

REVIEW

Informed consent for facial transplantationAnthony Renshaw,¹ Alex Clarke,² Andrew J. Diver,¹ Richard E. Ashcroft³ and Peter E. M. Butler¹¹ Department of Plastic Surgery, Royal Free Hospital, London, UK² Department of Clinical Psychology, Royal Free Hospital, London, UK³ Department of Primary Health Care and General Practice, Imperial College School of Medicine, London, UK**Keywords**

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Summary

Now that partial face transplantation has been performed, attention is focused on likely functional, aesthetic and immunological outcomes, and full facial transplantation is the likely next step. Facial transplantation has been the source of ethical debate, a key part of which focuses on valid informed consent. We review the process of informed consent in health settings, assessing how applicable the current standards are for facial transplantation. The factors which need to be assessed during the screening programme are outlined. We conclude that both individual and process factors are important in obtaining consent for radical new procedures, and outline our own gold standard for ensuring informed consent in facial transplantation.

Introduction

The recent first partial face transplant provides a potential new gold standard in the reconstruction of severe facial injuries [1]. Obtaining informed consent is always challenging in new procedures where risk cannot be quantified, as highlighted by the Royal College of Surgeons of England [2] and others [3–5]. The purpose of this review was to highlight the current issues surrounding informed consent as applicable to face transplantation and to present a strategy for ensuring a robust consent process as the procedure becomes established as part of the reconstructive hierarchy.

Informed consent has traditionally been interpreted as a legal rather than as an ethical obligation of doctors [6]. However, there is now greater emphasis on patient choice in the UK [7] with patients encouraged to ask questions particularly with regard to the risks of the procedure, alternative forms of treatment including the option of no intervention, and clear advice about the likely impact on lifestyle associated with their choice.

The process of informed consent can therefore be seen as a more open exchange of information structured under

five main headings: disclosure, decision, understanding, capacity to give consent and voluntarism [8].

Disclosure

The doctor is obliged to disclose any significant risks to the patient [9]. The emphasis must be on adequate information, enough to make a reasoned decision about whether or not to proceed. This should involve an exhaustive discussion of all known risks, irrespective of severity and including likelihood and impact, along with discussion of side-effects with potentially severe or fatal consequences.

Finding out how much information patients want to know is clearly important. As a group, for example, women with ovarian cancer want as much information as possible at every stage of the disease and prefer to be involved in any decision-making [10]. Not all patients wish to be informed, however. Some try to actively avoid information about their disease, reducing the emotional impact of the disease; this is termed cognitive avoidance. Some commentators warn that providing detailed information to those who do not want it and imposing choice on those who prefer their doctors to assume responsibility

for making treatment decisions is harmful and may increase anxiety levels [11].

Clinicians frequently underestimate patients' desire for information and discussion and overestimate patients' desire to make decisions [12]. A need for more information does not necessarily equate to a desire to become more involved in decision-making although some evidence supports this [13]. A lack of information giving is associated with heightened levels of anxiety, as is requesting greater patient involvement in decision-making [6].

Integrating all this evidence into a clear strategy for information giving is therefore difficult. However, for face transplantation it is proposed that a clear understanding of risk is necessary in order to justify the procedure on ethical grounds. For this reason, only patients who are prepared to engage in a working partnership with clinicians are appropriate for the procedure. This means full disclosure of information and an active role in decision-making. Information should comprise technical details avoiding jargon, screened with a readability formula, such as the Flesch-Kincaid [14] or Fry [15] formulae. Details of facial anatomy should similarly be appropriate to the individual level of understanding. Information could, in line with government initiatives [7], include details about the individual clinician or unit, as patients may wish to use this information to base their decisions.

