

Face Transplantation: *Changing Faces*' position, Spring 2010

Changing Faces has been involved in the public debate about face transplantation for many years and, in light of recent developments, decided to review its position – for internal purposes and to inform its external messaging.

Introduction

There have now been over 10 partial face transplants worldwide on patients with burns, facial trauma and neurofibromatosis; one has also involved a double hand transplant. Each procedure has been slightly different, most involving the facial skin envelope, but at least one also using the patient's own bone grafts. One patient has died from an unrelated cause but the others' recovery continues and the procedure is reported to be promising. It is now nearly 4 years since Isabelle Dinoire, the first patient, had her procedure. Two American patients consented to surgery if privacy were assured and the media respected this; one has since spoken to the media. The British team led by Prof Peter Butler at the Royal Free Hospital in London is understood to be planning to conduct up to four full face transplants in the future.

History of *Changing Faces*' involvement

The first public discussion of face transplantation in Britain was in 1996 when a plastic surgeon, Jim Frame, speculated that this operation was now technically possible and should be conducted. There was considerable media interest. James Partridge (JP), CEO and founder of *Changing Faces*, was asked for *Changing Faces*' view: he was cautiously supportive of further research whilst suggesting that there could be considerable risks especially in tissue rejection and the effects of long term immune suppressants and in psycho-social adjustment. Some sections of the media extended the story: a 'medical miracle for everyone with a facial disfigurement is about to be available'. JP's face was morphed with Steve McQueen's in one tabloid newspaper to show what he would look like, without his permission. An apology followed. The debate died down.

In July 2002, an article in *The Lancet* reignited interest. Peter Butler and Shehan Hettiaratchy, research surgeons at the Royal Free Hospital, London and Harvard, Boston, described their research and concluded: *"The idea of taking off a dead person's face and putting it on someone else appears to have come straight out of science fiction. However, recipient patients have serious physical and psychological problems that cannot be solved by conventional treatments. If face transplantation is shown to be the only effective way of treating these severely disfigured patients, then doctors would have a duty to use the technique."* There followed further media interest around the world – and again *Changing Faces* was asked for its opinion, which had not changed. Through the autumn and winter of 2002-03, media interest did not wane. By February 2003, *Changing Faces* was receiving daily enquiries from journalists seeking information and advice and was under pressure to open up press contacts with clients – which we strenuously refused to do. We did however consult a group of people with facial disfigurements on our advisory panels and they supported our position.

Finally, on 23.2.03, *The Sunday Times* carried a large feature in which Prof Butler was said to be nearly ready to undertake the first face transplant, was quoted as saying that a young Irish woman and three others were being "assessed" in the next few weeks. This intensified the media's hunt for that first patient whose name finally appeared in *The Evening Standard* on 28.2.03, only to be removed after legal threats. JP wrote to Sir Peter Morris, the President of the Royal College of Surgeons, that day calling on *"the Royal College of Surgeons as a matter of the greatest urgency to attempt to create a moratorium on further media coverage of the issue. We also urge that the College establishes a Committee, including scientists, surgeons, ethicists, psychologists and people with disfigurements, charged to investigate and report on all aspects of face transplantation prior to any experimentation whatsoever"*. (All letters sent are in Annex 1).

A Royal College Working Party (WP) was set up that Spring, reporting in November 2003.

The (first) WP Report broadly recommended that “a much more incremental approach (to the issue is taken) than some of the current hype surrounding it has suggested”. Further research on immunological, psychological and ethical issues was thought to be needed. In February 2006, in the aftermath of the first transplant, JP wrote again to Sir Peter and the WP sat again, reaching new conclusions. The second Report in November 2006 reviewed the three years of research since the first Report and the evidence after the first transplant. It accepted that some patients were now likely to be willing to take “the leap into the dark” (as the WP called it). To protect patients’ safety, the WP defined fifteen preconditions that should be met before the procedure is undertaken (see Annex 2).

