “field strength,” we think, that is necessary in order to take the next step of performing a human facial transplantation.

### *Ethical climate of the institution*

What is at stake here is ultimately the motivation for undertaking the innovative procedure. Moore was concerned that the innovation not be performed mainly for the purposes of institutional or professional self-aggrandizement. He thought that it should rather be carried out primarily for its potential contributions to those people who are in need of the procedure. As he expressed it:

When the epiphenomena of medical care, such as capital gain, investor profit, institutional representation, surgeon ego, municipal pride, and chauvinism, become the true objective of the procedure, then the ethical climate of the institution is no longer acceptable for therapeutic innovation (Moore 1988; Siegler 1998).

Adherence to this ethical requirement is essential but difficult to verify. How can we determine what a person’s or an institution’s motivations are? Usually people and institutions engage in sizable projects with a variety of motives for doing so.

We suggest that the ethical issues here pertain to possible conflicts of interest. If desires for enhanced reputation, financial reward, professional vanity, and so on motivate those involved to compromise the scientific, medical, surgical, or ethical aspects of the procedure, “then the ethical climate of the institution is no longer acceptable for therapeutic innovation.” An institution may seek an enhanced reputation and even financial profit from being “the first” to advance therapeutic techniques. Indeed, numerous health care institutions highly prize their public reputations for being “first” with innovative procedures, and this usually does not lead

people to suspect unethical conduct. The desire to be first becomes unethical only when it motivates the institution to undertake the innovation in a manner that fails to follow strict scientific, medical, surgical, and ethical demands. The key question then becomes this: Have the institutions and professionals involved adhered as much as can reasonably be expected to scientific, medical, surgical, and ethical requirements in performing this new procedure? If these requirements have been met, then it matters little what other motivations may be operative. And this would seem to be the case especially in view of the fact that such motivations can usually not be detected or proven.

### *Open display and public and professional discussion and evaluation*

Moore (1998) recognized that it is crucial that innovative surgical procedures be openly displayed before the broad community of professionals in the field as well as before the general public. In order to ensure that the issues surrounding facial transplantation would be submitted to public and professional discussion, evaluation, and criticism, we at the University of Louisville have organized and participated in several conferences addressing these manifold issues. Moreover, we have published the proceedings from these conferences in trade journals to make them accessible to as wide a professional audience as possible. Feedback we have received from public and professional discussion has allowed us to rethink and revise various components of our program. In fact, although our institutional review board proposal has been virtually complete for over three years, we have postponed submitting it for approval and have rather repeatedly fine-tuned it based on criticisms we have received from professional and public discussions.

Below we list the main examples of efforts we have made to meet Moore’s recommendation of open display and public and professional discussion and evaluation.

In November 1997, we hosted the first International Symposium on Composite Tissue Allotransplantation in Louisville, Kentucky. The workshop brought together international experts in immunology, transplant, plastic, and hand surgery, research, and ethics to evaluate the scientific, ethical, and clinical barriers standing in the way of performing the first human hand transplants. After two days of discussion the consensus was reached that sufficient animal research had been done and that it was time

to move on to the clinical phase of this research (Barker et al. 1998).

In May 2000, we convened the 2nd International Symposium on Composite Tissue Allotransplantation in Louisville, Kentucky to share the early results of the first human hand transplants and invited teams who had performed other types of composite tissue allotransplantation procedures (namely, larynx, bone, tendon, and nerve). Three hand transplant teams reported encouraging early immunological and functional findings. They reported that the immunosuppressive drug regimen [tacrolimus/MMF/Prednisone] they were using effectively prevented hand rejection, allowed for good recovery of hand function, and caused minimal toxic side-effects in their first patients (Barker, Breidenbach, and Hewitt 2000).

We have also published discussions of the present and future state of composite tissue allotransplantation in professional trade journals (Barker, Vossen, and Banis 2004; Barker et al. 2002; Gorantla et al. 2001)

On November 19, 2003, our team participated in a public discussion at the Dana Center of the London Science Museum. At this gathering four professionals from various fields related to facial transplantation explained their work and their respective positions on the question of whether the time had come to perform human facial transplants. This two-hour event specifically focused on the public's participation and their opinions (Morris and Monaco 2004). Following this meeting the proceedings were posted on the Dana Center's website, and the public was invited to post its views. Finally, in addition to these public forums for discussion, we have also openly made our program available to the public in several sources of print, radio, and television media.

#### IV. *Is It Time to Perform a Facial Transplant?*

In light of the above discussion we would like to put forward a set of criteria for determining whether the point has been reached, in the preparation and development of this innovative surgical procedure, at which it is justified to perform an experimental facial transplant. The criteria we propose are these:

1. Moore's criterion of "scientific background of the innovation." The preparatory scientific groundwork has been laid through laboratory and clinical investigations of the pertinent medications, technology, procedures, and ethical issues. This

preparatory work has significantly reduced the risks of the proposed procedure.

2. Moore's criterion of "skill and experience of the team ('field strength')." The surgeons and clinicians involved in the research project possess the knowledge, experience, skills, and technical abilities needed for it.
3. Moore's criterion of "open display and public and professional discussion and evaluation." Items (1) and (2) above have been publicized so that professional and lay persons who have so wished have had sufficient opportunity to discuss and criticize the performance of the procedure. Moreover, these responses and criticisms have been seriously considered by the research team and have, when appropriate, influenced the revision of the research proposal.
4. Moore's critique of the "ethical climate of the institution." The innovation is not being performed for purposes of institutional prestige or professional recognition. It is rather the criteria enumerated here that are the truly governing ones.
5. The remaining uncertainties regarding facial transplantation and its consequences can be resolved either by proceeding to actually performing the procedure on human subjects or by postponing it and waiting for further developments. Undoubtedly, postponing the procedure would allow for the development of medical innovations. An analogy can be imagined in the manned mission to the moon. This venture would have been aided by the development of the micro-computer, digital camera, and other innovations produced during the past three decades. Such innovations, however, were not essential for a successful moon mission. We submit that, in an analogous way, future medical developments will provide only minimal knowledge compared to that which will be gained from performing the procedure. An example of this is in the knowledge gained from performing human hand transplants. Despite the arguments made against them as too precipitous and uncertain, over twenty hand transplants have been performed. As a result, the field has gained a wealth of knowledge based on direct evidence that would not have been possible if we had not dared to perform the procedure in the face of the uncertainties.
6. There exist informed subjects who, deeming the procedure beneficial, want to undergo it and who will not be able to undergo it if it is postponed in order to wait for further developments.

7. There exist indefinitely many other potential subjects who could in the future benefit from this procedure if it proves to be successful.
8. The procedure has been subjected to the established regulatory scrutiny and reviews, including approval by the relevant IRB.

If these eight criteria are satisfied, we submit that it would be justified to actually perform the experimental procedure on qualified, voluntary, and informed human subjects. Furthermore, we maintain that at the University of Louisville these criteria have been satisfied for the procedure of human facial transplantation. There arrives a point in time when the procedure should simply be done. We submit that that time is now. ■

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#### **Competing Interests Statement**

The authors declare that they have no competing financial interests.

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2004

# Should We Be Putting a Good Face on Facial Transplantation?

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If the Phantom of the Opera were offered a face transplant, would he have the capacity to say “no,” or would he be so desperate for a new face that he would grasp at straws? The question of whether it is ethical to begin human facial transplantation at this time is complicated. Potential recipients are likely to be psychologically vulnerable because of their disfigurement. Affective factors may compromise their ability to weigh risks and benefits autonomously and to have realistic expectations about the success of the transplant. Transplant patients might experience psychological distress over their new appearance, even if it is aesthetically more pleasing than the old one, arising in part from the introduction of a new appearance into preexisting social networks. Moreover, an unfavorable aesthetic result could occur if the donor skin differs in appearance from the recipient’s in color, texture, shininess, thickness, or hair characteristics. This could make it difficult to find an appropriate donor. Also, tissue retrieval involves disfigurement of the donor’s face, adding to the difficulty of obtaining consent from the donor or donor’s family. These and many other considerations enter into the ethical analysis.

Wiggins and colleagues (2004) attempt to put a good face on facial transplantation. They hold that it is ethical to begin performing human facial transplants at this time. At one point they express this view using the concept of “equipoise,” by which they mean a balance between the potential benefits and harms. They assert that face transplantation is in such a position of equipoise. They claim that the central question concerning the ethics of facial transplantation is whether the benefits justify the risks posed by the immunosuppressive drugs. Presumably, they are referring to the risks of infection, malignancy, and organ toxicity, for these are the risks of immunosuppressive drugs that they discuss in their paper. In focusing on these risks, they have misstated the central question. The question is whether, in light of *all* the risks of the procedure, the benefits justify going forward. And there is a very important risk that is left out of their discussion—the adverse consequences that would follow graft loss.

To understand this risk, it is necessary to review what is involved in facial transplantation. There are several possible variations, in terms of the types of tissue that are transplanted. One involves transplantation of vascularized skin and subcutaneous fat, without muscles, facial nerve, or other tissues. Other variations might include, in addition to skin and fat, transplantation of muscles, facial nerve, and possibly some of the bony architecture of the face (Morris

et al. 2004). Presumably, transplants involving vascularized skin and fat would be attempted first. What is envisioned is a “mask” with openings for the eyes, nostrils area, and mouth. Tissues that generally would not be replaced include those around the eyes including eyelids, the nostrils area, and the lips, in order to preserve the functioning of those areas. Such a graft would be placed directly onto the recipient’s facial muscles. This would involve removal of the recipient’s facial skin and scar tissue. Survival of the graft would require satisfactory arterial input and venous drainage. The tissue would have to be removed from the donor in a manner that preserves selected arteries and veins. These would be joined to the recipient’s arteries and veins by microanastomosis (Morris et al. 2004).

Two prominent professional committees recently have expressed the opinion that human facial transplantation should not be carried out at this time. A working party of the Royal College of Surgeons of England created a valuable report on the pros and cons of such transplantation and concluded that it would be unwise to proceed at present, based in part on concern over the adverse consequences of graft failure (Morris et al. 2004). Similarly, the French National Ethics Advisory Committee concluded that the risks of the procedure make it currently unethical, also based partly on consideration that graft failure would make the recipient’s situation worse (Bosch 2004).

The graft could fail if adequate blood circulation is not successfully established, or if there is subsequent clotting of the arteries or veins. Inadequate blood perfusion of the graft could result in necrosis of the transplanted face. Another potential mechanism for failure is acute rejection that cannot be reversed by modifying immunosuppressive drug therapy. A third major cause of graft loss is chronic rejection, which involves narrowing of the arterial lumen and fibrotic changes within the vessel walls, resulting from mechanisms that have not been well defined but presumably are immunologic in nature. Progressive vessel damage leads to graft ischemia (Suthanthiran et al. 2001).

If the graft fails because of any of these factors, it would have to be removed. Such graft failure could be devastating for the patient. It would leave the patient with an extensive facial wound with potentially serious physical and psychological consequences (Petit et al. 2004). At that point, reconstructing the face would be challenging for the surgical team and the patient (Siemionow, Ozmen, and Demir 2004). The patient would need additional skin grafts, which could be autologous if the patient has sufficient donor skin

sites. Graft failure clearly would be a major setback for the patient.

The United Network for Organ Sharing (UNOS) provides statistics on solid organ graft survival. The most recent data for three-year graft survival are for transplants performed during the period 1996–1999. Based on this data, the best graft survival rate occurs in kidney/pancreas transplants, for which the three-year graft survival for all primary (first-time) transplants is 83.6%. The three-year graft survival rates for primary transplant of other organs is as follows: heart/lung, 42.9%; heart, 77.3%; intestine, 46%; kidney, 81.4%; liver, 73%; lung, 57.4%; and pancreas, 60.7% (UNOS 2004). Recent data from individual transplant centers suggests that the use of tacrolimus as part of the immunosuppression regimen lowers rates of chronic rejection for some solid organs (Jain et al. 2001).

Long-term graft survival for composite tissue transplants cannot reliably be quantified at present because a limited number of such transplants have been performed. A better graft survival rate for facial transplants in comparison to, say, kidney/pancreas transplants should not be expected because skin is more antigenic than solid organs; in fact, skin has the highest antigenicity of all tissues (Petit et al. 2004). If we assume, for the sake of argument, that the three-year graft survival rate for face transplants would be equivalent to the best success rates according to the most recent UNOS data—that is, approximately 80%—this would imply that, at best, one in five facial transplant recipients will lose the graft within three years. Graft survival rates for longer periods—five years or ten years—would presumably be even lower. Thus, some patients, including those who might not be able to consent autonomously because of affective factors, might be harmed terribly by graft failure. Given the psychological vulnerability of the potential recipients, this risk appears to be unacceptably high. These considerations support the view that facial transplantation does not have a favorable balance of risks and benefits at this time. Further research is needed

to find better ways to prevent immunologic rejection and to improve long-term graft survival before going forward with this experimental approach. ■

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## A Surgeons' Perspective on the Ethics of Face Transplantation

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The Target Article under discussion (Wiggins et al. 2004) develops a rather complete and prominent ethical view on human face transplantation. While a few transplant and

plastic surgeons recently opened the discussion on the surgical and immunological aspects of this procedure (Morris et al. 2004; Petit et al. 2004), its ethical aspects have mostly

been retained by professional “ethicists” whose positions have been released through governmental ethical agencies’ formal statements, for example, the Royal College of Surgeons of England (2003), and the *Comité Consultatif National d’Ethique* in France (2004). The authors should be congratulated for their substantial contribution to the debate. We will only add a few comments and focus on the still remaining aspects that we consider the most relevant at this time.

We have no doubts that human face transplantation will one day be performed. We still do not know *when, where, for, and by whom*, but these are irrelevant details. The main issue is not even success or failure of the procedure, but rather the ethical conditions surrounding it. An ethical face transplantation that would eventually lead to failure will be remembered as an honorable attempt (as were all the other first organ transplantations). An unethical face transplantation that would eventually lead to a technical success will be looked at as a “trick” made by mercenaries of science.

From our point of view, three ethical aspects should be taken in account in particular:

1. *On the recipient . . .*

One should be aware that, while the rationale for such a procedure is quality of life, it would also threaten the recipient’s life. However, plastic surgeons know that, in some rare cases, the health conditions of the patient are so miserable that he/she would accept a potentially shorter life if his/her quality of life could improve. This debate is not specific to disfigurement. Regarding hand transplantation, the French ethics committee has admitted that amputation of both hands could justify a double-hand transplantation. In such rare cases, the handicap is so important that the potential benefits of transplantation outweigh the risks from the procedure and from lifelong treatments. We believe that plastic surgeons are the right people to assess the risks and benefits of a face transplantation, not only because they have the best knowledge of the technical aspects of the procedure, but also because they deal everyday with patients’ distress related to physical and aesthetic disabilities.

2. *On the donor . . .*

In most societies, whatever the culture and the religion, great respect is due to the dead body, in order to accomplish the rituals for the gateway to “life after death.” In the aftermath of the death of loved ones, rituals should be respected to help ease the mourning. One can imagine how difficult it could be for relatives to proceed to the rituals and deal with a picture of a disintegrated body in mind. Thus, the issue related to the donor also becomes an imperative duty: restoration of the donor body’s integrity. When we started considering face transplantation as a potential solution and then announced our plans

to the French transplant agency (*Etablissement Français des Greffes*), one of the prerequisite they raised was restoration of the donor’s face. We are still looking for a fully satisfactory solution.

3. *On the population . . .*

The prospect of a face transplantation brings up the Frankenstein story. Care should be taken to not frighten or repulse the population. The mass media take great responsibility by systematically turning this topic into sensational news; face transplantation is *not* a weapon of mass distraction. In recent years, transplant teams have observed a decline in organ donation and now have to deal with a shortage of organs. If the population’s response to face transplantation (specially if seen as “unethical”) was the worsening of organ shortage, it would have a terrible impact on the practice of transplantation, one of the greatest achievements of modern medicine.

In conclusion, our position is that face transplantation could now be performed. The switch from “*could*” to “*should*” depends on the ethical conditions surrounding the procedure. As for any other medical procedure, face transplantation would have to be performed with adherence to strict medical and ethical guidelines: professional competency, clear therapeutic objective, and informed consent of the patient. We should be well prepared, and a great amount of tact will be needed, to face the questions and doubts that would rise soon after, among potential donors’ families and the population.

The following key questions remain:

- Have we lowered the risk of failure of the procedure enough?
- Would the procedure actually benefit the patient?
- How would the procedure affect people’s opinion of doctors and transplantation in general?

It is now the moral responsibility of each and every doctor involved in teams preparing for face transplantation to question his/her own soul and conscience and find the answers to the above questions before attempting the procedure. ■

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## Face Transplantation: When and for Whom?

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Transplanting a human face is technically possible (Hettiaratchy and Butler 2002), and an extensive period of discussion and consultation is currently underway prior to potentially making this possibility a reality (Barker, Vossen, and Banis 2004; London Science Museum 2003). However, it is not yet clear whether it would be ethical to proceed, and the subject is highly controversial. Facial transplantation is not only technically challenging but would require lifelong immunosuppression. These and other factors would expose any recipients to significant risk and the question is, To what benefit?

The procedure and the perceived “race” to be the first to perform the operation have caught the imagination of many journalists whose enthusiasm is threatening to thwart the integrity of a proper and adequate discussion of the ethical issues that should be addressed prior to any attempts at turning this operation from a possibility into a reality. A working party report from the Royal College of Surgeons of England in November 2003 urged caution and careful deliberation (Morris et al. 2004). The French National Ethics Advisory Committee rejected an application from the French facial transplantation team on the grounds that the inherent risks of the procedure make it unethical (Bosch 2004). It is essential, therefore, that society makes a carefully considered decision on this topic and that this is done in advance of any group actually attempting the procedure.