As with any new procedure, disclosure in facial transplantation is limited by the lack of data on outcome. Consent to innovative treatment is an area insufficiently explored in the literature. Conceptually, the component of our understanding of consent which involves the taking of an unknown degree of risk can be separated off from the component which involves the proposed benefits or harms of the procedure. It may be the uncertainty itself which predominates, or the sense of being 'first-to-go', or the sense of being at the hands of surgeons who are taking a step into the unknown. In most clinical trials, the degree of uncertainty may be relatively small – we may be uncertain how beneficial a new treatment is, or how common or severe the known side-effects are, but the likelihood of entirely novel and unexpected side-effects, or of dramatically overestimating the benefits of the new treatment, is small.

The disclosure of risk in facial transplantation should begin with general risks, such as anaesthetic complications, technical problems and graft failure [2]. Specific features of facial transplantation then require special consideration, such as immunological rejection. The Royal College of Surgeons report estimates the risk of graft loss to be around 10% from acute rejection, with chronic rejection accounting for loss of graft function in 30–50% at 2–5 years [2]. These figures are derived from studies of solid-organ transplant recipient populations. A more

analogous group would be hand transplantation [16]. Acute rejection episodes have occurred in 70% of hand transplants, but no grafts have been reported lost as a direct result [17]. The well-documented first hand transplant recipient underwent episodes of acute rejection but became noncompliant with medication and subsequently had the graft removed [18]. It is believed that another patient with acute rejection received inadvertent intra-arterial steroid injection leading to the only other graft loss reported, but it is unclear if the graft might have survived had this episode not occurred [19]. Chronic rejection has not been reported in hand transplantation to date, although the longest follow up is only 7 years. Comparison of chronic rejection rates to renal transplantation may also not be appropriate, as some long-term renal graft failure is due to drug parenchymal damage and is not immunologically mediated. Therefore, although long-term immunological reactivity of skin and subcutaneous tissue is not yet fully known, the incidence of chronic rejection in renal transplants may not predict the incidence of rejection in facial transplants, and there is no reason to expect that it will be worse.

Facial abnormality will rarely lead to death, but graft rejection could do, in serious cases; details must be given of alternative reconstructive options which would be undertaken if the transplant were to be rejected. Special consideration must also be given to altered appearance and its implication, even where there is already experience of extensive disfigurement.

A summary of the information which should be disclosed to face transplant candidates is highlighted in Table 1.

Decision-making

It is important to assess in what way the recipient of a face transplant would arrive at their decision. People have been broadly categorized into three distinct types of decision-maker in health settings: active (where the clinician provides enough information for the patient to make up their own mind), collaborative (where there is a two-way exchange of information) and passive (where the clinician decides which treatment to undertake) [20].

Certain patterns have become apparent when examining decisional preferences in certain patient groups. Approximately 20% of patients choose an active role, with 80% taking a collaborative or passive role [21,22]. Some patients thus prefer to take primary responsibility, the clinician taking no role in the decision-making process other than information provision [10]. A sizeable minority of cancer patients prefers to relinquish decisional control [6]. It could be argued that allowing patients greater control over their medical decisions might actually

Table 1. Information which should be discussed and understood by the patient.

Identity
The face will adapt to the shape of the underlying bony structure
There will be some superficial characteristics of the donor
A 'third' face is likely which will resemble the recipient more than the donor
The recipient will not take on the identity of the donor postoperatively
Immunosuppression
The need for immunosuppression will be life-long
Noncompliance will lead to graft rejection
There are significant side-effects of immunosuppression including cardiovascular, infective and neoplastic complications
Regular, thorough monitoring will be necessary for the rest of the patient's life
Rejection
Rejection may lead to complete graft loss
Graft loss can occur at any time
Graft rejection may be treated by altering medication or may require further surgery
Graft loss may result in an outcome worse than the patient's preoperative condition
Psychosocial issues
Psychological acceptance of the donor face may take a long time
Relationships may be challenging, especially in the early stages when family and friends are adjusting to altered appearance
Psychological challenges are not yet fully understood
Surgical issues
The risk of technical failure is about 4%
Perioperative risks, including mortality, are similar to other free flap surgery
Functional recovery
Return of facial sensation and function will be variable and difficult to predict
Time frame for functional recovery is likely to be months/years
Media issues
Media interest is likely to be high, particularly for the first several patients
The donor family may become aware of the recipient's identity through the media

disempower them. Patients may try to avoid regret and self-blame for the negative consequences resulting from a poor decision.