Changing Faces’ reactions to both WP reports were broadly supportive (see Annex 3). In both cases, we argued that the College’s authoritative Report should inform all decisions made by patients, surgeons and Research Ethics Committees in the future. We remained concerned on a number of grounds – as were some surgeons and advisers to the charity. These concerns, as at January 2006, are set out in Annex 1. In all subsequent media and academic discussions, JP and *Changing Faces* as a whole have maintained this position.

Prof Butler and his team at the Royal Free Hospital in London were given permission by their local Research Ethics Committee (REC) a week before the RCS’s 2006 Report to conduct four experimental full face transplantation operations. His team has published over the last 5 years a range of papers about their research and the protocols they intend to use to select patients and support them post-operatively. We assume that the Royal Free’s REC has assured itself that all 15 RCS preconditions are met by Prof Butler’s team – and that any other REC would do the same. Prof Butler has also set up a charity, called the Face Trust (www.thefacetrust.org), to raise funds. JP met Prof Butler in early 2009 to inform this paper.

Changing Faces’ concerns – have they all been addressed?

Changing Faces is pleased that the process by which face transplantation research is being undertaken in the UK is now informed by authoritative RCS Reports and totally supports the College’s 15 preconditions. Looking at our main concerns in light of present knowledge:

Technical surgical issues

- Functional or aesthetic reasons: it is clear that face transplantation is being conducted for a combination of reasons: functional (eg: re eating, speaking) and aesthetic (eg: complexion, appearance). Both are justifiable provided that, in the patient’s judgement, the benefits (ie: quality of life) outweigh the risks (eg: life expectancy, side-effects).
- Conventional surgery: we accept that conventional reconstructive surgery (with minimal side-effects) sometimes cannot achieve effective functioning and a ‘non-shocking’ aesthetic result – but these are very rare instances. Patients should be fully informed about what can be done conventionally and be able to choose such surgery.
- Last resort: we understand that face transplantation is not now being suggested only when all other conventional treatments have failed. It may be considered the best option if all other surgery has been discounted. This is acceptable as long as all conventional reconstructive options are offered for consideration by the patient and family.
- Functionality: it remains unclear how much sensation and mobility is being achieved by a face transplant – in Isabelle Dinoire’s case, a reported 60-70%. We continue to be concerned that if mobility is not significantly improved by the transplant, the ‘new’ face could still be a barrier to social interaction, although less so than the status quo ante.
- Post rejection plans (Plan B): we accept that a range of options (eg: replacement transplant, conventional surgery) has been described for implementation in the event of transplant failure. Debate continues about the options’ effectiveness.

Immunology

- Progress in research: *Changing Faces* understands that the current face transplant patients are receiving relatively low doses of immuno-suppressants but that, when they have episodes when the transplant appears to be failing, this dose is raised very greatly.

However, there remain areas of uncertainty: (a) has the risk of transplant failure has changed from the RCS's estimate (30-50% within 5 years)? (b) what are the side-effects from the regime (eg: similar to hand transplants)? and (c) has the risk of reduced life expectancy (up to 10 years according to the RCS) has been reduced?

Psychological issues

- New identity: although we accept that the recipient will not look identical to the donor, the new face at which the patient will look in the mirror and with which s/he will face the world, will not resemble their old face and its associated identity, and they will know that it was someone else's face and hence identity – and this relationship may dominate their thinking (whether the transplant survives or not). This is a fundamentally different change from that experienced by those undergoing conventional facial reconstruction.
- Patient selection: we have now read robust evidence-based articles (see the Face Trust website) in which Prof Butler's team outline their process and the criteria for patient selection which both stress the importance of identifying a psychologically stable recipient who is assessed as robust enough to handle media attention.
- Psycho-social adjustment: The need for long-term psycho-social support should not be underestimated. The team at the Royal Free have published papers describing how it aims to support the long-term adjustment of the recipient and their family, and of the donor's family too. We would expect any other UK team to follow those guidelines.