The debate on facial transplantation must consider the full surgical, anatomical, psychological, and ethical issues and the impact on any patient chosen for the surgical operation. Selecting appropriate recipients will be difficult and will take a considerable time. This process would involve identifying those patients who would have functional benefit and who also had realistic expectations of the procedure. The patient would have to be determined and resolute in

adhering to the prolonged rehabilitation and the need for chronic immunosuppression. The patient must be robust enough to cope with these challenges and the psychological effects involved. The ethical dilemma considered by Wiggins et al. (2004) in this issue is further compounded when one considers all candidates for facial transplantation as a single group. In fact, candidates for facial transplantation are quite disparate from both a surgical and a psychological perspective. From a surgical standpoint, the reconstruction of a face with a facial allograft is technically challenging but possible. However, the surgical challenge depends on the type of tissue to be transplanted, which in turn depends on the tissue needed to achieve facial reconstruction. The inclusion of craniofacial skeleton in the facial allograft makes the reconstruction difficult because blood supply through the facial artery is not adequate to keep it viable. Therefore, the maxillary artery would have to be raised with it and thus make the allograft harvest extremely difficult. It also raises issues of concern about the surgical options if an allograft of this size fails. Issues of concern are also raised in relation to what benefit a patient may gain from this procedure. The nearest facsimile to this procedure is the facial replantations that have been performed following traumatic avulsion of the facial skin envelop (Wilmelmi et al. 2003; Thomas et al. 1998). These have demonstrated that tissue can be reattached and remain viable. The reattached facial tissue regains some function but not normality. Transplantation of functional tissue requiring reinnervation has also been suggested. This also has severe limitations, as the return of normal function in the transplanted facial nerve and facial musculature would be doubtful (Myckatyn and Mackinnon 2003). It is imperative, therefore, that the desired outcome for this type of surgery clearly be improvement in facial function and appearance and not normality.

Wiggins et al. (2004) stress the psychological and social effects of disfigurement as being profound, noting social isolation and even suicide as a consequence of severely abnormal appearance. However, in supporting these assertions they rely on very old references, which do not take account of twenty years of intervening work. Rumsey and Harcourt provide an excellent review of this field, noting in particular that there is no identified relationship between severity and psychological distress and that “the extent to which a visible difference results in social disability involves a complex interplay of social and individual factors” (Rumsey and Harcourt 2004).

These findings are of great significance in the selection of potential candidates for face transplantation. In the first instance, it is clear that the appearance of the patient in itself, even when severely disfigured, is not an adequate criterion for surgery. Far more important is the evidence of the precise problem that this causes the patient in their day-to-day life. Ironically, it may be that people who have well-developed coping strategies and good social skills cope well with disfigurement, while those who find life generally more challenging, also cope poorly with disfigurement. The concern for us as clinicians proposing this complex procedure is that this group may also cope poorly with face transplantation; thus, the very group who might benefit most are those who are least likely to cope with the procedure, particularly if the results fall short of their expectations.

It is also very difficult to support face transplantation as an ethical procedure using the social adjustment model when there is good evidence that social skills can be learned and that this results in reduced social anxiety and avoidance (Robinson et al. 1996). It is of note that in this study, significant change was achieved after a workshop of only two days, and that the benefits of the intervention were maintained at follow up. We would argue that it is important that face transplantation be offered only when it is unlikely that psychosocial intervention will be unhelpful: there can clearly be no ethical argument for face transplantation and all its potential risks if the stated benefits can be achieved by noninvasive and very simple forms of intervention.

Thus, while generally supporting the conclusions of this essay which are concordant with our own assessment (Clarke and Butler 2004), we would argue that their own rigorous ethical standards require the authors to demonstrate a more thorough protocol for psychological assessment which takes account of the issues above and ensures that they are not, in effect, selecting patients who (a) are at risk of coping poorly with the procedure or (b) could achieve the objectives of face transplantation via noninvasive psychosocial intervention (Clarke and Butler 2004).

Each patient will be unique from all these points of view, and therefore blanket ethical approval for this pro-

cedure would be inappropriate, and each patient would need to be individually assessed and the risks and benefits weighed. There are a large number of ethical issues that require consideration, and it is imperative that this occur before any face transplants are carried out. The temptation to perform or receive the world’s first face transplant may relegate the ethical considerations to the sidelines while the surgical team and the patient take center stage.

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## Facing Ourselves

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### *Prophylactic Ethics: Form or Function?*

Wiggins and his colleagues (2004) are to be commended for their willingness to raise the question of the ethics of undertaking the world's first face transplant prior to initiating the experiment. The surgical group at the University of Louisville has shown a notable interest in engaging in "prophylactic ethics," having publicly raised questions and sought input about the ethics of hand transplantation prior to undertaking a series of such operations (Siegler 1998; Altman 1999).

Prophylactic ethics, engaging in an open public dialogue about the ethical and social questions raised by an experimental procedure, innovative technology, or proposed new public policy, is an activity that is not only endorsed by bioethicists (for example, Caplan 1998) but that has been usefully applied with respect to a variety of innovative experiments and technologies, such as xenografting (IOM 1996), neuroethics (Caplan 2003), and life extension technologies (Post and Binstock 2004). It is very difficult to raise thoughtful and well-informed ethical questions about a novel experiment once the experiment is already underway, as the examples of the Baby Fae xenograft and, much more recently, announcements concerning the cloning of animals and the creation of cloned human embryos (Cyranoski 2004) make clear.

However, a key presumption of prophylactic ethics is that those who are engaged in the dialogue not only listen closely to the comments and concerns that are elicited but also and most importantly be willing to delay or even forgo an experiment on ethical grounds. One gets the sense from reading the article by Wiggins and his colleagues (2004) that they have already made up their minds to proceed. Their recent request for IRB approval at Louisville would seem to bear this intent out (CNN.com 2004). Prophylactic ethical discussion is an important aspect of ethically sound clinical innovation, but the decision to engage in it does not in and of itself provide a rationale for innovation. Any experiment should not only be the subject of moral reflection and deliberation prior to its initiation, but also must be able to successfully engage the concerns and objections raised as part of that process.

Has this standard been met in the case of face transplantation? I do not think so. There are four problem areas for which the research team has not offered sufficient comment or persuasive ethical answers: the sufficiency of prior experimental work, the reasonableness of the risk/benefit ratio facing prospective subjects, the strategy for managing the experiment, and the impact on other parties, including

potential donor families and the general public, of undertaking the experiment.

### *Adequacy of Prior Work*

Wiggins et al. (2004) note that their experience with hand transplantation has made them confident that they have the surgical and immunological expertise to safely undertake a face transplant. But, others (Hausman, Masters, and Panozzo 2003) have raised significant questions about whether the results with hand transplantation have been impressive enough to justify the continuation of experimentation with this form of surgery except in very exceptional circumstances. The results of hand transplantation in terms of restoration of function have not been so impressive as to serve as an obvious rationale for moving forward with face transplantation.

Similarly, serious reservations have been expressed about the technical difficulties that still confront face transplantation in the areas of nerve reattachment, the management of acute rejection, and the prospects for muscle function (Bosch 2004; Morris et al. 2004). In light of these concerns, a case can be made that any attempt to undertake the first human face transplant should await further research on animal models, experimentation on cadavers, or those declared brain dead, and further advances in immunosuppression.

### *Risk and Benefit for Prospective Subjects*

Those who undergo severe facial disfigurement or who are born in such a state face enormous burdens in terms of function, social acceptance, and interactivity with other persons. It does not take an anthropologist to point out the enormous importance of the face in defining personal identity, social roles, and quality of life. Face transplantation may provide a useful option for those who must live with severe facial deformity.

However, the risks involved in undertaking the first clinical face transplant for the subject are staggering. It is not certain that the transplant will provide a functioning or even partially functional face. The drugs required to maintain a transplanted face are powerful, noxious, and potentially life-threatening. If the procedure should result in acute rejection, then the subject may die with the entire graft sloughing off his or her head. Even if that grim prospect does not occur, chronic rejection problems may be such that the recipient is exposed to doses of immunosuppression that lead to cancer, kidney failure, and other major problems. And this presumes the subject is compliant with

the postsurgical regimen, a state that some patients find very difficult to achieve post-transplantation.

Not only are the prospects for physiological complications and functional failure very real, but the first face transplant recipient will face enormous psychosocial challenges as well. Their ability to retain their privacy will almost certainly be nonexistent, given the public's fascination with this form of transplantation and the eagerness of the medical community to both promote and follow the first such surgery. And the first subject's ability to cope with a transplant that will be omnipresent to others and that will be a constant physical reminder of its origins from another person would challenge even the most well-informed subject and supportive recovery team (Caplan and Katz 2003).

It is understandable that there are subjects who would select facial transplant even in the face of a high risk of failure and even death. The willingness or even eagerness of a person to serve as a subject is not, however, a substitute for determining whether the state of the science supports attempting the experiment. Those seeking to learn from the first experiment should be able to state with confidence that they have taken every measure to minimize the prospect for harm that the subject could encounter, have thought through subject selection so as to maximize both compliance and the tolerance of failure, and have determined which prospective subject seems able to obtain the most support from family and friends in facing the enormous challenge of a face transplant. It is not clear that the Louisville group has met this admittedly high standard.

### *Management of the Experiment*

If anything can be learned from other high-profile medical experiments undertaken in the field of transplantation, it is that the prospects for failure are high. Xenografting of solid organs and bone marrow, multiple organ transplants, early forms of heart, liver, and lung transplantation, and the use of total artificial hearts have all shown that transplant teams need to have firm plans in place for managing failure (Burling 2002). This includes handling the media, supporting families and friends as well as the subjects themselves, the provision of financial support for unexpected costs that subjects and families may incur, handling depression and suicidal thoughts on the part of subjects, and providing the ability to decide to prematurely end the experiment should the subject so request or should the subject fall into a state such as PVS, where family members make requests for ending the experiment. It is not clear that the Louisville team has in place a well-thought-out strategy for managing all aspects of the experiment they propose to undertake.

### *Impact on Others*

One of the most worrisome aspects of undertaking a face transplant is the need to locate an appropriate donor. Rela-

tively little is said by Wiggins and colleagues (2004) about the selection criteria and management strategy they have in mind for dealing with this thorny problem.

Most organ donation involves organs and tissues that can be removed from a cadaver without causing grave disfigurement to the body. This will not be true of a face donation.

This raises the question of who should be approached about the prospect of donation. Putting aside technical issues of size, blood type, and antigen type which will shape who it is that can be a donor for a particular recipient, the pool of prospective donors who meet these biological criteria needs to be very carefully considered (Caplan and Katz 2003).

Will only those known to have filled out a donor card be approached? If so, can it be assumed that in doing so they intended to include in their range of donatable organs and tissues their face? If surrogates are to be allowed to make donation decisions in lieu of a known intent to donate on the part of the deceased, then on what basis will they be able to decide what a deceased person would have wanted with respect to his or her face? And who will approach the families of the deceased to make a request for a face? The professionals who currently are charged with the task of soliciting organs and tissues have little knowledge of face transplantation and, moreover, normally approach donor families with the rationale that any transplant that takes place will be therapeutic.

A case could be made that the optimal donor for such a procedure is someone who has considered this option prior to his or her death and agreed to permit it. It is not clear from the authors' discussion whether any consideration has been given to this option or how it might be implemented utilizing, say, terminally ill persons.

Similar questions about the reliability of consent to an unanticipated form of organ or tissue donation have been raised about donating sperm from deceased males. While sperm has been procured in a number of cases, it is clear that there is a need for a protocol for handling procurement (Batzler, Hurwitz, and Caplan 2003). The decision to procure a face from a cadaver source should not proceed without a clear protocol to govern procurement for this experimental procedure.

This is especially so since the negative impact of face transplantation on the attitudes of the general public about organ and tissue donation could be significant. If a donor family were to express dissatisfaction about any aspect of the donation of a face or should the transplant fail and the suffering of the subject receive widespread public attention, there could be an adverse impact on the public's willingness to support organ and tissue donation. Public trust in the competency and morality of those involved in transplantation is a key factor in facilitating the altruism requisite

for donation. Those involved in pioneering research in the field of transplantation must be sure that they have made every effort to minimize any adverse impact their experiment might have on that trust, something the Louisville group has not yet done.

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## How to Do Things with AJOB: The Case of Facial Transplantation

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If asked to read Wiggins et al.'s "On the Ethics of Facial Transplantation Research" (2004) with the aim of responding to it, I suspect that for most people the central question would be, "Did they get it right?" That is, have the authors accurately and thoroughly analyzed the moral issues that surround such experimental surgery? This seems to be the question that most of the respondents to this target article so far have addressed. Robertson (2004) states that he has "no quarrel with how they have worked the informed consent, risk/benefit, and privacy themes of that enterprise" but that he does think Wiggins et al. have not adequately described the social and psychological consequences of the procedure. Strong (2004) is concerned that in their analysis of equipoise the authors insufficiently attend to the risk of "the adverse consequences that follow graft loss."

These respondents scrutinize the essay in question as if it were what J. L. Austin, in his classic *How to Do Things with Words*, refers to as a "constative statement," a statement that strives to describe the world and can be evaluated in terms of its veracity (e.g., "This is my wife") (Austin 1962). Austin distinguishes constative statements from performative statements in which veracity is not the central issue. The most often cited example of a performative statement is a minister's wedding ceremony declaration "I now pronounce you husband and wife"; this speech act does not describe reality but rather performs an action. Austin's discovery of "the descriptive fallacy" in the philosophical study of language leads him to uncover the different kinds of social work we do with language.

I think it wrong to view—and thus evaluate—Wiggins et al.'s (2004) article as a constative statement. The authors

are not merely elucidating the ethical reasons for a third party to proceed with face transplants but are more significantly trying to get official approval to perform a face transplant themselves. We need, then, to evaluate their article as a particular type of speech act: a performative statement.

Austin (1962) distinguishes three types of performative acts in language: locutionary acts, illocutionary acts, and perlocutionary acts. Locutionary acts are the very acts of making statements. Illocutionary acts are those that are performed in the saying, that is, they are akin to the minister's statement that turns two single people into a married couple. Perlocutionary acts are those that are a consequence of saying something. If I say, "The alarm clock went off," it may be a mere locutionary act that can be evaluated as true or false; if, however, the context is that I am in bed with my wife (who was made my wife by the prior illocutionary act of a minister), my statement may indicate that it is time to for us to get up and get ready for work, causing us to perform an action. Austin has difficulty determining if statements are ever purely locutionary acts. Even those that seem at first to be purely statements of veracity are soon revealed, when the context in which they are made is described, to be related to human action in some way. As the issue of gay marriage has come to the foreground in recent years, for example, the desire of some state legislatures to define marriage as "a union between a man and a woman" is clearly a desire not simply to make a constative statement but to enshrine in law a statement that has profound illocutionary and perlocutionary consequences.

At first glance, Wiggins et al.'s (2004) article may seem to be a constative statement, but it is important to note that this essay, a locutionary act, is clearly also seen by the authors as illocutionary in nature. They state: "We view this essay as a component of the 'open display and public and professional discussion' required for proceeding in an ethical manner toward the performance of an innovative surgical procedure. As the reader will see below, this is one of the four ethical criteria that Dr. Francis Moore stipulated for undertaking such procedures." In other words, their statement in the essay of their criteria itself fulfills one of the ethical criteria for going forth with this surgery. They view the publication of their essay in *AJOB* as an important illocutionary speech act that will permit them to begin performing the surgery. As Austin (1962) observes, and his observation is certainly true of statements in bioethics, almost all locutionary acts have perlocutionary aspects. My description here of Austin is not merely a constative statement of a series of facts—that is, a series of statements whose primary goal is to be true to Austin's meaning—but is also a performative statement motivated by my desire to persuade readers that in evaluating Wiggins et al.'s article,

one needs to attend to the kind of performatives that occur in it. Because of the dual nature of all speech acts, we should always be aware of the motivations behind statements and remain watchful of the potential conflicts of interest that may exist between writers and the subjects about which they write.

Austin was interested in the issue of "infelicities," or the way in which performatives, unlike constatives, can be determined to have failed in accomplishing particular acts. A performative can be unsuccessful if the wrong agents are involved; for example, if the minister I hire for the wedding turns out not to be a minister at all, it would be a "failed" performance. Improper intentions can be a key feature in determining an act's capacity for accomplishment. Say, for example, that while taking my vows, I had no intention of "honoring" my spouse but pretended that I did. Intention is an interesting issue that is explicitly discussed in Wiggins et al. (2004) in relation to the "ethical climate of the institution." It is the one part of their article that the authors think they are able to fulfill and not fulfill the directives of the good doctor Moore. While they report in their conclusion that "the innovation is not being performed for purposes of institutional prestige or professional recognition" (Wiggins et al. 2004, 10), earlier in the article they note that in fact "such motivations can usually not be detected or proven" (Wiggins et al. 2004, 9). I concur with their claim that it is difficult to evaluate intention; this is the reason that we are always wary of the issue of conflict of interest, for we cannot at this time get objective confirmation of motivations. The "infelicity" of the essay resided in the fact that the wrong agents—Wiggins et al.—are carrying out the perlocutionary act of attempting to persuade us of the validity of their argument. Their interest in performing this surgery should make us judge their performance of evaluating the ethics of performing the surgery to be an infelicity. ■

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# **Psychological Aspects of Face Transplantation: Read the Small Print Carefully**

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As a member of the Working Party set up by the Royal College of Surgeons (RCS) in England to consider the technical, psychological, medical, and ethical aspects of face transplantation in 2003, I welcome the chance to comment on the article by the prospective team in Louisville. This commentary is offered from the perspective of a psychologist specializing in appearance and disfigurement. My understanding of other aspects of facial transplantation is derived from the discussions and final report of the RCS Working Party (Royal College of Surgeons 2003).