Married rather than single people [20], older rather than younger people [21], men rather than women [20] and those with lower educational attainment [10] tend to prefer the doctor to take decisions for them. Patients prefer passive decision-making more than nonpatients, suggesting that the 'sick role' (i.e. the act of being a patient *per se*) may be a significant factor in determining the decisional role taken [20]. The sick-role theory supposes that the sick do not hold themselves responsible for normal role behaviour; this may occur because they are in pain, fatigued, on certain medications, or simply 'unwell'.

In life-threatening scenarios patients tend to prefer to hand over control to doctors, whereas in cases, such as facial transplantation where morbidity and not mortality are affected, patients tend to prefer to assume greater control [22] although there is some disagreement [23].

Some cultures may indeed prefer to delegate their decision-making to family members. In some cultures, the wishes of the elders may override those of a younger member, although this challenges the concept of voluntarism (see below). Other groups often make decisions at a community or family level. Many cultural groups can find negative discussions offensive and some doctors have been supportive of withholding bad news to patients, such as is reported in China [8]. Whilst respecting patients own values and beliefs, we would argue that facial transplantation is a situation in which the decision to proceed must be made by the individuals themselves. Successful outcome is dependent on postoperative behaviour, and in order to comply with strict medical regimen, the individual must make the final decision about consenting to surgery.

Understanding

A patient can be said to have made an informed choice if they are knowledgeable about the operation, have a positive attitude to the procedure and choose to proceed, or have a negative attitude to the procedure and choose to decline [24,25]. Knowledge in itself has not been shown to increase the likelihood of screening; positive attitude on the other hand, has a strong association with increased uptake [26]. The patient's own values should be incorporated in the choice made to proceed with surgery; this may indeed be more important than the patient's level of knowledge. Moreover, the patients must appreciate the relevance to their own situation of any information given [27].

Increased disease severity has been shown to lessen the retention of information in the consent process [28]. There is evidence that patients undergoing breast reduction have very poor recall of risks and yet are on the whole satisfied with their understanding of the risks involved [29]. The literature has yet to reach consensus about what constitutes sufficient understanding and indeed the courts have not tended to agree that failure to understand invalidates consent, preferring to rely on evidence of adequate disclosure [8].

The UK facial transplantation team propose that adequate disclosure is not enough in the case of innovative procedures such as facial transplantation. The Evaluation to Sign Consent Form [30] has been validated in a variety of populations and can give the surgeon an appreciation of the extent of patients' understanding of a procedure.

Additional written or verbal information has been suggested to improve patient understanding, although in femoro-popliteal bypass and carotid surgery this did not improve a patient's perceived and actual understanding of risks and complications [31]. Use of the cognitive interview technique with independent validation of information retained has been utilized as a means of demonstrating understanding rather than simply disclosure in a service for people with learning difficulties, and this is being developed as a basis for the consent procedure in facial transplantation in the UK [32]. Assessment of pretransplant compliance can also provide evidence of patient understanding and partnership in care.

Voluntarism

One of the caveats of informed consent is voluntarism [33]. Although the patient's own wishes should be the only indication for facial transplantation, with every exciting and novel technique the surgical team is at-risk of imparting their own values upon the patient. Through the consent process they might unduly influence the patient's own choice. This would be achieved by either withholding information regarding other options or underplaying risk and the importance of operative and nonoperative alternatives. The ultimate decision about whether or not to go ahead with the procedure must however be left to the patient. There must therefore be noncoercion by the surgical team [2]. Added confounding factors are related to research into new procedures. In providing treatment, a surgeon's primary duty is towards patient care; it might be argued that in evaluating a new surgical procedure, the surgeon must generate valid data and has a commitment to the wider scientific community [27]. Therefore, the caveat of voluntarism must be rigorously pursued in facial transplantation, and can be ensured through the use of patient advocacy.