Informed consent

- Full information about all other interventions: we have been assured that all potential patients currently being assessed by Prof Butler's team are being provided with full, frank and as far as possible, objective information and assessments of risks and benefits not just of the face transplant procedure but of all alternative treatments including those of a psycho-social nature. No such patients have sought help from *Changing Faces*' services as far as we know. We assume/hope they have received high-quality support and have been exposed to positive role-models and the Face Equality campaign.
- Who counsels the patient? we have been assured, in the case of Prof Butler's team, that any potential patient will receive objective advice from the whole multi-disciplinary team and be able to talk to well-adjusted patients with similar conditions. We would expect any other UK team to offer the same.

Media presentation

Changing Faces continues to be very concerned about the way in which the British media portrays face transplants, as some kind of miracle 'fix' for all people with disfigurements. We will continue to challenge over-simplistic coverage which

- (a) implies people can't lead happy lives unless their disfigurement is removed by surgery
- (b) reinforces the stereotypical view that a disfigurement is undesirable and disastrous
- (c) suggests that public attitudes shift on disfigurement is either impossible or unnecessary
- (d) presume that surgery is the best – or only – option for someone with a disfigurement.

Overall conclusions

- *Changing Faces* continues to support the advancement of medical science (including stem cell research) to tackle the issues posed by facial and other disfigurement.
- We aim to have cordial relations with Prof Butler and his team and all other researchers and to offer constructive ideas and advice if asked.
- We retain an independent position from which to judge the balance of risk-benefit in face transplant research and be cautious about immunology and psychology issues.
- We will support unconditionally any patient (and family) who considers/undergoes a face transplant, and any clinical team that meets the RCS's 15 preconditions.
- We strongly support the privacy clauses respected by the media in the USA and hope that all British patients will be afforded the same – if they wish it.
- We will continue to solicit public and medical support for our Face Equality campaign partly because science has yet to solve the challenges of scarring, asymmetry etc.

ANNEX 1: Letters to The Royal College of Surgeons

28th February 2003

Sir Peter Morris
The President
The Royal College of Surgeons
Lincoln Inn's Fields
London WC2A 3PN

Dear Sir Peter,

Face Transplantation

You may be aware that a story appeared in The Sunday Times on 23rd February 2003 (attached) in which Mr Peter Butler, the British surgeon from the Royal Free Hospital who is claiming to be nearly ready to undertake the first face transplant, was quoted as saying that a 14 year old Irish woman and three others are being "assessed" in the next few weeks to establish whether she is a suitable candidate. Since that day, the media has been seeking information from all sources, especially from *Changing Faces*, about the identity of this young person. An intense media frenzy is developing to be the first to gain her story.

Changing Faces believes that this is an entirely inappropriate and potentially exceedingly damaging way to proceed with the development of what might be an important technological innovation. Whilst in no way wishing to halt scientific advance, we are extremely concerned by the way in which what should be a completely private clinical issue subject to strict ethical and scientific processes, is being conducted through the media. Along with many other observers and experts, including surgeons themselves, we also have serious questions to pose about the technology being proposed – on technical, ethical and psycho-social grounds. I believe that these issues should be resolved in a careful and transparent fashion before any such transplantation trial is undertaken.

In the interests of all present and future patients with disfigurements, their parents and families, I call on you and the Royal College of Surgeons as a matter of the greatest urgency to attempt to create a Moratorium on further media coverage of the issue. We also urge that the College establishes a Committee, including scientists, surgeons, ethicists, psychologists and people with disfigurements, charged to investigate and report on all aspects of face transplantation prior to any experimentation whatsoever.

Yours faithfully,

James Partridge OBE, DSc
Chief Executive

3rd February 2006

Mr Bernard Ribeiro, FRCS
President
The Royal College of Surgeons
Lincoln Inn's Fields
London WC2A 3PN

Dear Mr Ribeiro,

Face transplantation

You will have followed with interest, I am sure, as we and many others have the recent developments in face transplant surgery. I am writing to you to suggest that the time is right for the Royal College to reconvene the Working Party on this subject to take stock of progress and develop pointers to the future.