In addition to being an experimental surgical procedure, face transplantation is experimental from the psychological perspective. Previous research and current understanding indicate that the psychological risks are more complex and extensive than the Louisville team suggest.

## ***Psychological Effects of Other Forms of Transplantation***

Researchers are increasingly aware that transplantation results in a particular set of psychosocial stressors, challenges, and adaptive demands (Ziegelmann et al. 2002). These include fears relating to the viability of the transplanted organ or limb, fear of the aftermath of rejection, the burden of adhering to complex postoperative medical and behavioral regimes and associated fears of personal responsibility for the success or failure of the transplant, coping with the side effects of immunosuppression, the difficulties of integrating the transplant into an existing body image and identity, and emotional responses, including gratitude and guilt, in relation to the donor and family. The probability is that some of these effects will be exacerbated in the case of face transplantation for the following reasons:-

### ***The significance of the face***

The crucial role of the face in perceptions of identity and the self, as well as in our dealings with others, has long been recognized. Our faces help us understand who we are and where we come from, with indicators of our genetic inheritance, ancestry, and racial identity. Wrinkles and marks serve as reminders of each individual life history. Disruption to one's facial appearance, in particular, disruption to the process of recognition of oneself, has been described as a major life crisis, resulting in a bereavement reaction, with only a slow process of adaptation (Lansdown et al. 1997). Some people affected by facial disfigurements re-

port that their facial appearance no longer reflects the "real me." The proposed early recipients of face transplants may well prefer the prospect of a normal appearance, however, the effects on self-perceptions of "wearing" a face that previously fronted an entirely different identity is entirely unknown. Issues about projecting the "real me" are likely to remain.

The face is central to our recognition by others and represents us in passports, identity cards, and photos cherished by family and friends. The responses from others to a new face will be different, even if only in subtle ways, and will be difficult to second-guess ahead of time. How difficult will transplant recipients find the changes in the responses of others? Will others find it more or less difficult than dealing with a damaged version of the original face?

Nonverbal communication and facial expressions of emotion are crucial in our encounters with others. These processes involve very fine movements, which may be impaired in those with facial disfigurement. Difficulties with communication are likely to play a part in motivating potential recipients to seek a face transplant; however, if the ability to communicate fully remains compromised, or later deteriorates (see risks below), difficulties with social interaction will persist.

### ***Psychological effects of facial disfigurement***

The psychosocial difficulties experienced by many people with visible disfiguration are well documented. However, less well known is the consistent finding that levels of adjustment are not well predicted by the severity of the disfigurement (Lansdown et al. 1997). Some cope well with extensive disfiguration, while others struggle to deal with an apparently minor difference. Severe visible disfigurement does not condemn the affected person to the life of a social recluse. Powerful elements of adjustment include levels of self-esteem (and the extent to which esteem is derived from qualities other than outward appearance), a person's disposition (in particular an optimistic outlook on life), the quality of a person's support network, and the effectiveness of his/her social interaction skills (Rumsey and Harcourt 2004). Those who are most distressed by their appearance are more anxious and depressed, lack self-confidence, feel they cannot control social encounters, and do not believe they can use other techniques to compensate for their visible difference. These are the people most likely to seek a

face transplant, yet they are also the more psychologically vulnerable and less well equipped to deal with the rigors of complex surgery, uncertain outcomes, and demanding postoperative treatment regimes.

### *Making the decision to undergo a face transplant*

As the Louisville team point out, the decision to undergo a face transplant should involve a detailed consideration of the risks (potential “costs”) and benefits of the procedure. This will involve the assimilation of a large amount of complex information relating to surgical, immunological, and psychological risks. The proposal of the Louisville team to require an advocate for the potential recipient is welcome, but concerns remain. Attempting to imagine how this process might work in practice, I have summarized information relating to surgical and immunological aspects from the RCS report, adding the possible psychological consequences in parentheses. Doubtless, experts in particular aspects of transplantation will wish to contest the specific estimations of risk, however, the “take home message” is not the precise risk calculation, but rather the accumulation of potential risks—each with potentially dramatic psychological consequences—and the sheer amount of risk information that must be both conveyed and weighed-up if truly informed consent is to be achieved.

- Risk of acute rejection of the transplant in up to ten percent of cases (high levels of early postoperative anxiety; very significant psychological trauma associated with transplant failure and subsequent skin-grafting of the recipient’s face; dealing with the return to preoperative levels of disfiguration and facial function).
- Risk of a significant loss of graft function from chronic rejection in thirty to fifty percent of patients during the first two to five years postgraft, due to the progressive replacement of skin by fibrous tissue. This may reduce mobility and the capacity for finer facial movements/expressions, or in some cases, the removal of the transplanted face (ongoing anxiety and hypervigilance for signs of rejection; need to adjust to changes in ability to communicate effectively; consequences of rejection, as above).
- Need to comply with a complex, ongoing postoperative immunosuppressive regime and associated changes in behavior. (Some degree of nonadherence to post-transplant regimes is surprisingly common, with levels of fifteen to eighteen percent reported in previous studies; feelings of ongoing responsibility for the success or failure of the transplant.)
- Significantly increased risk of most types of malignancy, especially where a viral cause is implicated. (Pressure to minimize risks through behavioral change, for example,

to diet, sun exposure. This type of behavior change is acknowledged in the health psychology literature to be difficult.) If a malignancy results, the choice would be to reduce or halt immunosuppression with the concomitant risk of loss of the transplant (see above), or to continue immunosuppression and risk the progression of the malignancy (increased vigilance and worry; fears of morbidity and mortality).

- Occurrence of infections in up to a third of patients. A minority would require reductions, or in rare cases, a halt to immunosuppression (increased vigilance and worry; severe consequences of rejection of transplant).
- Occurrence of diabetes in 7–11.9 percent of transplant patients (associated changes to diet, need to use insulin, distress associated with possible weight gain).

### *Additional Psychological Risks*

As initial indicators are that donors will be few and far between, the potential recipient is likely to have to endure a long wait for a suitable donor. Will life be put on hold in the interim, with efforts previously invested in improving quality of life reduced? How will potential recipients cope during the wait with the inevitable anxieties about their eventual postoperative appearance? The transplant team will need to match the donor for blood and tissue type, but what about other characteristics more central to identity, such as gender, skin color, skin tone, and age? Will the recipient have any choice or veto in relation to the donated face? Will recipients wish or be permitted to see the donor face in order to exercise choice?

The psychological consequences are also likely to be complex postoperatively. Intrusive media coverage will surround the first face transplants. In the unlikely event that the identity and details of the donor remain secret, the recipient will still speculate about the identity, history, and personality of the face that has been acquired. Recipients will have to find ways of explaining the visible signs of surgery and any changes or deficits in nonverbal communication, as well as dealing with the reactions of friends and family both to the appearance of the donated face and to changes in familiar patterns of nonverbal communication. Some degree of mismatch between the recipient’s preoperative expectations and the actual reactions of others is likely.

It is well established in the psychological literature that decision making is influenced by the way in which risk information is presented (for example compare “the chances of success are 60%” with “the chances of complications/failure are 40%”) (Ogden 2000). How will the risk information be presented and by whom? What if this was a member of the team, very excited about the prospect of innovative and “high trapeze” surgery (Ward 1995)? Will potential recipients be told that although short-term gains

have been reported, the long term psychological benefits of appearance-enhancing surgery have yet to be demonstrated (Sarwer and Crerand 2004)? Will the results of psychosocial interventions such as social interaction skills or cognitive-behavioral interventions (see, for example, Robinson, Rumsey, and Partridge 1996; Kleve et al. 2002) be outlined?

Teams should arrange an expert assessment of the psychological competence of potential recipients to evaluate the relevant risk/benefit information. In order to justify the considerable risks, potential recipients' expectations of outcome are likely to be high. Research concerning other appearance-enhancing procedures has indicated that overoptimistic preoperative expectations are frequently associated with poor postoperative adjustment (Lansdown et al. 1997). In addition, when innovative surgery is proposed, potential patients tend to be more attuned to the benefits than the risks (Bradbury and Middleton 1997).

#### *The recipient's family*

There is an absence of research on the effects of transplantation on recipient families; however, teams should consider how to support families coping with the pressures associated with the wait for a suitable donor, with acceptance of the altered postoperative appearance of the loved one, with efforts to maximize levels of adherence to the postoperative treatment regime and to minimize the risk of the negative consequences of immunosuppression, worries about the recipient's future physical and psychological well-being and the pressures of intrusive media coverage.

#### *The donor family*

The motivation of the donor family to offer the face of their loved one should be carefully explored; for example, is there an expectation that the dead person might live on in some way? The decision will have been made or confirmed in the highly stressful immediate aftermath of the death of the loved one, yet is irreversible. Will families want to know the identity of the recipient? As they are likely to discover the identity through media coverage, what would be the consequences of contact? Support will also be needed in dealing with media intrusion at a time of great stress.

#### *Issues for Society*

The impact of new appearance-enhancing procedures on society should not be underestimated. Experience suggests that the publicity surrounding face transplantation will promote unrealistic expectations of the benefits, and is likely to fuel the notion that a good quality of life cannot be achieved by people with disfiguring conditions. The very existence of an operation such as a face transplant will further decrease tolerance of difference and increase the pres-

ures on those with disfigurements to improve their appearance. Grealy (1994) wrote poignantly that others were "always telling her about the wonderful things that surgeons can do nowadays."

#### *Conclusion*

The Louisville team feel that the time is right to undertake face transplants. The headline benefits of a normal appearance and fully functioning facial communication are certainly seductive, however, the message in the small print is much less clear-cut. I have no wish to minimize the distress experienced by many people with severe disfigurements, but to my mind, the current risk/benefit ratio of face transplantation is dubious at best. A face transplant is not only a surgical "experiment," it is an undertaking that involves considerable risk to psychological well-being. As surgical solutions rarely provide miracle cures for complex psychological issues, prospective teams should be prepared to provide expert psychosocial assessment, follow-up, and ongoing support for recipients, recipients' families, and donor families. ■

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## ***Facing the Ethical Questions in Facial Transplantation***

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In “On the Ethics of Facial Transplantation Research,” Wiggins and colleagues (2004) build an ethical case for the University of Louisville’s plan to undertake facial transplantation. Their approach significantly relies on public discussion, which they view as an ethical requirement for innovative surgery based on their reading of the work of Moore. Moore’s (1969) main theoretical paper on therapeutic innovation was published in *Daedalus* in 1969. It offers a more nuanced view of the problems associated with therapeutic innovation than the two articles they cite. In none of this work, however, does Moore articulate a clear requirement for publicity. In the papers that Wiggins et al. cite, there is a mention of publicity in Moore’s 1989 *JAMA* editorial on four disastrous pediatric transplantation cases. He states that the subsequent report of these cases is “now a matter of open display, public evaluation, and discussion” (Moore 1989). Although he praises the open discussion of these cases, he nowhere lists it as a separate ethical criterion. Their reading may come from a paper by Siegler, which Wiggins et al. also cite. Siegler (1998) attributed *six* ethical criteria for innovative treatments to Moore: “(1) the scientific background; (2) skill and experience of the team (‘field strength’); (3) the ethical climate of the institution; (4) open display; (5) public evaluation; and (6) public and professional discussion.” Interestingly, Siegler only explicitly discussed the first three of these criteria, the only ones that Moore offered as ethically relevant criteria (Moore 1969, 1988, 1989). These points are of more than scholarly interest, because they go to the heart of Wiggins et al.’s approach to facial transplantation.

Moore’s (1969) original essay focused on informed consent and the protection of the welfare of patients who suffer from conditions that lack effective treatments. He strongly advocated for innovation in patient care. Although Moore’s reading of the ethical obligation to develop innovative treat-

ments for desperately ill patients strongly supports innovations like facial transplantation, nowhere does he explicitly argue that “open display and public and professional discussion” is an ethical requirement for performing an innovative surgical procedure (Wiggins et al. 2004). Is this commitment to publicity simply a misreading of Moore or does it reflect deeper program commitments that deserve ethical scrutiny?

Wiggins et al. (2004) argue that Moore’s criteria require a full public *prior* disclosure and discussion of innovative procedures like facial transplantation. They acknowledge that patient confidentiality and privacy conflicts with this publicity requirement. They state that because the prospect of the facial transplant has attracted significant media attention already, it is difficult to imagine how the media could be prevented from discovering the identity and other information about the recipient and its family. Perhaps this is true, but it is not a very strong justification for not trying to preserve patient privacy. As Flamm (2004) has commented, “The fact that investigators in routine clinical research are not obligated to provide even periodic updates directly to the public ought to make us question the assertion that the obligation exists in high-profile settings.” The question is whether media attention is unavoidable or simply accepted by the transplant team because it augments the institution’s own efforts to publicize innovative treatments. If the latter, then willingness to waive privacy of one’s medical situation becomes a selection criterion for any of the initial recipients of facial transplantation. If so, how is that criterion ethically justified?

A reasonable approach to the issue of publicity in significant clinical innovations like facial transplantation would focus on the unique alliance between the patient(s) initially receiving the innovative intervention and the research team. This would recognize the recipient as being purely

neither a patient nor a subject, but perhaps a “collaborator” with a new ethical status. In these terms, what role might such a patient collaborator in clinical innovation play in controlling the team’s publicity approach? As it stands, Wiggins et al., have determined the publicity approach in advance without offering a compelling ethical justification, and their exploration of the difficult question of the collaboration between the team and the initial recipient needs more discussion.

Morreim rightly points out that claims about society’s “right of free press” and the public’s “desire to know” do not mean that “anyone is required, in the first place, to provide the reporter with whatever information he wants” (Morreim 2004). Wiggins et al. couch their commitment to “open display and professional and public discussion and evaluation,” which they inaccurately attribute to Moore, as leading to the conclusion that “we are obligated to release to the public basic clinical and surgical information about facial transplants” (Wiggins et al. 2004). One can accept this as a statement of belief, but no sound ethical argument is offered to support this conclusion.

Public discussion has accompanied facial transplantation since the issue was raised at the winter meeting of the British Association of Plastic Surgeons in December 2002. Media interest has generated a host of questions and produced a number of “ethical” pronouncements that deserve fuller analysis. A genuine contribution to the ethics of facial transplantation would address the specific issues raised, for example, in the Working Party Report of the Royal College of Surgeons of England (2003), which soundly rejected facial transplantation.<sup>1</sup> This report argued that “the psychological consequences of graft rejection would be immense” and that issues associated with facial identity present a significant ethical impediment. (Royal College of Surgeons of England 2003).

We regard neither of these objections as insurmountable, and the arguments and evidence offered by the Royal College of Surgeons to be inadequate. First, the psychological consequences of graft rejection would undoubtedly be significant, but the significance relates to the fact that the patient would return to a situation of disfigurement that preceded the facial transplantation. The graft failure would return the patient to a state of disfigurement similar to the pretransplant disfigurement. The reconstructive surgery that would be needed should a graft failure occur is well known to any patients who would be ethically eligible for this procedure, because

they would have undergone numerous prior reconstructive surgeries.

On the point of graft failure, Arthur Caplan has been widely quoted as saying, “What will you do if a face transplant fails? . . . I understand a disfigured face may be terrible to live with. But if a transplant should be rejected, you’re basically dying. That’s a serious, high-stakes issue” (Allen 2003). This is clearly an overstatement, one that Caplan would not likely claim in a published article, but nonetheless the perception is that the risks associated with facial transplantation and failure of the facial graft would be so high as to make the procedure unethical. The Royal College of Surgeons Working Party Report also stresses the hazardous nature of the facial transplantation that in its judgment makes attempting such transplantation unethical at this time. While we concur with Wiggins et al.’s (2004) assessment of the risks associated with the surgery, it is unfortunate that their discussion was not linked with the portrayal of these risks in the media.

Second, the objection regarding identity is philosophically complex and, unfortunately, beyond the scope of this brief commentary. In the present context, we only point out that the Royal College of Surgeons’ position that the problem of identity constitutes an insurmountable ethical objection is based primarily on the observation that others would have difficulty adjusting to or appreciating the new facial identity of the patient. The orientation of the Working Party Report is less on the ethically relevant identity problem, namely that involving the patient’s own self-experience, than it is on the perception of others, an approach that allows social bias to masquerade as an ethical objection. Nowhere in the Royal College Report is there a discussion of the rights of severely disfigured patients to seek opportunities for an improved quality of life. Wiggins et al. unfortunately, do not sufficiently discuss the public controversy that colors the media fascination with facial transplantation. We think that the inordinate suffering of patients with such severe disfigurements should be recentered in the public ethical discussion. It is inconsistent for Wiggins et al.’s (2004) to ignore these controversies while insisting on the importance of “open display, public evaluation, and discussion” for the ethical justification of facial transplantation.