Capacity

Patient capacity to consent requires sufficient ability to maintain and communicate stable choices. These choices must be maintained long enough for their implementation [34]. The ability to make one's own decisions is in practice hard to evaluate and we tend to assume that an adult has the capacity unless there is strong conflicting evidence. Guidelines exist examining the ability of patients to evidence a choice and make rational decisions [35]; these include the ability to manipulate information rationally and to appreciate the situation and its likely consequences. Certain conditions may preclude this capacity: thought disorder, short-term memory impairment or even extreme ambivalence may lead to a rapid change in

the health decision that is made. A patient will require enough memory for words, ideas and sequence of events; intelligence, memory and attention-span may affect this cognitive capacity [34].

Attitude to risk

Attitude to risk is important in making rational choices. This however, is difficult to define because an individual's attitude to one type of health risk does not necessarily predict their future behaviour towards a different health risk. A health risk-taker such as a smoker, for example, is not more likely to undergo life-endangering surgery than a nonsmoker, although they may underestimate their own risks from smoking and ignore social conventions which dictate what they do to their health [36]. Nevertheless some evidence exists that burns patients (who constitute a considerable proportion of potential face transplant candidates) may have a higher propensity for risk-taking behaviour, as evidenced by increased rates of accidental or violent death in previously burned adults [37].

There is some evidence showing that people exhibit more risk-taking behaviour when there is a chance of erasing a loss [38]; framing an event as a gain leads to more risk aversion [39]. This is because a loss reduces perceived desirability of a health outcome more than a gain increases it [40]. It is arguable that in the acute stages of recent injury, patients are more likely to be focused on the consequent loss and therefore more likely to accept greater levels of risk involved in reconstructive options. As their postmorbidity develops, however, with the gradual evidence that altered appearance does not automatically mean a loss of opportunity or life chances, decisions may be made more in terms of potential gain, with a reluctance to incur unreasonable risks. It can therefore be argued that the stage at which facial transplantation is contemplated, i.e. immediate or delayed, will have an impact on attitude to risk and therefore on informed decision-making.

For the patient a face transplant is a one-off gamble, whereas the surgeon incorporates clinical evidence into their decision-making process. Patients are also more likely than doctors to accept radical treatments even if they have little chance of success. Doctors may feel they have a responsibility for bad outcomes when they have supported a particular treatment regime, especially if this treatment is viewed as more radical. Without accepting risks of radical treatments; however, many major advances in medicine could never have been achieved.

Organ transplant recipients perceived risk/benefit ratios of facial transplantation similarly to nontransplanted groups in one preliminary study [17]. Recent evidence suggests that some composite tissue transplant procedures

(facial transplants especially) convey benefits which are perceived by individuals (including those living with immunosuppression) to warrant the risks involved [41]. There is some evidence that the facially disfigured may have different attitudes to immunosuppressive risk [42], suggesting that familiarity with the concepts and treatment of facial disfigurement impacts on attitude. However, the emphasis on face transplantation as a quality of life procedure may inadvertently trivialize the major problems that this group experience in their day-to-day lives.

In planning the way ahead we therefore propose a strategy for informed consent in facial transplantation. This is framed under the headings of factors relating to the individual, and factors relating to the process of consent.

Assessment of the individual

Cognitive function

Patients undergoing complex appearance-enhancing surgery must have the ability to retain and comprehend proposed risk/benefit information. In one study of heart transplant candidates 35% were found to have significant cognitive impairment as measured by verbal learning and memory [43]; lung transplant candidates had essentially normal cognitive function for most tasks but between 25% and 50% of patients were impaired on verbal and visual memory tasks [44]. Therefore, a face transplant recipient should be of at least average intelligence, with no evidence of cognitive impairment affecting their decision-making capacity. Although it is not appropriate rule out a patient requiring facial trauma reconstruction because of an accompanying head injury; it must be clear that such injuries do not affect capacity to consent.

