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Facial transplantation

A new option in reconstruction of severe facial injury

The world's first facial transplant has been reported in France (see News p 1359), but whether this signals the opening of a new frontier in reconstructive surgery depends on clinical outcome. Facial transplantation has long been recognised as technically challenging but clinically possible.[1] The key area of debate is whether the benefit of this procedure to someone with severe facial deformity—in terms of improvement of function, aesthetics, and psychology—outweighs the risk of long term immunosuppression.

Two years ago the Royal College of Surgeons identified the key issues as patient selection, immunosuppressive risk, informed consent for an untried procedure, and psychological issues (notably altered identity).[2] In the two years that have followed the college's report, considerable progress has been made in answering the questions it raised.

Selecting the right patients is paramount. The overall aim of this form of transplant surgery is twofold, as with any facial reconstruction: to facilitate social interaction (a shared goal for both surgical and psychological interventions), and to re-establish basic facial function such as blinking, mouth closure, and facial expression. The three main facial transplant groups (in France, the United Kingdom, and the United States) have developed different technical approaches and therefore target different groups of patients. The French have adopted central facial transplantation, namely of the nose, lips, and chin. These elements are very difficult, if not impossible, to reconstruct adequately using conventional methods. The UK team has focused on reconstruction in panfacial burn injuries. The US group originally included craniofacial reconstruction but now has a similar approach to the UK team. Despite differences in patient groups and surgical preferences a robust process for selecting patients is essential to avoid long term problems, such as those that arose after the first hand transplant.[3]

One of the main areas of concern has been the risk to patients from the side effects of long term immunosuppression.[1] To date, many of these fears have not been realised. The current cohorts of hand transplant recipients—the group of patients who are the most comparable because their operations also required complex and intricate reconstruction of several tissue types—have not experienced any serious complications during a maximum of six years' follow-up.[4] Minor complications have been tolerated by patients and have not led to any change in treatment. The level of immunosuppression required by these patients is similar to and in some cases lower than that needed by renal allograft recipients,[3 4] and a patient having a facial transplant would probably require a similar level of immunosuppression. One of the main justifications for renal transplantation is improvement in quality of life, and the same argument should apply to facial transplant.

Clarke and Butler have proposed a model for informed consent before facial transplantation.[5] The model is derived from Marteau et al[6] and is based on a well validated model of health related behaviour. It puts the individual's current beliefs and attitudes at the centre of the process and builds around this framework, challenging incorrect assumptions and adding missing information in a form that is consistent with the patient's level of understanding, attitude to risk, and clear expectation of outcome. Evidence from the many previous episodes of treatment which people needing facial transplantation will have had provides the source for much of the information required. The consent process is therefore unique to each individual and is dynamic because it is informed by ongoing research.

A psychological change is not necessarily a psychological problem. When reading about the potential psychological effects of facial transplant it is easy to lose sight of the fact that facial transplantation is being proposed as a potential benefit for a patient with combined functional, aesthetic, and psychological impairment. Building on evidence from analogous groups (such as those with head and neck cancer and those having solid organ transplantation and hand transplantation), we have set out a detailed review of expected psychological change and strategies for intervention.[5] Our premise is that the psychological impact of facial transplant can be anticipated, planned for, and managed, and we have developed a protocol for doing so over the short and long term.

Members of the lay public often worry that the donor's identity will be transferred to the recipient through facial transplantation.[7] But modelling of the change in appearance, using laser scanning and photography, shows that such transfer does not occur after facial transplantation. Indeed, preoccupation with altered identity risks becoming too much of a distraction from the important issue of managing immunosuppression.

Now that research has made the concept of facial transplant a reality, concerns about long term

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immunosuppression do remain. But, instead of considering why facial transplantation cannot be justified, we may find it hard to justify why it should not be done.

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Extra scrutiny for industry funded trials

JAMA's demand for an additional hurdle is unfair—and absurd

Suppose that a biomedical journal invoked a new policy requiring that all authors based in western Europe or North America would receive ordinary peer review, but authors from other countries would receive a peer review with additional hurdles. This policy may seem unfair, but suppose the journal claimed that research has shown that there is a greater prevalence of fraud, bias, and sloppy work among papers coming from these other countries.

If these events actually transpired, we hope that other biomedical journals would rapidly point out that adopting such a policy would be unfair to authors from non-western countries, even if the premises for it were valid. Indeed, we hope that other editors would decide that it would be unethical to create any hierarchical system for submissions of papers to a biomedical journal. Peer review ought to rest on the content of a submission rather than solely on the basis of presumptions inferred from group affiliation such as nationality.

We would hope so, but we are not sure. A logically similar situation has actually occurred, with a few small differences from the above scenario. The new instructions for authors at *JAMA* include the following[1 2]:

> For reports containing original data, at least 1 author (eg, the principal investigator) who is independent of any commercial funder should indicate that she or he 'had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.' For industry-sponsored studies, the data analysis should be conducted bystatisticians at an academic center, rather than only by statisticians employed by the company sponsoring the research.

The additional hurdle for research submissions with industry funding comes before peer review, and requires authors to hire an academic statistician before their submission will be considered by *JAMA*. Other submitters need not be concerned about this requirement.

This policy is manifestly unfair. It violates the proposition that each submission should be considered on its merits and it creates a hierarchy of purity among authors. We presume that the intent is well motivated, in the sense that the editors at *JAMA* have recognised the potential for a problem—perhaps bias, fraud, or shoddy work—in submissions funded by industry. *JAMA*'s draconian solution, however, punishes the innocent along with the guilty, and denigrates the reliability and professionalism of industry-employed statisticians, whose credentials *JAMA* apparently considers insufficient.

Following these new instructions raises many questions that require arbitrary distinctions. The instructions require an academic statistician either to conduct or to bless the analysis. But what is the mark of a qualified statistician? A degree? Certification by the Royal Statistical Society? And who is academic? A retired professor who becomes an industry consultant? A retired industry statistician who joins a university? Once paid by industry, would an academic statistician remain independent? Will mail order universities be acceptable, or must the universities meet specific accreditation requirements?

These questions are meant only to illuminate the absurdity introduced by these new instructions. We suspect that if the new rule were to spread to other journals there would soon be a thriving cottage industry among "academic statisticians" to vet analyses from the private sector, along the lines of professional expert witnesses in tort cases. Even if the rules could be clearly and cogently stated, they would be objectionable simply because it is unfair to judge work solely on the basis of affiliation of the authors.[3] We recognise that there is growing and legitimate concern about the methods used by commercial enterprises to influence publication and consequently the public perception of their products.[4] Even so, as Smith says, "The companies seem to get the results they want not by fiddling the results, which would be far too crude and possibly detectable by peer review, but rather by asking the 'right' questions—and there are many ways to do this."[4] The broader problem will need imaginative solutions, not an attempt to police the work of industry funded statisticians as *JAMA* has proposed. The decision to publish should be based on content, and the process

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