Finally, more discussion of the ethical questions associated with the harvesting of facial tissue for transplantation is needed. These questions certainly involve the issue of identity as noted above, but include other ethically important matters as well. Wiggins et al. (2004) devote only four sentences to donation of facial tissue. They discuss neither the sensitive issue of informed consent of the donor family nor preparation of the donor face after harvesting. Harvesting of facial tissue needs special consideration, because it

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1. The more recent rejection on February 6, 2004 of a proposal for facial transplantation by the French National Consultative Bioethics Committee similarly deserves critical analysis (Comité Consultatif National d’Ethique pour les sciences de la vie et de la santé 2004).

complicates open-casket funeral practices. Caplan and Katz (2003) correctly point out that “a family or partner may feel guilty burying a faceless corpse, especially when American death rituals often involve open caskets” and that, If “while cadaveric organ donation almost never involves disclosure of the donor’s identity, the identity of the face transplant recipient would be very difficult to conceal from a donor’s relatives or friends.” They do not argue that proper informed consent of the donor family is unattainable. Addressing how to accommodate the sensitivities of the donor family, the content of donor consent forms, and the consent process are thus a critical ethical concern. The donor family should understand exactly what tissue would be removed, its effect on the presentation of the corpse, and that it is impossible to rule out that an identifiable linkage to the donor could be drawn. Defining this protocol is another key requirement for an ethically complete approach to facial transplantation. ■

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## About Face: Downplaying the Role of the Press in Facial Transplantation Research

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About a decade ago I spent a week as guest faculty for a summertime intensive bioethics course. My hotel was several miles from campus, necessitating daily cab rides. Most mornings I was picked up by the same cabbie. I didn’t actually see him face-to-face as I climbed into the back seat, but glances to the rear-view mirror indicated he had some sort of facial anomaly. Periodically I could hear him make a soft sound with his mouth, apparently to retrieve errant saliva.

On my last day in town he drove me to the airport. We had become comfortable chatting and by now it had become evident that this otherwise reasonably attractive man was missing both lips. It occurred, he volunteered,

when a drunken teenager crashed head-on into his cab, destroying his lips as his mouth hit the steering wheel. He didn’t have health insurance and could not afford plastic surgery.

I ventured that this must be difficult for him, socially and emotionally as well as physically. He replied that people often cross the street to avoid passing by him on the sidewalk. For a time, he had considered suicide. But now he was simply living with it, trying to save enough money for plastic surgery some day.

This is not the story of someone who would qualify for a face transplant. But it hints at the enormous difficulties facing people whose appearance is abnormal. What outsiders

might categorize in dry academic terms as “quality of life” is for some of these people a very real assault on their personhood and their membership in society. Their problems will not be remedied by urging people to be more tolerant. Neither can we downgrade the idea of transplant because facial anomalies are not life-threatening. As autonomous adults we routinely do, and must be free to, undergo substantial risks to improve our quality of life and act on the many other values we hold dear. If general anesthesia is an ethically permissible risk for a cosmetic face lift, then so, surely, can significant medical risks be acceptable in hope of a significantly greater gain for those who are grievously disfigured.

Nevertheless, the question of whether facial transplant is medically plausible at this time cannot yet elicit a clear affirmative. Strong (2004) discusses a serious question that I, too, found curiously absent from Wiggins et al’s (2004) iteration of potential risks—namely, the possibility that the transplant might simply fail and leave the person even worse off than before.

Other interesting issues remain. In the spirit of the open discourse and continued feedback the authors seek, I shall focus on the role of the press in such a high-profile project. As the Wiggins et al. (2004) note, principles of patient privacy precipitate unique challenges. Among other concerns, the scientific community cannot assess the success of the procedure without photos that would at least partly identify the patient and potentially even the donor, depending on the transplant’s technique and results.

While acknowledging privacy’s importance, the Wiggins et al. (2004) suggest that researchers in such a project have an obligation periodically to reveal “‘materially significant trends in the progress of the trial,’” citing my recent work on high-profile research and the media (Morreim 2004).

I must differ with their conclusion. I do not recommend, simpliciter, that everyone undertaking high-profile research has a duty to release periodic updates while such a trial is underway. Rather, in the context of the AbioCor artificial heart trial, I proposed such a duty only in a rather narrow set of circumstances.

I first responded to the controversy surrounding ABIOMED’s corporate policy of limiting media disclosures by arguing that taxpayers’ investment in the AbioCor project did not warrant ongoing press releases, because the government already has surveillance mechanisms in place to monitor the public’s investment. Further, although the public is of course entitled to know the outcome of such a trial, discussion of important social issues can take place without daily updates on individual patients’ ups and downs.

Rather, I suggested that disclosure duties arose from such a corporation’s obligations to its private investors. Un-

like taxpayers, who have government agencies to look out for their interests, private investors have no one but themselves to monitor their investment. Even so, in most circumstances this fact does not warrant ongoing press releases about a company’s research-and-development ventures. Indeed, large, broadly diversified corporations might disserve their investors and compromise their competitive position by revealing too freely the early information about products in development or testing phases.

However, this particular trial was undertaken by a small company whose success, even its continued existence, could potentially hinge on the success of this one clinical trial. Investors stand to lose substantially if the trial fails or, if things go well, may wish to adjust their investment in mid-stream. Under these circumstances they can only look out for their interests if they receive periodic information about the progress of that trial. They need to know when the long-anticipated implants have actually begun, and thereafter whether significant successes or problems have emerged. Such revelations should not, however, be so frequent or so colorful as to invite either “artificial success” or “artificial failure” of the project—success or failure based not on the merits of the product but instead on positive or negative media hype that can distort the realities.

Because the laws governing publicly traded securities require that any such disclosures be made openly, not just to privileged “insiders” or existing investors, information on the trial must be provided to the public at large. Hence, I argued that in these limited circumstances there appears to be a corporate duty to release periodic updates.

This argument does not give rise to any general duty to disclose information on the progress of high-profile research such as facial transplantation. Wiggins et al. (2004) discuss a surgical procedure, not a clinical trial evaluating a device or other concrete product; there are no private investors who need information to monitor their investment. In my view, there is no ethical imperative to release information about the progress of this trial until evidence about the procedure’s viability is scientifically reasonably clear. A stream of press releases may or may not be ethically permissible, but they are not obligatory.

In a related vein, Wiggins et al. (2004) consider the ethical climate of the institution at which the proposed facial transplants would take place, an issue heavily tied to the attention that hospitals and academic medical centers often enjoy when publicized as leaders in cutting-edge medicine. Wiggins et al. (2004) argue that institutions’ mixed motivations pose a problem only when they prompt the institution to undertake projects that do not honor scientific, medical, surgical, and ethical requirements. This contemplated project, they argue, “is not being performed for purposes of institutional prestige or professional recognition,”

but rather because it is medically and ethically warranted (Wiggins et al. 2004).

While this may indeed be the case, hazards still lurk. Institutions often select projects based on the recognition, and thereby revenues, they may bring. The hospital at which the first AbioCor implant took place, for instance, avowedly embraced the project to position itself as an international referral center for this device and related procedures:

Jewish Hospital set aside \$8.2 million for the project. . . . While they were aware of the risks, administrators agreed to the financial commitment in large part because they knew its potential benefits. . . . The July 2 implant was a “medical milestone” that created “a level of international attention toward Louisville that we otherwise would not have,” said [the] president of Jewish Hospital HealthCare Services. (Kaukas 2001)

For Jewish Hospital, the AbioCor project fit a larger institutional strategy to focus its research on a handful of medical specialties in which its surgeons have developed expertise:

[Douglas E. Shaw, Jewish Hospital president] said that when the ABIOMED project was suggested to him . . . in 1997, the hospital was actively looking for such research opportunities, and administrators quickly embraced it. If the AbioCor experiment works and the hospital eventually attracts heart patients from far and wide to receive implants and other treatments, there will be a sizable return—both financially and in terms of enhanced reputation. (Kaukas 2001)

If the institution does not gain adequate media attention, even a scientifically successful project may, from the institution’s perspective, be less than successful. Reciprocally, a project that ultimately fails can be a net benefit to the institution if the early press coverage enhances its reputation while the eventual failure is either inconspicuous or is attributed to other parties.

Hence, institutions can levy strong pressure for frequent, flowery press coverage with institutional logos featured prominently—potentially impinging on patient privacy and perhaps creating unduly rosy images that may later be contradicted when the scientific results are in. Such bright coverage can upstage the science in the minds of the public, who may then demand a product or procedure even without strong scientific support, as exemplified by autol-

ogous bone marrow transplant for breast cancer. Many hospitals profited enormously from that procedure, despite the initial dearth of evidence that preceded its eventual scientific refutation (Kolata and Eichenwald 1999; Stadtmauer et al. 2000; Lippman 2000).

Wiggins et al. (2004) are quite right that objectives like these need not compromise the internal scientific or ethical integrity of a research project. However, even if aspirations for publicity do not compromise the science, they can significantly affect the tone and frequency of media coverage and thereby steer the public’s demand for the procedure in potentially inappropriate directions. If the authors believe that sponsoring institutions have an obligation to provide ongoing press updates, and if the institutions themselves are eager for favorable publicity, the combination could be problematic. On the whole, a quieter approach to media may be considerably preferable.

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## **A Face is Not Just Like a Hand: pace Barker**

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In 1998, the year of the first hand transplant, Dr. John Barker (director of plastic surgery research and member of the hand transplant team at the University of Louisville, Kentucky) publicly announced that “a face is just like a hand” and that it would not be long before there would be face transplants (BBC News Online Newtork). At the time, the team in Kentucky had not yet performed a single hand transplant.

Today, more than 20 hand transplants have been carried out worldwide, two of these by the team in Kentucky (Hettiaratchy and Butler 2003). With this experience behind them, Barker and colleagues want research ethics approval to move forward with facial transplantation, still confident in the belief that “a face is just like a hand.” In their article “On the Ethics of Facial Transplantation Research,” Wiggins (a philosopher), Barker (a leading proponent of facial transplantation), and colleagues note that faces and hands contain mostly the same tissues; that the life-long immunosuppressive regimen for transplanted faces would be the same as for transplanted hands; and that although facial transplantation, like hand transplantation, is not physiologically life-saving, it is possible for the potential functional, aesthetic, psychological, and social benefits to outweigh the risks of transplantation and in particular the risks of immunosuppression (e.g., increased risk of cancers and susceptibility to deadly infections). Indeed, the authors assert that the central question with facial transplantation is: “Do the benefits of a facial transplantation justify the risks posed by the immunosuppressive drugs?” (Wiggins et al. 2004, 3). Their answer to this question is unequivocally “yes.” They maintain that there are informed subjects who consider the procedure beneficial; that there are skilled researchers who dare to perform the procedure in the face of the uncertainties; and that the time to proceed is now.

### *Techne and Arguments from Analogy*

A face may be like a hand from the perspective of a surgeon interested in the technical problem of repair. Both face and hand transplants are composite tissue allotransplants involving a number of tissues including muscle, nerves, blood vessels, arteries, veins, and skin. According to the proponents of facial transplantation, success with hand transplantation serves as proof of principle that tissue composites can survive transplantation.

As well, both facial and hand transplantation require the use of immunosuppressive drugs. It is anticipated that similar drug regimens would be used and that there would

be similar risks of rejection. With facial transplantation there is an estimated ten percent chance of immediate rejection within the first year and a thirty to fifty percent chance of chronic rejection (resulting in significant loss of graft mobility and functional failure) in the two- to five-year period following transplantation (The Royal College of Surgeons of England 2003).

Third, there may be similar issues with respect to compliance. In general terms, the incidence of noncompliance with organ transplantation is estimated at fifteen to eighteen percent. This noncompliance invariably results in graft rejection (The Royal College of Surgeons of England 2003). Clint Hallam, the first hand transplant recipient, could not tolerate the side effects of immunosuppression. Eventually he stopped taking the medications, the tissue began to deteriorate, and finally his transplanted hand was amputated. A face transplant recipient might have similar difficulties with the required immunosuppressive regime or the required lifestyle changes concerning diet or sun exposure. This common risk highlights an important difference between facial and hand transplantation. In the event of technical failure or immunological rejection, the transplanted hand can be removed and the patient can be offered a prosthesis. In sharp contrast, a total or partial loss of face would be devastating for a recipient who could not be returned to her previous state of being. Significantly, Barker and his colleagues do not have an “exit strategy” in the event of failure (Klotzko 2004). This is an important consideration given that facial transplantation, like hand transplantation, is aimed at improving quality of life in otherwise healthy individuals.

These similarities and differences are important for those interested in the art, craft, or skill of facial transplantation. Their relevance to the moral questions associated with facial transplantation, however, is limited to a narrow range of concerns to do with the harm/benefit ratio as these apply to the research ethics review process. These concerns, though important, by no means exhaust the relevant ethical issues.

### *Ethics and Arguments from Analogy*

Arguments from analogy can be used effectively to support decisions regarding the morality (or immorality) of a particular action. Such arguments work by bringing an undisputed case to bear on a disputed case. It is suggested that the cases are similar in morally relevant respects and that since the analogue is known to be morally acceptable, so too is the disputed case (or alternatively, since the analogue

is known to be evil, the disputed case is also evil) (Govier 1985).

Wiggins and colleagues use arguments from analogy to reason from the presumed clear case of morally acceptable hand transplantation, to the morally problematic case of facial transplantation. Their arguments are not persuasive, however, for two reasons. First, they do not show unequivocally that hand transplantation is morally acceptable—the fact that something is done does not in itself constitute evidence of its moral acceptability. Second, they do not show unequivocally that hand and facial transplantation are sufficiently similar *in morally relevant respects* to warrant being treated similarly. The fact is that there are several morally significant differences between these two types of transplants, the most obvious one having to do with issues of personal identity.

Recognition of the self is key to identity formation and this recognition is mediated, in part, through the face. To quote James Partridge, founder of Changing Faces (a charitable organization in the UK that helps people with facial disfigurement): “Even for those like myself with severe disfigurement, the face carries a lot of identity, the sense of self” (McDowell 2002). A similar perspective can be found in the Royal College of Surgeons of England report on Facial Transplantation (2003): “The face is central to our understanding of our own identity. Faces help us understand who we are and where we come from.” For these reasons, the face is not fungible in the way that other human organs and tissues used for transplant might be. As Linda Hogle, a medical anthropologist, writes about facial transplantation: “You’re really transplanting more than the tissue itself. You’re bringing someone else’s identity and overlaying it on the recipient’s body. . . . The face is the most intimate, most individual characteristic of your body. It’s who you are” (cited in Bowen 1999).

Clearly the hand is not intimately linked with personal identity in the way that the face is. This is true not only from the perspective of the transplant recipient, but also from the perspective of the donor family. In this regard, it is interesting to note that with organ transplantation a motivating factor for many donor families is the belief that transplantation allows their loved one to somehow “live on” (Sharp 1995). Intuitively, we know that this is not an understanding likely to be encouraged in the context of facial transplantation, as the face has unique symbolic and affective meaning.

Recognition of the self is not limited to appearance, however; it is more than skin deep. Lock, another medical anthropologist, writes “that donated organs very often represent much more than mere biological body parts; the life with which they are animated is experienced by recipients as personified, an agency that manifests itself in some sur-

prising ways and profoundly influences subjectivity” (Lock 2002). Some recipients of organ transplants report “that they experience embodiment in a radically different way after a transplant” (Lock 2002). As well, some develop new eating habits and new recreational interests that they experience as foreign to the self; typically they assume that these “belong” to the donor. What is the meaning of these self-reports by organ recipients? Is there such a thing as somatic memory? If so, what are the implications for facial transplantation? To be precise, what if the transplant recipient not only woke up and saw someone else in the mirror, but also had experiences she did not recognize as her own?

Identity formation is an ongoing process of self-construction influenced by personal attributes, life experiences, introspection, and the storying of one’s life. As well, personal identity is shaped by interpersonal networks of relations of mutual recognition. It follows that recognition by others, not just recognition of self, is key to identity. This raises another challenging question for facial transplantation given that two-thirds of our communications are facial. In all likelihood facial transplantation would profoundly affect both intimate and forlorn spaces between self and others, which in turn would affect identity formation in potentially disruptive ways.

To be fair, Wiggins and colleagues (2004) recognize that there are important issues of personal identity associated with facial transplantation. Unfortunately, in their haste to persuade others that now is the time to begin facial transplantation, they don’t meaningfully explore what it means from a personal, metaphysical, social, and cultural perspective, to wear someone else’s face. Instead, they focus on the technical aspects of facial transplantation and issues relevant to the research ethics review process, thereby finessing the enormously complex ethical issues to do with personal identity. ■

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## Face Transplants: Enriching the Debate

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The Louisville composite tissue transplant team deserves plaudits for its transparent approach to the highly charged topic of face transplants. They are fully aware of the applicable ethical norms for conducting research and make scrupulous efforts to comply with them. Prior experiences at Louisville with hand transplants and the Jarvik artificial heart reinforce the need for doctors who push the transplant envelope to reassure the public that they are acting responsibly.

Face transplants are electric because they are aimed, not at treating end-stage organ disease, but at improving the patient's quality of life in a central aspect of personal identity. In this case the improvement appears to be so crucial to the patient's well-being that the risks and costs of life-time immunosuppression seem justified. But that judgment is complicated by the importance of "face" to the identity of both recipients and donors.

The Louisville team's article emphasizes the experimental nature of these procedures and their efforts to comply with the common rule's provisions for ethical research. I have no quarrel with how they have worked the informed consent, risk/benefit, and privacy themes of that enterprise. But I do wish that they had said more about the social and psychological meanings that the face carries and how those meanings are likely to enter into the decision process of both recipients and donors. Such a discussion would enrich the debate and help patients, families, review committees, and society come to terms with face transplants and the procedures for performing them.

One wants also to hear from psychologists, humanists, and philosophers about the role of face in personal identity.