Compliance history

The issue of compliance in transplantation has been reported elsewhere [45]. A previous compliance history comprising attendance to clinic, dressing changes and the taking of prescribed medications gives us documented evidence of the ability to understand, prioritize and execute health behaviours consistently within the patient's own environment.

Cultural assessment and attitude to facial transplantation

The attitudes of both patient and health professionals towards facial transplantation should be positive and concordant, with clear evidence that motivation for surgery lies within the individual not the family.

Decision-making role

Given the large stakes involved in undergoing facial transplantation, we would suggest that the patient should be collaborative rather than active or passive in their decision-making, which will be evident from their compliance history. The reason for this assertion is that an active decision-maker may be biased in the way they elicit information and therefore may not weigh up fully the risks against the benefits; they may have already made up their mind to have a face transplant prior to full discussion with medical professionals. A passive decision-maker, on the other hand, may not appreciate the risks of rejection or long-term immunosuppression, and may thus be at-risk of coercion; the notion of voluntarism must always be preserved. Decision-making role can be objectively assessed using the compliance history or from the Autonomy Preference Index, a validated set of questions used to establish decision-making role [22].

Attitude to risk

Population studies have assessed attitudes to risk in general. Evidence of high risk-taking behaviour in one area, such as smoking or indulging in illegal activities or high-risk sports, for example, does not necessarily predict an individual's attitude to risk in every health decision. Therefore, the assessment of attitude to risk is not a particularly helpful construct in face transplantation.

Personality assessment

Personality disorder is three times more prevalent in populations of cardiothoracic transplant recipients [46] and it is postulated that this may predict future noncompliant behaviour. Some hand transplantation literature suggests personality assessment as a screening tool [47]. There is ambivalent evidence, however, for the value of assessing personality factors, or an emphasis on biological traits, in health settings. It is doubtful if population studies are helpful in the assessment of individual patients' suitability for face transplant. Although there is a role in assessing psychiatric co-morbidity when obtaining consent, beliefs and behaviours may be more useful in predicting health decisions. Screening programmes need to identify patients who have a negative attitude to the operation or who have an unrealistic optimism about the risks involved [48].

Assessment of the process of consent

The process of obtaining consent should be as important as the content. Therefore, an assessment of the efficacy

and validity of this process should be made by someone not directly involved with the technical aspects, ideally by an informed health professional such as a psychologist within the face transplant team.

The surgeon performing the procedure should ideally obtain consent, as they are usually the person best placed to answer questions about operative aspects, but this is not exclusive. Indeed it might be argued that the surgeon performing radical new surgery might not be best placed to take consent as they might introduce their own bias.

Screening needs to identify those who have a lack of information or who are using it inappropriately, but it is not enough to be sure that there has been adequate disclosure of information in facial transplantation. There must be both disclosure and confirmation of patient understanding. This can be evaluated as described above.

It is true that in highly innovative procedures such as face transplantation, there is no way of assessing if a patient has made the right decision and will later regret their autonomous choice, but the psychologist can assess if the decision has been made which is in line with the patient's attitudes. The psychologist should also enquire about the patient's personal goals in having a face transplant.

Conclusion

An approach to informed consent that recognizes the importance of both perceptual processes and realistic attitude to risk is proposed as a model for informed consent in face transplantation. The assessment framework outlined makes use of the best evidence available in health settings to identify both individual and process factors which must be considered in informing and consenting patients

Any new procedure can be challenged on the grounds that informed consent is impossible, but this is effectively a barrier to any form of progress. By examining each of the core requirements for informed consent in detail, and reviewing the evidence base, it is possible to propose a standard for facial transplantation, which not only meets, but also extends the current gold standard for consent in new medical procedures.

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