Changing Faces was very pleased that your predecessor, Sir Peter Morris, responded so positively and promptly to our suggestion back in 2003 that he should set up the Working Party in the first place – and we were broadly supportive of the cautious approach taken in its Report in November 2003.

As we understand it, having tried to keep pace with French surgery developments and with Mr Butler's arguments (see, eg, the BMJ 10.12.2005), it is now argued that the all the reservations and research deficits identified by your Working Party have been answered and therefore approval should now be given for UK face transplantation research to be instigated.

Changing Faces has very important questions about some of the key issues that we would want the Working Party to address – as outlined on the accompanying pages.

In making this request, we would like to make it abundantly clear from the outset that we are not and have never been against face transplantation per se. Our position is that as a charity supporting and representing people with disfigurements of any kind, we wish to see improvements in the health care and other services available to them and to bring about changes in public attitudes and behaviours towards them. We fully recognise that many people with disfigurements have reason to be extremely grateful to surgeons – I certainly am myself. We therefore consider it inappropriate for some proponents of face transplantation to characterise *Changing Faces* as being against such potentially important scientific developments.

Our concern has always been and will continue to be that vulnerable patients should be able to make fully informed decisions about the choice of treatments available to them as individuals (to meet their physical, functional, aesthetic, psychological and social needs) as far as possible behind a veil of clinical privacy.

I hope that you will be able to draw these questions and our concerns to the attention of the Working Party – we would be happy to give fuller evidence on each if they would like this. We should also say that these are our chief concerns but they are not an exhaustive list; others will pick up on different aspects.

Yours sincerely,

James Partridge OBE, DSc, FDSRCSEd (Hon)
Founder and Chief Executive

Royal College of Surgeons, 31.1.2006

Questions from *Changing Faces* on Face Transplantation

Although Mr Peter Butler and other surgical teams in the United States claim that they have done extensive further research since November 2003 and are now 'ready' to undertake a full face transplantation, the following questions and points have not, to the best of our knowledge, received adequate answers and therefore continue to give rise to concern:

Technical surgical issues

- Functional or aesthetic reasons: there is confusion as to whether such radical surgery is being proposed for functional or aesthetic reasons, or a mix of both. The justification for such surgery seems to flip-flop between the two depending on which audience is being addressed.
- Conventional surgery: evidence suggests that conventional surgery (with minimal long-term side-effects) is already able to achieve acceptable non-shocking aesthetic results with no functional loss (sometimes with benefit), such as using full-face grafting using Wolfe grafts. How will face transplantation improve on this procedure?
- Last resort: will face transplantation only be suggested when all other conventional treatments have either failed or been discounted?
- Functionality: it is very unclear how much sensation and mobility will be achieved by a face transplant – if this is less than 80-90%, it is arguable that the 'new' face, where movement is so fundamental to social interaction, will continue to be an impediment to psycho-social well-being.
- Skin, bone and other tissue: proponents of face transplantation have proposed a range of different approaches, each carrying their own set of risks – can they be considered as carrying similar risks for the purposes of ethical debate?
- Aesthetic matching: it is unclear how perfect will be the skin and complexion matching which is being sought; since advocates of face transplantation cite 'poor cosmetic results' of conventional surgery for severe burns as justification for the new operation, how much improvement and 'normality' will there be in the patient's appearance?
- Plan B: given the likelihood of rejection is up to 20% and higher, the lack of attention to what happens in the event of graft failure is a cause for concern.

Immunology

- Progress in research: the Royal College's Working Party was especially concerned that more progress should be made to reduce the impact of immuno-suppressant drug regime which any patient will have to comply with throughout the rest of their life. Have new drugs or cocktails of drugs been developed that significantly reduce the side-effects of taking them? Has the risk of reduced life expectancy (up to 10 years has been cited) been significantly reduced?