Faces are the external manifestation of our persons (our souls?). They provide information about age, gender, ethnicity, and emotional states, and help form the image that others have of us. Indeed, our face often provides the image that we have of ourselves. We know also that faces are not static, but show the furrows of time. Losing "face" is to lose our dignity. Persons of mature age are often said to have "chosen" or to have "deserved" their face. Yet face is a less reliable indicator of unique identity than are fingerprints or random loci of DNA. Nor is the face as central to personal identity as internal lived experience and memories are. Transplanting A's face to B changes neither person's true personal identity; transplanting A's brain to B does.

A deeper investigation into the meaning of face would help the Louisville team and others to fashion the correct policies and procedures for performing face transplants. The previously disfigured recipient is likely to welcome the new physical identity that the transplanted face brings, despite the risks and costs of chronic immunosuppression. It is precisely the new face and associated physical identity that the recipient craves, even if internally he or she remains the same individual. But the questions of authenticity and identity that remain for the recipient still demand careful attention.

Less clear are the implications of donating a deceased loved one's face to a stranger. Because face donations can be made only after the source's death, they implicate the rules for cadaveric donation (Robertson 1999). The deceased when alive by organ donor card or advance directive may direct what shall be done with his tissue and organs, including his face, after death. If there is no advance directive, next

of kin in designated order of priority may decide. Indeed, most organ procurement organizations will allow the family to trump the deceased's advance directive in favor of transplant, even though taking organs and tissue on that basis is explicitly legal.

Face transplants quite obviously complicate such transactions. A face transplant implicates continuation of the deceased in a way that an internal organ or tissue transplant does not. Because the face is so tied up with the deceased's personal identity, the idea of transplanting his or her face will be a highly charged one. In many cases the family is likely to think of their loved one in terms of their face. The connection between face and the deceased might be so unique that a family otherwise willing to donate organs will recoil at the idea of donating the deceased's face. Given this risk, it is especially important that donors give explicit consent to face donations and not have them occur as part of a generalized consent to donation of tissue and organs. Special counseling of donors and donor families may be necessary to accomplish this. Also, face donations may be too complicated to be considered in cases of sudden death (uncontrolled non-heart beating donors) where there is little time to explore these issues.

On the other hand, some donor families might welcome donation of the deceased's face as a continuation of that person, thus fostering the misperception that the deceased is still alive when he or she is dead. But, they are likely to be barred from any information about or contact with the recipient, and may suffer frustration and further anguish as a result.

Deep emotional concerns about continuity are especially important when the cadaveric source is a child or

young person. The temptation to think that the dead child lives on in the recipient will be a strong one for grieving parents. The consent process for donation of the face must pay special attention to the family's perceptions and fantasies about what transplanting their child or loved one's face to another person will mean.

The Louisville team deserves great credit for its open efforts to do the right thing. If they broaden their ethical grappling to include psychologists, philosophers, humanists, and others who can help plumb the meaning of face and personal identity, they will have made a unique contribution to research ethics and to incorporating humanistic perspectives into surgical practices. The President's Council on Bioethics has recently shown how compendia of literature and art can deepen bioethical assessments of modern technology (President's Council on Bioethics 2003). It is time for the Louisville transplant team to do so as well. ■

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## Facial Transplantation Research: A Need for Additional Deliberation

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In their article, "On the Ethics of Facial Transplantation Research," Wiggins et al. (2004) list eight criteria that must be met before facial transplantation research can go forward. They assert that because the facial transplant team at the University of Louisville has met these criteria, it is time that the team conducted the experimental procedure. Our commentary will focus on two broad themes related to the criterion involving institutional review board (IRB)

approval of facial transplantation research: (1) the authors' thin discussion of human research ethics, including their analysis of research risk and informed consent, and (2) the authors' ethical and policy stance that stands in stark contrast to the recommendation by a Working Party of the Royal College of Surgeons of England that, for the time being, ethics review boards should not approve protocols for facial transplantation (The Royal College of Surgeons of

England 2003). According to the Working Party, patient-subjects cannot give informed consent because the known risks of the experimental procedure outweigh the benefits and because it is still too early to know all the risks those patient-subjects may be asked to assume.

In their discussion of risk/benefit assessment and informed consent, Wiggins et al. (2004) do not acknowledge that federal human subjects regulations impose different requirements for research involving adults and children. Thus, we assume the authors' ethical and policy stance on facial transplantation research applies only to adult subjects.

The authors' assessment of the surgical, psychological, and social harms differs markedly from that of the Royal College Working Party. The main harms posed by facial transplantation include acute rejection, technical failure, and side effects of immunosuppressive therapy. Wiggins et al. (2004) contend that facial transplantation does not pose more risks to recipients than do conventional reconstructive procedures which involve use of the recipient's own tissue. Yet the Working Party notes that "skin is particularly susceptible to rejection" (The Royal College of Surgeons of England 2003, 7). Wiggins et al. also claim that successful facial transplantation will require a few additional surgeries, whereas conventional reconstructive surgery "can require over one hundred revision surgeries over many years" (Wiggins et al. 2004, 4). However, the authors provide no empirical evidence to support either of these assertions.

In the view of the Royal College Working Party, "there are insufficient reliable data to estimate risks to physical safety." The Working Party goes on to say, "analogies with the data to other types of transplantation are too poor to use this evidence as a basis for judging the risks of facial transplantation. The most important of these risks is that of rejection" (The Royal College of Surgeons of England 2003, 19). Although the Working Party acknowledged that it is impossible to accurately predict immunological rejection, "a graft loss of around ten percent from acute rejection within the first year and significant loss of graft function from chronic rejection in around 30–50 percent of patients over the first 2–5 years" was offered as a reasonable estimate (The Royal College of Surgeons of England 2003, 7). If the surgery proves to be a technical failure or acute rejection occurred, the Working Party points out that the transplant would have to be removed, requiring additional surgeries and possibly resulting in "even more scarring than there was originally" (The Royal College of Surgeons of England 2003, 6).

Unlike the Working Party, Wiggins, et al. (2004) do not take into account the possibility of rejection and its aftermath when assessing psychological risks. They say these risks will "be similar to those experienced by solid organ

transplant recipients, for example, a desperation that creates unrealistic hopes, fears that his or her body will reject the transplant, guilt feeling about the death of the donor, difficulty conforming to the treatment regimen and its side-effects, and a sense of personal responsibility for the success of the procedure" (Wiggins et al. 2004, 13). The Royal College Working Party did not look solely to the literature on solid organ transplantation for information about possible psychological risks. Drawing from studies of individuals with visible disfigurements, including those who underwent hand transplantation and individuals who had plastic surgery, including surgeries for congenital disfigurements, the Working Party concluded that, "in the absence of studies involving long-term follow up, the jury is still out on whether appearance-enhancing surgery produces lasting psychological benefit" (The Royal College of Surgeons of England 2003, 12). The Working Party also noted that the research literature indicates that those who don't cope well with their disfigurement are more psychologically vulnerable and "will be less well equipped to deal with the aftermath of complex transplant surgery, uncertain outcomes and ongoing treatment regimens" (The Royal College of Surgeons of England 2003, 10).

Wiggins et al. (2004) refer primarily to the literature on solid organ transplantation in discussing potential immunologic risks of facial transplantation, whereas the Royal College Working Party reviewed studies involving composite tissue transplants such as upperlimb and abdominal wall transplantation. The Working Party also factored noncompliance with immunosuppressive medication into its risk analysis and noted that the world's first hand transplant resulted in graft failure due to patient-subject noncompliance. Wiggins et al. did not appear to include the fifteen to eighteen percent noncompliance rate of organ transplant recipients into their risk assessment.

Equally problematic is the *AJOB* authors' inattention to commentators who raise concerns about the hand transplants that have been performed, given the immunosuppressive risks that recipients must assume. In an editorial published in 2000 in the same issue of the *New England Journal of Medicine* in which the Louisville hand transplant team published their one-year follow-up of the first hand transplant in the United States (Jones et al. 2000), James Herndon concluded that given the risks of immunosuppressive drugs, "the ideal candidate is a patient who is already taking immunosuppressive drugs for a life-threatening problem and who loses a hand. Other candidates would be patients who have lost both hands, especially if they are blind. If the procedure is limited to this select group of patients, it should continue to be performed while we wait for advances in immunosuppressive therapy" (Herndon 2000, 505). Three years later, Hausman, Masters, and Panozzo assessed the status of hand transplants performed up to that

time and reached the same conclusion as Herndon. "Without more substantive evidence of an expectation for good outcome," said Hausman et al., "the procedure should be limited to patients who have lost both hands or who are already receiving immunosuppression for another reason" (Hausman 2000, 152).

Given the known and unknown risks associated with immunosuppressive therapy, it is not evident that IRBs should approve a facial transplant protocol and permit potential recipients to decide for themselves whether they are willing to be exposed to both known and unknown risks. The role of an IRB is to protect the rights and welfare of human subjects, including protecting them from themselves. According to the Federal Policy for the Protection of Human Subjects (Department of Health and Human Services, 2001), which is the relevant regulatory framework (not the 1971 Institutional Guide published by the Department of Health, Education and Welfare that Wiggins et al. cite), in order to approve human research protocols IRBs are required to ensure that "risks to subjects are minimized by using procedures which . . . do not unnecessarily expose subjects to risk" and "that risks to subjects are reasonable in relation to the anticipated benefits" (45 CFR 46.111).

As the Royal College Working Party notes, the fact that individuals are willing to undergo risky procedures or those with unknown risks, and that surgeons are willing to conduct such procedures, does not mean that such surgeries should be performed.

Moreover, the Working Party points out that surgeons should sometimes refuse to perform procedures even when their patients want the intervention, and that IRBs should not approve some surgical research.

Finally, in the spirit of "open display and public and professional discussion and evaluation," we believe that the research protocol for facial transplantation at the University of Louisville should be released for review. Wiggins

et al. (2004) maintain that the eight criteria, which include IRB approval of the research protocol, have been satisfied at the University of Louisville. In light of the fact that they assert it is time for facial transplantation research to go forward, it is not clear whether the relevant IRB has indeed approved their protocol. Reasonable people will disagree with the ethical and policy analysis of the Royal College Working Party. However, in order to assess whether the Louisville IRB has taken into consideration the Working Party's risk/benefit assessment and its recommendation that facial transplantation not be approved at this time, public and professional review of the research protocol is warranted. ■

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## On Not Taking Objective Risk Assessments at Face Value

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Despite the recent failure of committees in several countries (Anonymous 2004) and the Royal College of Surgeons Working Party (Morris et al. 2004) to endorse experimental procedures involving facial transplantation, Wiggins

et al. (2004) urge pursuit of facial transplants. A number of commentators have been critical of this proposal, pointing to problems with the team's empirical claims, particularly their assessment of biomedical and psychological risks

associated with graft rejection (Strong 2004). Underlying these critiques are basic disagreements with the Louisville team about whether the experimental procedure is too risky, especially since it is not necessary for survival, but relatively little conflict over the appropriate methods for measuring and assessing risk.

The question posed in this commentary is not whether the research team got its facts right or jumped through the ethical hoops gracefully, but a deeper one about the production and use of “objective” empirical data associated with composite tissue allotransplantation (CTA) and the assessment of their ethical relevance to the determination of whether this experimental procedure should proceed. As the authors write, risk/benefit assessments must be made by the research team, an institutional review board (IRB), and potential subjects. In part to assess the “patient” point of view, a research instrument was designed by the team to evaluate the amount of risk that individuals would be willing to accept in exchange for the benefits of facial transplantation, (Cunningham et al. 2004). The results of this study are intriguing: university students reported perceptions of improvement of quality of life to be lowest for kidney and highest for hemiface (full face was rated slightly lower) transplants, and both this study group and a subsequent population of waiting room patients ranked a hand transplant higher than a foot transplant in terms of improvement of quality of life. But even if, for the sake of argument, we accept that these results are accurate (as assessment of the validity of the instrument would require considerably more information than is provided in the published literature), the relevance of these results remains open to debate. The team writes that further data yet to be published indicate that there are different levels of risk acceptance for various CTA procedures and that some groups may be willing to tolerate increased risk—relatively unsurprising empirical conclusions. More dubiously, they also claim that their study of risk acceptance provides a way to “objectively address this question” (Cunningham et al. 2004, 16).

But what is the question? On the surface, it is what people’s risk perceptions are with regard to various forms of CTA, undoubtedly a question that may be answered empirically. However, the deeper question is whether it is ethically appropriate to offer experimental face transplantation, and more precisely, whether the benefits of transplant justify the risks, particularly those associated with immunosuppression and rejection (Wiggins et al. 2004). The team maintains that physicians must provide patients “with the latest and complete knowledge about the risks associated with new treatments”; however, “ultimately, the decision to accept risk to receive the benefits of a given treatment belongs to the patient” (Cunningham et al. 2004, 16).

This last statement is particularly revealing: first, the emphasis on patients choosing between available treat-

ments recasts the introduction of an experimental trial for which subjects would be recruited in terms of a more routine clinical decision made by a patient between alternative proven therapies, and thus obscures the experimental nature of the procedures under examination. Second, and more importantly, it depends on a literal and minimalist definition of what considerations should enter into estimations and assumptions of risk; it fails to account for the wealth of literature suggesting that perception of risk may be determined by a series of values, including regret, dread, experience, awareness, proximity, trust, and a sense of control (Smith 1996); and it implies that risk can be determined “objectively.” While the process of informed consent does, in some senses, transfer the assumption of responsibility from the surgeon to the patient for whatever harms might occur, assuming no malpractice and valid consent processes take place (see Morris et al. 2004, 335), responsibility still rests with the clinicians to understand the risks and benefits associated with a therapy and to make the initial decision about whether a procedure should be offered and to which potential subjects, and to an even greater degree in the case of research where the therapy is unproven.

Empirical evidence that people would accept relatively high levels of risk to undergo these procedures is objective only in the weakest sense: it reveals opinions based on the information provided. This comment is intended to cast doubt on neither the reliability of the survey instrument nor the adequacy of the subjects’ understandings of risk, but to lead to deeper interrogation of the ideal of objectivity invoked, as well as its validity and ethical implications. As argued by one of us (RA) elsewhere in reference to candidate selection for solid organ transplantation (Majeske 1996), it is essential for the “objectivity” of biomedical research and practice to be assessed not merely in terms of its empirical validity, or whether it is “value free,” but through recognition of the social nature of scientific inquiry and practice. What counts as “objective” is determined by a particular community, in a particular context. As Longino argues (1990; see also Longino 2002), “objectivity” is best understood as a characteristic not found in the connections between hypotheses and evidence (since our background assumptions are always value laden), but as something that is secured through collective inquiry. Therefore, only when background assumptions are articulated and subjected to criticism can the influence of subjective preferences (of an individual or a particular research group) be checked, resulting in an increased degree of objectivity (albeit of a different sort than the naïve, intuitive idea of being “value free”). However, even this type of objectivity is not guaranteed by the process of transformative criticism; for example, consider cases where background assumptions are shared by all participants and thus are invisible.

Hence Wiggins et al. (2004) are to be commended for offering their proposals to the medical and bioethical communities and to the broader public for scrutiny, as this step is essential to the process of transformative criticism. However, their reliance on empirical evidence about risk perception and implicit confusion of the factual and empirical with the ethical is troubling. The problematic nature of the production, status, and use of this evidence about differential risk perception related to CTA as gathered through their own studies may run the danger of being rendered invisible and overlooked due to our shared tendencies to advocate autonomy and choice for subjects and to eschew paternalism, especially when considering persons experiencing severe facial disfigurement. The decision about when and whether to pursue experimental face transplantation is one that must be made in partnership with potential subjects and relevant professional communities; however, empirical evidence about differential subject perceptions of risk cannot replace researchers' responsibilities to debate and accurately assess the physical and psychological risks presented by these procedures using appropriate critical processes. ■

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## ***Facing the Consequences of Facial Transplantation: Individual Choices, Social Effects***

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The Louisville transplantation team may be commended for initiating a public dialogue on the prospects for facial transplantation and for considering the likely risks and benefits for the individuals who might undergo such procedures (Wiggins et al. 2004). However, I am struck by the failure of the research team to account for two significant points: (1) the potential individual harm of facial graft loss relative to the possible benefits attained (see Strong 2004), and (2) the narrow focus on individual subjects who desire the surgery rather than on the effects of the surgery on others with facial disfigurements, and society at large. I focus on the latter point, given that the former has been discussed by others. The broader social concerns arise even if we assume a

relatively high rate of success with facial transplants. I raise three related areas of concern that deserve more attention: the sources of suffering for people with facial abnormalities, the relation between autonomy and pressures to normalize, and the link between facial transplantation for serious disfigurement and likely future uses of the surgery for cosmetic purposes.

Wiggins et al. (2004) portray the procedure as one intended to help individuals who are suffering from facial disfigurement. That goal, in itself, is admirable. Yet more attention should be paid to the *sources* of suffering as we attempt to alleviate distress. Individuals with facial disfigurements are often socially ostracized, and may internalize

the appearance norms of society, resulting in low self-esteem or a sense of inferiority.<sup>1</sup> They may thus jump at the opportunity to normalize their faces. But are their faces truly the source of their suffering? Our faces are intimately tied to our identities, and accepting oneself requires coming to terms with one's face. Such acceptance is not a solitary task. Rather, we rely in part on others to create an environment in which we can be, and be accepted as, ourselves. The suffering linked to facial disfigurement is in great part dependent on the attitudes and reactions of others toward the person who looks abnormal. Figuring out a suitable response is not easy, as we are all prone to express surprise when we encounter unexpected difference, and the range of facial conditions that might appear to warrant transplantation surgery is wide. Ignoring facial differences may not be appropriate (just as colorblind policies are not always best when dealing with matters of race in a racist society), but neither is the presumption that the face rather than the attitudes must change. In saying this, I do not mean to ignore or minimize the real psychological suffering experienced by individuals who do not fit appearance norms. But such suffering can be addressed in multiple ways, and we should be careful about offering services that frame the problem as primarily an individual deficit. Such a focus may exacerbate our tendency to misidentify sources of suffering. For instance, disability scholars have argued that often what is *most* disadvantageous about having an impaired or anomalous body is the unwelcoming social reception of that body or the refusal to adapt the built social environment to fit it (Silvers 1998). Other people's attitudes and biases (and resulting actions) are often more disabling and cause more suffering than nonstandard bodies (or faces) themselves. Mindful of the sources of suffering, we should be reticent to offer an otherwise healthy person a treatment that carries significant risk of harm.

Of course, given the entrenchment of appearance norms and the desire to avoid paternalism, we might argue that individuals with facial disfigurements should assess the risks of transplantation themselves, once provided with adequate information. Individuals are free to choose what risks they are willing to take. Yet this way of thinking, focusing primarily on individual decision making in isolation, doesn't take into account the effects of individual choices on others. Writing on other forms of elective surgery (toe-shaping for high heels, limb-lengthening, craniofacial surgeries, etc.), Arthur Frank suggests, "Some people's discovery of choices that they find liberating will force others to confront choices they would rather not have recognized

in the first place. . . . [A]s we choose for ourselves, we also confront others with choice" (Frank 2004, 23). Although offering a new option may appear neutral—it just expands the array of options available to the individual—in fact it often shifts the moral landscape, in this case changing the benchmark for what faces will count as socially acceptable and reframing how we treat individuals whose faces fail to conform. Individuals who might otherwise have adapted to their disfigured faces (and asked for acceptance from family, friends, and society at large) may now be held responsible for keeping their faces, for resigning themselves to abnormality rather than exploring their options for achieving normality. (Katz Rothman 1992, discusses this effect in regard to the introduction of prenatal testing as an option for expectant mothers.) The psychological force of this shift (putting the burden on the individual to defend her choice rather than putting the burden on others to alter their attitudes) is reportedly quite significant (e.g., women who make the nonstandard choice to keep a fetus that will have Down Syndrome) (Press 1998). Thus, the availability of a new option combined with strong pressures for achieving normality alters the acceptable norm and may unintentionally narrow the range of options rather than expanding it. The authors recognize the possibility of such pressures: "The facial transplant might be interpreted as conveying the message that a good quality of life cannot be achieved by people with disfiguring conditions" (Wiggins et al. 2004, 5), but appear not to be overly concerned with them, despite the vulnerability of their patients.

Finally, while the authors acknowledge concerns about possible future cosmetic uses of the procedure (e.g., for reduction in the appearance of aging), they claim that this problem is not in their purview. Their job, they claim, is to be open about the reasons they take to be good ones for proceeding with the experiment to correct disfigurement, and then let the public debate the issue of other uses. This strategy represents an unfortunate disregard for the dangers of the burgeoning cosmetic surgery industry and its morally suspect entrance into the realm of erasing or minimizing facial features considered characteristic of nondominant and/or stigmatized groups. Surgeons contribute to this climate by advertising such surgeries. In the name of reducing psychological suffering or of creating supposedly universal beauty, the cosmetic surgery industry minimizes racialized characteristics (through eyelid shaping, nose alterations, and lip treatments) and promotes a White Western ideal of beauty (Kaw 1993; Haiken 1997). Similarly, cosmetic surgery has been used to alter facial features characteristic of Down syndrome apparently with the aim of helping alleviate individual suffering from social stigma (Katz and Kravetz 1989). The cosmetic surgery industry not only helps to create this demand through the questionable link between health and beauty (and the surgeons' assumed

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1. For a good history of cosmetic surgery and its relation to psychological health, see Elizabeth Haiken (1997), *Venus Envy: A History of Cosmetic Surgery*.

authority as an expert in what is clinically beautiful), but it takes advantage of the problematic norms of appearance by using them to make money from people's anxiety over their appearance. Surely we ought to assess the surgeons' complicity with these "suspect norms of appearance" (Little 1998) even as we acknowledge their real concern for their patients' mental and physical well-being. I don't doubt the good intentions of the Louisville team and their hopes for helping individuals who are suffering, but I wonder about their narrow scope of concern. Although the prospect of facial transplantation is exotic and might promote mental health for a few individuals, we ought to take seriously the likely social harms that will follow in its wake and rethink our efforts to link health and appearance. ■

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## Medical Ethicists, Human Curiosities, and the New Media Midway

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### Abstract

Medical ethicists have assumed a role in justifying public voyeurism of human "curiosities." This role has precedent in how scientists and natural philosophers once legitimized the marketing of museums of "human curiosities." At the beginning of the twentieth century, physicians dissociated themselves from entrepreneurial displays of persons with anomalies, and such commercial exhibits went into decline. Today, news media, principally on television, promote news features about persons that closely resemble the nineteenth century exhibits of human curiosities. Reporters solicit medical ethicists for soundbites to affirm the newsworthiness and propriety of public voyeurism of these medical stories. Ethicists' soundbites are usually ambiguous or self-evident and rarely enable viewers to morally engage the is-

ues. The precedent of early twentieth century physicians disengaging from such exploitive public shows is a useful example for medical ethics.

### Introduction

The article "On the Ethics of Face Transplantation Research" (Wiggins et al. 2004) is the latest example of how medical ethicists are drawn into an unfortunate and once abandoned role in American culture: providing academic justification for public voyeurism of human "curiosities." The traditional attractions of the Dime Museums and midways of a century ago have been updated. The promoters of Chang and Eng, the original Siamese twins (they were really from Thailand), drew physicians into the human-interest story of, "Could they be separated for their privacy and freedom?" (Bogdan 1988, 202) Today, medical ethicists comment on the conjoined Iranian Bijani twins: "Meet them and

their families as they choose risky surgery to try to live as individuals!" In the 1920s, albino, dreadlocked black brothers "Eko and Iko" were exhibited as ambassadors from Mars. Today, bioethics sidebars on cloning help lift the Raelians' alien burlesque from tabloids to CNN. Once, natural scientists and moral philosophers wondered at P. T. Barnum's Phineas Gage, whose brain's morality center was speared by a crowbar (Harlow 1868). He has been replaced with bioethics' exhibit in Madame Tussaud's wax museum: the flaky serial killer and defrocked physician Jack Kevorkian whom many medical ethicists once credited with raising a serious moral issue. Self-mutilating "tattooed ladies" have been supplanted by "amputee wannabees" under the medical ethics voyeurscope. Medical ethicists are summoned so that television may primly speak of Ted William's frozen head and babies born of the sperm of dead men who contend as heirs. (Brain) dead women give birth! Test tube babies were a great bioethics story until, like nineteenth century snake charmers, they flooded the market. Grandmothers giving birth to their daughter's children were a passing novelty. President Bush's ethicists fret about husbands cloning their wives for incest with clone-daughters or cloned-trophy wives. Bioethics is into X-treme birthing: octuplets are losing their caché; nonuplets will be sensational. Are cyborgian trans-humans in your future? Medical ethicists ponder! You'll be amazed!! It's educational!!!

### *The Educational Diorama*

Persons with physical anomalies have long been objects of public curiosity (Fiedler 1978). They have been seen as personifying traits such as the eternal childhood of dwarfs or the strength of acromegalic giants. They have been used as evidence of the presence of evil or the punishment of sin. Though such people have been "collected" for centuries (court dwarfs, for example), commercial freak shows had a relatively brief popularity, essentially the last half of the nineteenth century (Bogdan 1988). Commercial exhibitors of human "curiosities" had to overcome public aversion to staring at people who were different and a Victorian sentiment against amusement for its own sake. The public would not pay to simply gawk at people that the impresario P. T. Barnum called "curiosities," "oddities," "creatures," or "freakish." Thus, promoters appealed to the educational value of their exhibits. At their heyday, display institutions were called "museums." P. T. Barnum's mid-nineteenth-century American Museum was the premier tourist attraction in New York City. Hundreds of smaller Dime Museums dotted the United States.

The educational appeal required a curriculum. Exhibitors constructed "dioramas," settings and stories, to create the educational draw for their exhibits. For example, ethnographic displays and texts often depicted explorers discovering dark-skinned "Missing Links" and "Cannibals"

which resonated with popular interest in ethnography and evolution and reinforced the widespread appeal of racism and Social Darwinism. Primitive or savage dioramas or allusions to collapsed civilizations reassured a White American audience that it embodied the most advanced stage of evolution and civilization (McGowan 2001). Some persons were exhibited as having medical educational value. Promotional material typically contained a medical note, comments on the importance of the exhibit by medical scientists, and a bogus biography highlighting the extraordinary accomplishments of the exhibited person. P. T. Barnum, for example, showcased the dwarf Tom Thumb with a phony military title and marketed an elderly black woman, Joice Heth, as the 161-year-old slave who swaddled the newborn George Washington. Promoters were showmen first and educators by necessity.

Nineteenth-century promoters secured the willing or unwitting endorsement of physicians, scientists, anthropologists, sociologists, psychologists, natural philosophers, clergy, and prominent figures to promote public interest and attract paying customers (Bogdan 1988). Experts discussed the human curiosities in light of the scientific controversies of the day. Some medical articles read like the hype of bribed movie critics. For example, an 1888 *JAMA* report of "a four-legged child" concludes, "The reality in this case surpasses expectation and we are of the opinion that this interesting *living monstrosity* [emphasis in original] exceeds in its curious manifestation of the power of nature in abnormal productions, the celebrated 'Siamese Twins'" (Jones 1888). Such medical articles discussed cases by their show names: The Siamese Twins; The Hungarian sisters; the South Carolina Negresses, Millie and Christine; the Two-Headed Nightingale; the Bearded Girl of Louisiana; and so on. Central Americans with microcephaly were regularly procured and exhibited as descendents of the Aztecs. In 1887, Dr. John Langdon Down, for whom Down's syndrome is named, referred to the "Aztec type" of mental retardation, a gaffe in scientific nomenclature that persisted for fifty years (Down 1990). Scientific articles and promotional pamphlets often included prurient allusions to the sexual lives of conjoined twins or marriages between persons of various anomalies or the abilities of persons lacking limbs or having unusual stature. In England, Joseph Merrick, "The Elephant Man," moved from disrobing for public spectacles in 1884 to disrobing for medical societies in 1886 under the protection of a physician. He would unbare his genitalia, which were normal, at the end of such conferences.

### *The Museum of Curiosities is Dead: . . .*

During the first third of the twentieth century, commercial exhibits of persons with physical anomalies faded from museums to circus sideshows, and finally to tawdry itinerant

county fair exhibits. The scientific professions whose comments had been employed to market the spectacles distanced themselves from them. Physicians recast persons with anomalies from being freaks to being persons with unfortunate medical conditions. Anthropologists undermined the foundations of “Missing Links” and microcephalic “Aztecs.” Physicians and scientists increasingly resisted being drawn into publicity stunts that showmen had used to promote their exhibits. Mainstream media followed the scientific community’s lead. For example, in 1908, the *Scientific American* reprinted an article from the *New York Medical Journal* that listed the human curiosities by diagnosis (e.g., acromegaly, dermatolysis, argyria). It noted, “Most of these humble and unfortunate individuals whose sole means of livelihood is the exhibition of their physical infirmities to a gaping and unsympathetic crowd are pathological rarities worthy of more serious study than they usually receive. . . . A more refined and human popular taste now frowns upon such exhibitions and they are less profitable to their promoters” (Editor 1908).

A 1937 case report on gigantism in the *Journal of the American Medical Association* is exemplary, as it marks the approximate end of the medical trumpeting of persons as freaks (Humberd 1937; Bogdan 1988, 272–277). Dr. Charles Humberd went unannounced to the home of the eight-foot eleven-inch tall Robert Wadlow. Though Mr. Wadlow did not want to be examined, Dr. Humberd was undeterred, noting that “physicians and laymen find it impossible to [comply].” He describes his “lavish and continued expenditure of much cajolery, flattery, servility, wheeling, and exaggerated politeness and persistence” in his unsuccessful effort to examine Mr. Wadlow. In *JAMA* (Humberd 1937), the rebuffed Dr. Humberd described the “surly and indifferent” affect and the blurred functions of the “highest centers in the frontal lobes” of this giant and published data from Mr. Wadlow’s hospital records. Mr. Wadlow, a dignified, intelligent, and aspiring lawyer, sued for this inaccurate and demeaning presentation and many witnesses testified on his behalf. Though the suit failed, the plaintiff’s sentiment prevailed. From then on, mainstream consumption of human deformity was largely metaphorical, as in the novel *A Canticle for Liebowitz*, movies (e.g., *Satyricon*, or *Freaks*), television (*Wild Wild West*), and comic books (*The Hulk*). Today, fictional evildoers are often signified by their deformities.

### ... Long Live the Medical Docu-Soap

Television reopened the museum of medical curiosities. In his aptly titled *Freakshow*, Dovey describes how televised news documentaries have shifted from expository analyses to brief presentations of personal stories. This shift spotlights formerly private tribulations and requires “hygienic” rules to justify the public display and attract viewing of

these personal experiences (Dovey 2000). He calls this form of television news a “docu-soap”: it is a form of “edutainment.” The docu-soap is fundamentally a human-interest story, a form of entertainment. Postman says that news packaged this way differs from journalism in that it is presented without a historical or cultural context, requires little prerequisite knowledge, and is designed to leave the viewer satisfied (rather than perplexed) so that he or she is ready for the next message. The rapid interspersing of major and trivial news with commercial messages levels the importance of all information (Postman 1985, 80–150; Kendrick and Costello 2000). This leveling of hard news, soft news, and commercials reflects the confluence of the objectives of television news show: to inform, draw audiences, and sell things.

The modern medical docu-soap is a close kin to the nineteenth-century Dime Museum. Like the promoters who preceded them, modern producers make their money as their exhibits and pitch draw an audience. This audience brings advertising revenue rather than ticket fares. In the nineteenth century, natural scientists and moral philosophers were recruited to make the exhibits palatable and so to market the public spectatorship of human curiosities. Today, docu-soaps promote voyeuristic viewing with “educational” dioramas (Kendrick and Costello 2000). The pith-helmeted explorer discovering aboriginal “Missing Links” has been replaced by intrepid scientific explorers moving amidst exotic computer animations and twinkling machines. The message is fundamentally unchanged: our most advanced civilization is colonizing each part of the world. The camera flits from white-coated professionals to dangling stethoscopes, ICU monitors, anxious faces, and the “curiosity.” The viewer sees the bioethicist as a prop in this display, one of other symbols of an advancing, authoritative, and wisely self-governing culture.

A tacit contract governs the display of medical ethicists in docu-soaps about medical curiosities.

- First, medical ethicists are not allowed to reflect publicly on why particular subjects or framings of the issues have been chosen. For example, bioethicists were recruited to legitimize, rather than challenge, the media hoopla over the Raelian hoax, which featured extraterrestrials, clones, space travel, and a beautiful woman scientist. (P. T. Barnum would have loved that farce, which so closely echoed his promotion of Feejee Mermaid, a monkey head sown on a fish body and advertised with posters of a beautiful woman.) There is little more than television’s pandering to the curious to explain why the Iranian conjoined adults Laleh and Ladan Bijani and the Egyptian conjoined babies were spotlighted to discuss the everyday issue of patients confronting grave surgical risks.

- Second, medical ethicists must not challenge the intrusive spotlight on the private lives of media patients (Kendrick and Costello 2000) even when the media spotlights poignant and anguished stories about children (Jones 1999). Many medical ethicists freely commented on the misleading videotapes of Terry Schiavo that her parents and right to life groups released despite a court order and against the wishes of her legal guardian husband. Some even opined from these tapes on whether or not Ms. Schiavo was in a persistent vegetative state without reviewing other publicly available medical data or testimony that was available in public (though less publicized) court records. It is ironic that bioethics, which lifted up the principle of medical privacy and confidentiality, is so ready to collaborate in public unveiling for the media spotlight (Iserson 2001). Ms. Schiavo and her husband had a right to expect much more of these commentators.
- Third, the media agree to broadcast the words and names of cooperating medical ethicists just as impresarios did with reputable scientists a century ago. Despite this celebrity, the medical ethicist is an oddly anonymous collective-person who is usually sandwiched in front of a background of books and behind the floating label “medical ethicist.” His or her values, qualifications, or methods of analysis are irrelevant, invisible, and not to be reflected on or questioned. The ethicist is rarely allowed to probe like a Greek chorus. In that television news does not allow time for debate, medical ethicists’ soundbites are often edited to ambiguous embroideries. A common theme is, “This case illustrates the promises and perils of issues raised by new technologies. Society must grapple with the moral implications of this kind of technology.” Such banalities echo scientist Baron Von Humboldt’s mid-nineteenth century commendation of two microcephalic Indians who were displayed as the ‘Last of the Aztecs:’ “They appear to offer a worthy study to those who seriously occupy themselves with types of human organization and with the laws respecting them.” Or, as Horace Greeley said of the same exhibit, “To the moralist, the student, the physiologist, they are subjects deserving of careful scrutiny and thoughtful curiosity (Bogdan 1988, 130–131). Medical ethicists are stuck inside a diorama of their own making.

### *Stepping Back (but Not Out)*

In the twentieth anniversary issue of the *Hastings Center Report*, Leon Kass warned that bioethics was in danger of moving “still further from the rich context of our moral life by concentrating mainly on the *extreme examples* [emphasis in original]” (Kass 1990). He did not anticipate how medical ethicists’ penchant for the extreme would coincide with the media’s inclination to sell the bizarre. However

complicit with the new media midway, medical ethicists did not create and do not sustain the phenomenon of sensational medical docu-soap by themselves. Hospitals and drug companies push stories for institutional entrepreneurial reasons as well (Moynihan and Sweet 2000; Geiderman 2001). Even so, it is time for medical ethicists to create a critical distance from participation in these productions.

I believe that the reputation of medical ethics is harmed when medical ethicists are recruited into the format of the docu-soap. Dispensing truisms and cultivating this kind of celebrity does not enhance its prestige. The media will bruit a bioethics gloss on chimpanzee-to-human transplants and ignore its perspective on problems facing persons with disabilities or who lack health insurance. As this repeatedly happens, medical ethicists risk being seen as dilettantes or gatekeepers at the portals to the health care system’s most lavish and exclusive rooms (Turner 2004).

Medical ethicists must recognize that journalism often invites a comment to fill in a story line rather than to educate the public about the moral dimensions of an issue (Hopkins 1998; Manson 1997, 32–34). Medical ethicists should follow the example of early twentieth century physicians and establish a professional distance from constructing educational dioramas for the display of human curiosities. This does not imply a complete withdrawal from media presentations. The exceptional and extended documentaries like Bill Moyers’ series on end-of-life care have value. A soundbite on a one-minute news collage on a person who commits suicide in a hospital parking lot in an effort to give a relative an organ does not.

A principled media engagement might follow these rules. First, bioethics is a reflective activity. The rapid news cycle serves celebrity better than reflection. Medical ethicists should spend more time backgrounding reporters, rather than throwing themselves forward with soundbites. Second, we should seek to engage stories when coverage is centered on an issue rather than when it is built around an arresting image. Medical ethicists are just background banners when the image of the day is Dr. Kevorkian parading around in an Uncle Sam suit or a kitten in the beaker is being hawked to illustrate the Missy “clone your pet” Project of the now defunct and discredited Genetic Savings & Clone. Third, the headline-breakthrough news cycle invites errors. Good reporters will appreciate it if you ask and take time to read the primary data and some secondary data before commenting. As in any teaching activity, a medical ethicist should know what he or she wants to teach before the reporter asks a question and should stick to that message rather than being drawn into a docu-soap’s prefabricated story line. Quips that fit a news display of a human curiosity do little to educate the public or edify the discussion. Fourth, do not comment on improperly obtained information, images, or stories about personal medical care.

Privacy and confidentiality are important. Being a medical ethicist is different than running away to join the circus. ■

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## **Response to Selected Commentaries on the AJOB Target Article “On the Ethics of Facial Transplantation Research”**

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### *Main Response Topics*

- Introduction
- Open display and public evaluation
- Publicity versus patient privacy
- Facial tissue donation
- Validity of Louisville Instrument for Risk Acceptance
- Patients' understanding of risk
- Face versus hand transplantation
- Rejection rates/risks
- Patient compliance
- Exit strategy
- Functional recovery
- Societal implications
- Psychological implications
- Conclusion: Uncertainty likely to persist

### *Introduction*

We are delighted that our essay on the ethics of facial transplantation research has accomplished precisely what we hoped it would: It has produced a wide-ranging, deeply informed, and philosophically forceful discussion of this topic. We are flattered that so many acknowledged experts on these matters agreed to comment. We have certainly learned much from their insights and arguments.

As we document in our essay, we have over the years participated in numerous professional and public discussions and debates on various aspects of facial transplantation, and we have almost always learned valuable items from them that we have then incorporated into our research proto-

col and Institutional Review Board proposal. Our thoughts and writings on facial transplantation have been evolving for years because of these open discussions with others in various fields. Now our reflections on ethics have become the beneficiary of criticisms and commentaries that too will be used to further improve our program and our Institutional Review Board proposal.

We are especially glad to see these multifaceted commentaries because one of our most difficult tasks in completing our own ethics article consisted in paring it down to conform to the word limit for target articles in *The American Journal of Bioethics*. We were aware then that in so doing we were leaving numerous crucial topics insufficiently treated. We were able to console ourselves with the thought that commentators would discuss them, and even expand the topics beyond what we had conceived. We are pleased to see that precisely this has occurred. For example, while we were only able to hint at—or at best mention—the psychosocial issues involved in facial transplantation, the thoughtful comments of Nichola Rumsey (2004), John Robertson (2004), Sara Goering (2004), and others emphasized just how complex these issues are.

Reading these commentaries has left us more convinced than ever of the fruitfulness and, indeed, the necessity of “open display and public evaluation” of innovative scientific/medical procedures prior to the experimental use of them. This demonstrates the truth of what Ankeny and Kerridge (2004) write: “‘Objectivity’ is . . . something that is secured through collective inquiry.” Our intention in writing this essay, raising questions and seeking “input about the ethics of face transplantation prior to undertaking a series of such operations” (Caplan 2004), coincides

exactly with Arthur Caplan's conception of "prophylactic ethics."

Regarding this response, we must add one caveat: Again we have been unable to say everything that needed saying. The commentators will find many of their valuable points still unaddressed by us. But, then, that is one of the advantages that comes with thinking, as we do, that the discussion is never over.

In an attempt to address as many comments as possible we have divided our response into this introduction; twelve separate sections, each addressing a common topic; and finally our conclusion. The following individual responses were written by the member(s) of our team whose field of expertise is related to the respective commentary.

***Open Display and Public Evaluation (Caplan, Morreim, Agich/Siemionow, Maschke/Trump)***

Agich and Maria (2004) maintain that Francis Moore, a surgeon on whose writings on transplantation we draw, never specifies that what we call "open display and public discussion" is an "ethical requirement" of innovative surgical research. While we concede that in his 1989 editorial, Moore does not explicitly call open display and public evaluation an "ethical requirement," it is clear that he does place great value on such openness (Moore 1989). In his *JAMA* editorial, Moore discusses four unfortunate cases of innovative transplant surgery and writes:

One of the most important aspects of these four remarkable cases is that the suffering and trials weathered by the patients and their families, the physicians, and the social support structure have now been reported in full and that the experience has been documented and is now a matter of open display, public evaluation, and discussion. That openness is a remarkable characteristic of our society that must never be lost in the competitive secretive atmosphere of current corporative medical work. It must be cherished and protected. The authors and the editor of *The Journal* are to be congratulated. (Moore 1989)

Of note here is that in this case cited by Moore, open display, public evaluation, and discussion occurred *after* the innovative surgeries had been performed and their actual outcomes were evident and could not be reversed. Our position goes a step beyond Moore's: we believe that this sort of discussion should occur *prior to* performing such surgeries. Hence we echo Caplan's call for a "prophylactic ethics." Current practices of performing innovative surgeries before open display, public evaluation, and discussion has occurred, of course, have the great advantage that after the fact, one can evaluate the outcomes with reference to their actual results, whereas prior discussions and evaluations occur in the ominous shadow of much ignorance. This is especially true when, as in the case of facial transplants, there will be

"outcomes" of many types that simply cannot be predicted in advance.

Our commitment to this kind of prior and continuous open display is based on a principle that we should state here, even if this cannot be the place where it is defended. We think that *in a liberal democratic society scientific advances which by their very nature and consequences will produce controversy and debate should be placed in the domain of public discussion prior to the actual occurrence of those advances (unless there is some overriding reason not to do so, such as national defense)*. We think this because we believe that *in a liberal democratic society scientific advances with significant consequences for human life should, at least to some extent, be placed under democratic control*. This is a sprawling and complex topic, and therefore many qualifications ought to be appended to it. We found it necessary to state it here because some key features of our "Ethics" essay depend on it.

***Publicity versus Patient Privacy (Agich/Siemionow, Morreim, Rumsey, Caplan)***

Agich and Siemionow (2004) criticize our teams' commitment to what they call "publicity" as needing more discussion than we devote to it. Like all the issues in our article, we concur that this too needs more discussion than we were able to give it. We had nevertheless in our article sought to distinguish what Morreim (2004) calls the public's "desire to know" from our ethical obligation to inform the public of some aspects of the transplant. We said that "at this point we intend to fulfill this obligation through our publications in professional journals and press releases."

As it relates to professional journals we state in our article, "If components of adequate scientific publication require a compromise of privacy and confidentiality, then we intend to seek the subject's voluntary, informed consent for it" (Wiggins et al. 2004).

Releasing information through press releases poses a larger ethical problem. We intend to strictly circumscribe this release of information. At any particular time we shall say only so much, namely, only as much as *we* think the public deserves to know at that time. We shall undoubtedly be asked questions that we will not answer, but this is a practice of refusal to which we have grown amply accustomed. We have acquired extensive experience in refusing to answer a wide variety of questions.

The anticipated press releases are based on our premise that surgical and scientific innovations should occur in an atmosphere of openness and not occur in a purposefully maintained secrecy unless there is some overriding justification for it (national defense or patenting rights, for instance). This obligation is quite different from any attempt to satisfy the public's "desire to know."

We agree with Morreim (2004) that no one is required to provide a reporter with whatever information he or she

wants. As we have said, we have repeatedly refused to answer innumerable reporters' questions. Carefully circumscribed press releases fall within a different ethical category, however. Yes, this does require a compromise between the subject's right to privacy and confidentiality and our obligation to release certain pieces of information. This is a compromise that must be defined and redefined with the subject's voluntary, informed consent.

In response to Rumsey's comment that, "In the unlikely event that the identity and details of the donor remain secret, the recipient will still speculate about the identity, history, and personality of the face that has been acquired" (Rumsey 2004), we agree but have no reason to think that such curiosity would be more obsessive, or lead to more problems in recovery, than is the case with a recipient of a donated kidney, heart, or hand.

Caplan comments that psychological stress will be caused by the inability of the first face transplant recipients "to retain their privacy . . . given the public's fascination with this form of transplantation and the eagerness of the medical community to both promote and follow the first such surgery" (Caplan 2004). We recognize this and are taking it into consideration in our patient selection criteria. The first face transplant recipients must be selected to have a personality that can withstand media attention and invasions of privacy.

#### *Facial Tissue Donation (Agich/Siemionow, Rumsey, Caplan, Robertson)*

We agree with several of the commentators concerning the unprecedented complexity posed by facial tissue donation in comparison with traditional organ and tissue donation. In the paragraphs below we address briefly some of their comments regarding facial tissue donation.

To assure that donor families are treated with the utmost sensitivity, professionals trained in working with organ donor families will interact with the potential donor families. A precedent exists with respect to soliciting the donation of a decedent's hand. Once the proposed procedure has been approved by the IRB, we will work closely with professionals trained in working with organ donor families to create a script for approaching donor families. These professionals will, of course, have to be aware of the special concerns that families may have regarding the novel and puzzling issue of donating the face of a loved one. Therefore, they need to anticipate the range of questions and worries such families may express. As in all kinds of informed consent in research, care must be taken to guard against any kind of undue influence or manipulation. We shall seek the fully voluntary support of donor families and shall exclude donation in the event of family resistance.

With regard to the issue of burial of the donor, his or her family may be offered several options, including a closed

casket, cremation, or the use of a facial prosthesis (as was done with the families of hand donors).

In addition to the customary blood- and tissue-type matching involved in transplantation, our current plans include matching the recipient and the donor on gender, racial skin color, and general age.

From our experience in hand transplantation we recognize that finding the right donor and the right recipient at the same time will be a challenging endeavor.

As was done in our hand transplant program, we will work closely with our regional and national organ donation organizations to address the many unique challenges that facial tissue donation brings. The conversations we have had with professionals from our regional organ donor organization, Kentucky Organ Donors Association, have been reinforced by remarks by several of the commentators here, and we concur with them in the need for procedures to educate the public and especially prospective donors and their families.

#### *Validity of Louisville Instrument for Risk Acceptance (Ankeny/Kerridge)*

In the following lines we respond to Ankeny and Kerridge's (2004) comments regarding the validity of our instrument for assessing risk acceptance. We believe that independent evidence about differential risk perception related to composite tissue allotransplantation procedures takes on added importance when patient autonomy is emphasized. Rather than rely on the opinion of a few local authorities, empirical research affords the patient access to the opinions of hundreds of peers. However, we concur with Ankeny and Kerridge that:

The decision about when and whether to pursue experimental face transplantation is one that must be made in partnership with potential subjects and relevant professional communities; however, empirical evidence about differential subject perceptions of risk cannot replace researchers' responsibilities to debate and accurately assess the physical and psychological risks presented by these procedures using appropriate critical processes. (Ankeny and Kerridge 2004).

We concur with Ankeny and Kerridge (2004) that the creation, execution, and interpretation of scientific evidence will always entail an element of social construction, which is mediated through language, history, and embedded values. That said, we still regard it as useful to assess differential risk perception related to composite tissue allotransplantation procedures in the community from which potential transplant recipients will be drawn.

We feel that this target article and the commentaries it has generated are fulfilling part of our responsibility to debate these risks.

*Patients' Understanding of Risk (Caplan, Ankeny/Kerridge, Maschke/Trump, Petit et al.)*

We have a high respect for the thoughtfulness of patients and are committed to full patient informed consents. The risks of immunosuppression are very well studied and known as a result of their use in tens of thousands of organ recipients. Such risks can be forthrightly described to potential face transplant recipients. Further, preliminary results from our own studies using a psychometrically reliable and valid instrument indicate that organ transplant recipients, who possess direct knowledge of surgical and immunosuppressive risks, evaluate the risks versus benefits of face transplantation similarly to other individuals, who are given such information in a manner similar to a patient informed consent document. The similarity in perception of the experienced and inexperienced patients suggests that informed consent documents can be effective educational tools.

*Face versus Hand Transplantation (Baylis, Maschke/Trump)*

Baylis (2004) and Maschke and Trump (2004) comment on the analogies we draw between hand and face transplantation. Baylis claims that we "use arguments from analogy to reason from the presumed clear case of morally acceptable hand transplantation, to the morally problematic case of facial transplantation" (Baylis 2004). In fact, the similarities we describe between hand and facial transplantation pertain solely to immunology and, in some instances, surgical procedure. We contend that since the hand contains the same tissues as those that would be transplanted in a face transplant, the body's immunological response to hand tissues should be similar to that of facial tissues. For further discussion on the immunological analogies between hand and face, we direct the reader to the following section that discusses "Rejection Rates." The analogies we make between the hand and the face as it relates to the surgical procedure involve many technical aspects of the tissue viability and function we expect to be able to achieve following the reattachment of facial blood vessels and nerves.

We are acutely aware that facial transplantation poses its own unique set of ethical problems. In order to move this medical frontier forward it is nonetheless essential to draw on what we have learned from scientific, surgical, and medical procedures that resemble facial transplantation. It is essential to use and indeed even depend on this secondary knowledge as we go where others have not.

*Rejection Rates/Risks (Baylis, Caplan, Strong, Ankeny/Kerridge, Maschke/Trump, Rumsey)*

In discussing rejection, the commentators focused primarily on the rates of and risks associated with rejection. While

these two important topics are related, we will respond to them separately for the sake of clarity.

*Rejection rates*

Several commentators cited well-known reports from the Royal College of Surgeons (2003) and the United Network for Organ Sharing (UNOS) (2004) citing rejection rates of 10 percent for acute "immediate" rejection and 30 to 50 percent for chronic rejection. These figures are based on large numbers of solid organ transplants and are extremely valuable for studying the "antirejection" effects different immunosuppressive drug regimens have in solid organ transplantation. These data, in fact, were instrumental in the early planning stages of our hand transplant program to predict "risks" associated with the immunosuppressive drug regimens we planned to use in our first hand recipients. While these statistics are of unquestioned reliability in the transplantation of solid organs, they may not necessarily correspond to, and therefore be predictive of, the rejection of facial tissues. Owing to the difference in the composition and the antigenicity of hand and face tissues versus solid organs, these data are not necessarily analogous to hand and face transplantation. Reviewing data from hand transplant cases, a more salient data source for predicting rejection of facial tissues might offer a better indicator of the probability of rejection.

Let's begin with acute rejection. If we look at the early outcomes of the first twenty-four hands transplanted in eighteen recipients, 75 percent of the cases (including both patients at the University of Louisville) experienced acute rejection within the first year. In all these cases, however, *rejection was completely reversed* through temporary adjustment in antirejection medication (Dubernard et al. 2003; www.handregistry.com 2004). Thus the loss of a transplanted hand due to acute or "immediate" rejection at two years follow-up is *zero*.

Briefly, in response to the question concerning our management of acute rejection, we offer the following statement from our Institutional Review Board application:

Rejection episodes are an anticipated event after any transplant operation. Typically these episodes can be controlled with the administration of small amounts of additional immunosuppressive drugs. On occasion, the rejection process may be more severe and will be inadequately controlled unless more powerful immunosuppressive medications are used. In these cases medications such as OKT3, FK506, and Atgam are very effective at controlling rejection. . . .

Turning to chronic rejection, it is important to note that acute and chronic rejection are disparate disease processes, differing in time course, histological manifestations, and treatment. Above we discuss acute rejection; in the following paragraphs we will discuss some important

points about chronic rejection as they relate to facial transplantation.

Several commentators, as stated above, referred to the Royal College of Surgeons (2003) reporting a “30 to 50 percent chance of chronic rejection (resulting in significant loss of graft mobility and functional failure) in the two to five year period following (facial) transplantation.” As in the case of acute rejection, these figures represent chronic rejection in solid organ transplantation. Therefore, our argument here is the same as above: solid organ and hand/face data and conditions are not directly analogous.

In spite of the great threat chronic rejection poses in transplantation, relatively little is known about the mechanisms of this disease. This is due, in part, to the fact that there are no good animal models in which to study chronic rejection. Existing animal models tend to develop a modified version of subacute rejection rather than the characteristic signs of chronic rejection seen in human solid organ transplantation (Libby and Pober 2001).

Most of what is known about chronic rejection in solid organs has been learned from biopsy and necropsy studies of transplanted organs in humans. While the actual cause of organ failure in chronic rejection is not known, biopsies from human tissues report a combination of factors including pretransplant factors, aging, and post-transplant immune and nonimmune injuries. Fibrotic changes within the vessel walls of small arteries in the transplanted organs is a frequent finding, but there is disagreement as to whether these changes cause reduced blood flow and in doing so cause the damage seen in the parenchyma (nonvascular tissue) (Gourishankar and Halloran 2002).

Another factor that further complicates investigations of chronic rejection is the fact that it manifests itself differently from organ to organ and therefore it is difficult to draw parallels from one organ to another. Projections from solid organs to composite tissues (hand/face) are even more untenable. In fact, data bear this out. At the time this response was written, 15 of 18 hand transplant recipients were two years post-transplant and 2 of 18 were five years post-transplant (chronic rejection appears in solid organs between 6 months and 5 years post-transplant). Of these 18 cases *none* had reported signs of chronic rejection (Dubernard et al. 2003; www.handregistry.com 2004).

We acknowledge that data on the first human hand transplants are limited by sample size and time removed from surgery. At present, models of hand tissue rejection based on statistical probabilities are not possible, although the time needed to collect the data necessary to define such models is fast approaching. Nonetheless, early rejection-rate outcome data on hand transplantation are encouraging and provide a valid basis for forecasting favorable rather than unfavorable outcomes for hand and face transplantation.

### *Risks associated with rejection*

To address the risks associated with rejection we turn to the medical and psychological risks of tissue rejection outlined in our Institutional Review Board application. The nature of these risks and our plan for responding to them are likewise reported in the Institutional Review Board application and are summarized in our discussion in the Exit Strategy section found elsewhere in this response.

As with projected rejection rates, much of the commentators’ responses on rejection risks rely on data from the Royal College of Surgeons’ report (2003). Once again, our position is that these data are not legitimate correlates of the risks in face transplantation. The RCS reports are based on early studies of solid organ transplantation where, in many cases, the use of immunosuppressive medicines less sophisticated than those currently available were standard practice.

Additionally, the physical health of solid organ and composite tissue recipients are not comparable, thus lowering further the validity of using solid organ risks to predict risks associated with face transplantation. Whereas disease conditions indicating a heart, lung, kidney, or liver transplant are by definition serious and typically affect all the organs, causing a constellation of other critical health problems, candidates for face transplantation are quite likely to be healthy individuals who have no health problem other than the need for facial reconstruction. One of the important risks to which organ recipients are exposed is the toxic side effects that the antirejection medications they must take have on their already damaged organs. A healthy face recipient will have far higher chances of resisting secondary disease after surgery than a person who enters a transplant procedure already in severely poor health. Lastly, we also believe that a face transplant recipient otherwise in good to excellent health will have a higher probability of recovering from tissue rejection should it occur.

### *Patient Compliance (Baylis, Caplan, Maschke/Trump)*

Medical noncompliance is a challenging problem that can be addressed through careful patient selection, education, and monitoring. There is a great deal of experience and literature using the same drug regimens as that proposed for face transplantation, so it is clear that the regimen can be tolerated. Indeed, the rate of medical noncompliance in hand transplant recipients is one in eighteen, and there is anecdotal evidence that this one patient would have been excluded in a careful patient selection process.

### *Exit Strategy (Baylis, Strong, Caplan, Goering, Maschke and Trump, Morreim)*

Several commentators have quoted Klotzko (2004) in stating that our team has no exit strategy in the event of tissue

rejection or aversive response to immunosuppression medications. This is simply untrue. Our exit strategy is a key component of our clinical protocol; it follows standard and objective practices in the field; and it is outlined in detail in our Institutional Review Board application. We did not include a discussion of our exit strategy in the present article because we felt that the topic went beyond the paper's scope and intention. Below we address the commentators' concerns with excerpts from the "Exit Strategy" section of our Institutional Review Board application.

As in all transplants, the risk of rejection and life-threatening complications caused by the life-long anti-rejection drugs the recipient must take exists in facial transplantation. Even if reversed, the rejection event may lead to permanent alterations in the appearance and/or function of the transplanted tissues. Therefore, the lengths to which the recipient and the transplantation team are willing to proceed in their efforts to reverse rejection episodes are of critical importance.

If the facial transplant recipient begins to exhibit signs of severe rejection that can not be controlled or reversed with the use of conventional immunosuppressive regimens, the diagnosis of graft failure will be given and plans will be made to surgically remove the transplanted tissue.

At that point, the patient, in essence, will be back at "square one" in terms of his or her treatment, and the transplant team will employ the same conventional reconstructive techniques that were used following the original trauma.

In solid organ transplantation (e.g. liver, heart, or lung) where tissue rejection results in death of the recipient, the decision to use powerful immunosuppressive therapy is not necessarily considered extraordinary. However, as in the case of kidney and hand transplantation, transplantation of facial tissues facilitates non-vital organ function and/or social reintegration, the use of extremely strong medications would be considered extraordinary and unjustifiable. Extraordinary attempts to salvage the transplanted facial tissue may place the recipient at substantial risk for complications related to immunosuppressive therapy, as well as the sequelae of rejecting tissues near vital anatomic structures in the head and neck.

It is important to note that in the event that the transplanted facial tissue must be removed we shall take measures to assure that the patient is not worse off than he or she was before the transplant. Patient selection is critical in this regard. One of our selection criteria is that a patient must be early in his or her reconstructive treatment. Thus, in the event the transplanted facial tissue must be removed, returning the resulting facial deformity to the immediate post-trauma condition is only two or three surgeries away. In our experience, conventional techniques used to reconstruct this type of complex facial deformity can require more than 100 surgeries over periods of 15 to 20 years. Selecting a patient who is early in this reconstructive process would

assure that "square one" is not far away and that the surgical team's reverting to conventional reconstructive methods would be the same as the patient would have experienced without the transplant.

Every effort will be made to screen potential facial transplant recipients to insure that a clear understanding exists and that no extraordinary means to reverse severe rejection episodes will be undertaken. Only candidates who understand the risks of potential reconstructive procedures and are willing to agree to the surgical removal of the transplanted facial tissue (once advised to do so by the transplant team) will be eligible for transplantation. These risks will be clearly explained to the recipient prior to enrollment into the facial transplantation protocol.

The psychological consequences of rejection may become a key factor in the patient's willingness or resistance to pursue extreme means to save the transplanted part and have been considered as well. Psychological trauma will be minimized by selecting an emotionally resilient transplant recipient and by promptly initiating remedial reconstructive surgery. The protocol that will be reported to the Institutional Review Board includes an intensive social and psychological assessment prior to surgery. This assessment is designed, in part, to provide a basis for predicting the recipient's ability to deal with tissue rejection.

No screening process, of course, can accurately foresee human behavior in the face of adversity. Rational decisions made by potential recipients preoperatively in response to hypothetical case scenarios may not predict the emotionally charged environment surrounding an actual rejection episode.

Conflicts over the decisions concerning tissue failure may arise and the issues may be obscured by subjective criteria such as cumulative effort expended, the rarity of the transplanted tissue, emotional attachment to the patient and of the patient to the transplanted tissue, a sense of dedication, as well as the patient's feelings of fear, failure, and of inadequacy. The recipient may, in short, view the benefits derived from the transplanted part quite differently from the members of the transplantation team.

The recipient may not be willing, for example, to give consent for reconstructive surgery if he or she believes that more aggressive therapy would reverse rejection. The recipient may feel that the added risk incurred from the use of extraordinary immunosuppressive therapy would be acceptable given his or her own subjective analysis of the benefits derived from the transplantation. This scenario will create an unavoidable moral dilemma.

In the event that a clinical treatment impasse is reached, every attempt at reconciliation will be made using the available resources of the transplant team such as psychiatry, social services, prosthetics, rehabilitation, etc. If, however, the recipient is not willing to consent to the surgical removal of the

transplanted tissue, and no additional means to reverse the rejection process are implemented, the recipient may experience severe morbidity and, in all probability, death. Extraordinary means will be used to reverse the rejection episode only in life-saving circumstances. If the recipient continues to experience rejection and is unwilling to terminate the immunosuppressive regimen, supportive care will be provided as indicated.

The recipient, as stated in our Institutional Review Board protocol, will be fully informed at the time of enrollment in the facial transplantation selection process that the above described scenario may occur and that death may be a consequence of the transplantation.

### **Functional Recovery (Caplan)**

Several comments focused on the *technical difficulties* of surgically attaching the donor facial tissues and the subsequent *restoration of facial function*.

#### **Technical difficulties**

We concur with the commentators that transplanting a face from a donor to a recipient will be technically challenging. If the facial defect requires that a full face be transplanted, it is expected that four arteries and four veins would be reattached, and as many as twenty facial motor nerve branches and major sensory nerves would need to be repaired. Reattaching all of these delicate structures and nerves could take as long as 8 to 16 hours to complete. However it is important to note here that in many respects current methods that repair and reattach damaged tissues or that remove, transfer, and reconfigure autologous tissues to reconstruct facial deformities are more technically challenging than transplanting healthy facial tissues from a donor. The technical expertise and techniques needed to transplant human facial tissue are common practice and are performed daily in most centers where complex facial reconstructive procedures are performed. These methods have been developed and improved over the years and are the basis for current facial reconstructive and aesthetic techniques.

#### **Restoration of facial function**

Based on our previous experience reattaching amputated body parts, transplanting muscles and nerves from one part of the body to another and more recently transplanting hands in two recipients, we believe that facial transplantation will be able to provide 50–80 percent functional recovery to the face. We base these estimates on our teams' extensive experience restoring function to the face through a variety of different microsurgical reconstructive techniques. These techniques are well established and involve transplanting muscles and nerves from other parts of the body to the face and are very effective (Van Laeken and Manktelow 1992; Terzis and Noah 1997). In facial trans-

plantation these same techniques will be used and should provide similar, if not better functional recovery. We base this last statement on the favorable functional outcomes achieved by our own team as well as other hand transplant teams. Functional recovery in the first hand transplant recipients has been reported to be better than expected (Francois et al. 2000; Hand transplantation: comparisons and observations of the first four clinical cases 2003). This effect is thought to be due to a collateral effect of accelerating nerve regeneration provided by the primary anti-rejection drug, tacrolimus, being used in these recipients (Gold 1999; Doolabh and Mackinnon 1999).

While the functional recovery we expect is not 100%, it is far superior to that which is achieved with conventional reconstructive methods (skin grafts, transplanted autologous tissues, and facial prosthetics) in the population of patients we are considering.

### **Societal Implications (Rumsey, Goering)**

Rumsey (2004) and Goering (2004) point out how "appearance-enhancing procedures" like facial transplantation will "promote unrealistic expectations of the benefits (they will provide) and [are] likely to fuel the notion that a good quality of life cannot be achieved by people with disfiguring conditions." We noted in our target article:

In addition to these risks to the family of the recipient there are other risks that we might imagine affecting the larger society. For example, a successful facial transplant might be interpreted as conveying the message that a good quality of life cannot be achieved by people with disfiguring conditions. There also exists the possibility that the public may develop unrealistic expectations for the outcomes of such surgery, perhaps to the point of creating an inappropriate demand for its use in less worthy cases, such as cosmetic enhancement for the aging rich or for criminal identity concealment. The facial transplant research team cannot prevent these or other misconceptions. What the team can do is provide accurate information in order, it is hoped, to shape public opinions in a responsible manner. (Wiggins et al. 2004)

### **Psychological Implications (Robertson, Rumsey, Caplan, Butler et al.)**

Robertson (2004) has expressed a desire for more discussion of the social and psychological meanings of the face and its role in personal identity. In the target article, space limitations prevented us from elaborating on this fascinating topic, and we realized then that the psychological and social aspects of facial transplantation would require an article unto itself. In our target essay we simply stated:

What is unique to facial transplantation, however, is that facial appearance is intimately and profoundly associated with one's sense of personal and social identity. Therefore, the recipient of a face must adapt to his or her own responses to

this new “identity” as well as to other people’s responses to it. Such adaptations will probably not occur once and for all; rather, they will probably repeatedly occur and undergo modification over time. (Wiggins et al. 2004)

Rumsey (2004) noted the many stresses associated with transplantation, such as that a face transplant involves unique challenges due to the significance of the face, the effects of disfigurement, and the decision to undergo a face transplant, and that “teams should be prepared to provide expert psychosocial assessment, follow-up, and on-going support for recipients, recipients’ families, and donor families.” We concur with her analysis. As we stated in the target article, “Such risks might be mitigated by careful patient selection, ongoing monitoring, and psychiatric intervention, as indicated.”

Rumsey (2004) also cited the articles by Bradbury and Middleton (1997), which suggested that patients are often more attuned to benefits than risks, and by Lansdown et al. (1997), which suggested that optimistic preoperative expectations are frequently associated with poor postoperative adjustments. We are familiar with that literature, which is why the target article noted: “The psychological risks that facial transplant recipients will confront will be similar to those experienced by solid organ transplant recipients, for example, a desperation that creates unrealistic hopes, fears that his or her body will reject the transplant, guilt feelings: about the death of the donor, difficulty conforming to the treatment regimen and its side-effects, and a sense of personal responsibility for the success of the procedure” (Zdichavsky et al. 1999). We plan to address possibly biased evaluation of risk/benefit calculations through careful interviewing, correction of misperceptions, and informed dialogical consent procedures.

Caplan (2004) noted that a face transplant will be an omnipresent physical reminder of its origins from another person, which will challenge the most well informed subject and supportive recovery team. We agree, but also note that every beat of a transplanted heart, or movement of a transplanted hand, could elicit comparable patient reflections, but have been effectively managed. We believe that properly selected patients, with the target interventions by professionals, can develop a meaningful relation with the transplant, and successfully incorporate it into an expanded identity.

Caplan (2004) encourages the first transplant team to take every measure to minimize the prospect for harm that the subject could encounter, think through subject selection so as to maximize both compliance and the tolerance of failure, and determine which prospective subject seems able to obtain the most support from family and friends in facing the enormous challenge of a face transplant. In this comment, Dr. Caplan has clearly articulated the standards

that we have set for ourselves. If it is not clear, however, that we have met this high standard, we welcome specific suggestions (measures, procedures, interventions, etc.) to enable us to do so.

Butler, Clarke, and Ashcroft (2004) suggest that face transplantation should be offered only when it is unlikely that psychosocial intervention, such as that described by Robinson, Rumsey, and Partridge (1996), will be unhelpful. We agree that transplantation should be contemplated only when less invasive approaches have been attempted and found to be unsuccessful in achieving desired outcomes.

We also agree with Butler, Clarke, and Ashcroft that those who failed to respond well to therapy due to pre-existing psychological problems or poor coping patterns would be poor candidates for a face transplant. Mindful of the Rumsey and Harcourt (2004) review, we have been working to develop procedures to identify the ideal patient, who possesses the apparently paradoxical profile of the excellent coping skills necessary to pass successfully through a demanding therapeutic regimen, but continued dissatisfaction with conventional reconstructive outcomes following serious disfigurement. The screening procedure for face transplant candidates will include a multidimensional psychological battery, followed by a psychiatric interview, to assess the nature of motivation for transplantation, reasons why psychosocial interventions have produced inadequate results, coping pattern, temperament, and other relevant dimensions.

#### *Conclusion: Uncertainty Likely to Persist*

In reading the opinions of several commentators on the many facets and ramifications of facial transplantation we are left wondering just what one ultimately does in the face of this set of considerations. Of course, we can be sure that prospective subjects of facial transplantation research are informed of these challenges and risks insofar as they can be foreseen. Nevertheless, questions concerning psychosocial risks and benefits that several of the commentaries pose finally elude precise definition, not to mention precise measurement and prediction. For this reason, do we simply conclude that the risks and benefits remain too weighty but at the same time too unknowable to venture forward with facial transplantation? In other words, does the complexity and unpredictability of the psychosocial dimension serve to prohibit the procedure? Do we undertake more extensive empirical research in order to render this mass of considerations more definable and, to the extent possible, measurable? Even if we adopt the latter alternative, as Ankeny and Kerridge (2004) argue, “objective findings” can never obviate the ethical perplexities of the procedure. It seems to us that, even at this early stage of reflection on facial transplantation, we can expect that, after much more inquiry and factual research has been completed, we shall

still remain unable to devise a rational procedure that would allow us to determine *in advance* a convincing weighing of all the psychosocial risks and benefits. This inability, then, leads us either to conclude that the procedure is probably too risky or to perform the procedure with as many ethical and empirical safeguards as we can muster and watch the outcome. Only then shall we be able to answer *a posteriori* the psychosocial questions that cannot be answered *a priori*.

Granted, the hand transplants did not implicate nearly as many unknowns as a face transplant would; but nonetheless, the hand transplants posed questions that could be answered only *ex post facto*. We will now allow ourselves to play on the many meanings of “face” just as several commentators did and state: we need to admit our insurmountable *a priori* ignorance and discuss what to do even in the “face” of it. ■

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