Psychological issues

- New identity: it has been suggested that because it has been proven unlikely that the recipient will look identical to the donor, the problem of taking on a new identity is diminished. This argument misses the fundamental point that the face at which the patient will look in the mirror and with which s/he will face the world, will not resemble their old face/identity, and they will know that it was someone else's identity. This change of face is fundamentally different to the change that someone who goes through conventional plastic surgery reconstruction (which is hard enough anyway).

- Patient selection: no protocols have yet been published, to our knowledge, that describe the process and the criteria for patient selection – though we understand that Mr Butler has now received ethical permission from the Royal Free to start the selection process. The question of how to identify a recipient who will be psychologically stable and robust is a crucial one for clinical and scientific discussion.
- Psycho-social adjustment: although there have been frequent mentions of the importance to be attached to supporting the long-term adjustment of recipient and their family, and perhaps of the donor's family too, no carefully planned scheme has been provided that describes how and in what form the support will be provided.

Informed consent

- Full information about all other interventions: as was made clear in the Royal College's Report, ethical considerations require that potential patients are provided with full and frank information and assessments of risks and benefits not just of the face transplant procedure but of all alternative treatments including those of a psycho-social nature. Assurance about this is fundamental.
- Who counsels the patient: it is, in our view, absolutely essential in order to ensure that the patient receives an objective and 360° picture that (a) the composition of the clinical team which advises the patient and family is open to public view (and should include an immunologist) and (b) the team should have as an integral member a representative of patients with similar conditions.
- Donor family issues: many questions remain to be answered about how donor families' understandable concerns can be addressed such as about their anonymity, the funeral arrangements and how they too will be fully informed.

Overall, to our knowledge, we doubt if sufficient research has been conducted as yet to justify a decision in favour of face transplantation research. We hope that the Working Party will be able to take soundings and advise on their view about face transplantation in the UK.

Media presentation

Changing Faces continues to be very concerned that the way in which the media is portraying face transplants, as some kind of miracle 'fix' for people with disfigurements is far removed from reality – which is that the procedure might be a last-resort possibility for a very few patients worldwide each year. The simplistic coverage, which authoritative medical statements should be able to correct, could have undesirable effects on public opinion by (a) suggesting wrongly that people with disfigurements can't lead happy and valuable lives unless their disfigurement is removed, (b) reinforcing the stereotypical view that having a disfigurement is so undesirable that it needs to be removed and (c) that the much-needed but difficult changes in public attitudes and behaviours to ensure that people with disfigurements are socially included may not be necessary.

Changing Faces' position

Changing Faces is a charity supporting and representing people with disfigurements of any kind. We seek to bring about improvements in the health care and other services available to them and changes in public attitudes and behaviours towards them. Many people with disfigurements have reason to be extremely grateful to surgeons. We are certainly not against such potentially important scientific developments. Our concern has always been and will continue to be that vulnerable patients should be able to make fully informed decisions about the very best treatments available for them as individuals (to meet their physical, functional, aesthetic, psychological and social needs). We also believe that such decision-making and clinical treatment should be done entirely behind a veil of complete privacy.

ANNEX 2: The RCS's 15 preconditions, November 2006

The RCS's Second Report considers that a patient may wish to take what it calls a "leap in the dark" and that this would be acceptable if a local Research Ethics Committee (REC) can be assured that 15 minimum requirements are all satisfied:

1. The surgical unit has sufficient technical skill and experience to optimise the chances of a successful transplant
2. An institutional structure exists within the hospital to ensure integrated clinical care between the transplant team and other surgical and medical units for both short- and long-term treatment
3. A comprehensive and coherent protocol for the selection of suitable patients exists
4. The hospital's or institution's Research Ethics Committee (REC) protocol provides potential patients with adequate information on the basis of which valid informed consent can be given
5. The REC protocol provides adequate information for potential patients about how little is known about some of the risks associated with facial transplantation
6. The surgical unit has integrated links with a team with appropriate psychological expertise to provide support adequate to ensure that prospective patients can give valid informed consent
7. People in the process of acquiring informed consent who are sufficiently independent from the transplant team to ensure that they are not influenced by any factors other than respect for and protection of the patient
8. Sufficiently trained people are involved in the process of seeking the consent of appropriate donor relatives for the donation of facial tissue
9. Confidence exists that the psychological team can provide effective long-term therapeutic support to the patient in the aftermath of both successful transplantation or potential and/or actual failure
10. Mechanisms are in place to ensure satisfactory delivery of the duty of care towards the recipient's family
11. Mechanisms are in place to ensure satisfactory delivery of the duty of care towards the donor's family that extends beyond obtaining their consent for donation
12. Guarantees exist that the transplant and psychological teams and the hospital can provide the long-term funding required to ensure that all patients will continue to receive the care and support outlined in the protocol approved by the REC whether the transplant has been successful or not
13. Provision of the extra surgical, medical, psychological and social care resources that will be required for facial transplantation are in place without reducing the quality of care of other patients with facial disfigurements at the host hospital
14. Equitable management in the care and support offered to the families of potential donors of facial tissue is planned both when they are approached to obtain consent and afterwards, in the event of subsequent distress
15. Any body that considers an application for facial transplantation must include experts in reconstructive surgery, immunosuppression, psychological problems posed by severe facial disfigurement and a representative of one of the organisations that provides support for those with such disfigurement.

ANNEX 3: *Changing Faces* reaction to the RCS Report, November 2003

Embargo until 1101 hours, Wednesday 19th November 2003

Media Release

National disfigurement charity *Changing Faces* welcomes the Royal College of Surgeons Report on face transplantation

Dr James Partridge, Chief Executive of *Changing Faces*, who was severely facially burned in a fire at the age of 18, said:

“Having prompted the Working Party to be set up in the first place, the charity is delighted that the Royal College has produced such an authoritative and informative Report which concludes that ‘until there is further research and the prospect of better control of (technical, psychological and ethical) complications, it would unwise to proceed with human facial transplantation’.

The charity also welcomes the Working Party’s recommendation that ‘a much more incremental approach (to the issue is taken) than some of the current hype surrounding it has suggested’.”

The charity’s position has consistently been that there are a great many questions to which answers are needed before this extremely risky and experimental surgery could be considered a viable option for patients with severe facial disfigurements.

The Report provides some of these answers and emphasises:

- technically, the very significant risks of transplant rejection and the immense immunological burden that would be involved
- psychologically, the major problems about taking on a changed identity and the risk that already vulnerable people with unrealistic expectations about the surgery might be placed in even greater emotional difficulties
- the complex ethical questions that have yet to be answered convincingly such as how to ensure informed consent by all parties.

Changing Faces believes that face transplantation may, at some time in the future after much more research, be a part of the reconstructive surgeon’s repertoire. Whether or not this happens, it is vital that we continue to push for comprehensive health and social services for people with disfigurements (in which surgery is complemented by psycho-social and other interventions) and a fairer, more informed society for the 400,000 people living with disfigurements in Britain today.

The charity is committed to enabling *everyone* to face disfigurement with confidence.

END

Embargoed until 10am, Monday, 13th November 2006

Media Statement

Re Royal College of Surgeons' Report on Face Transplantation

“*Changing Faces* supports the high ethical stance taken by the Royal College of Surgeons on face transplantation”

Leading disfigurement charity, *Changing Faces* warmly welcomes the Royal College's fair and cautious report on face transplantation with its robust advice to Research Ethics Committees about the 15 preconditions that should be met before the procedure is undertaken. The College's authoritative Report should inform all decisions made by patients, surgeons and Research Ethics Committees in the future.

James Partridge, CEO of *Changing Faces* who was himself severely disfigured in a car fire as an 18 year old said:

“By recommending 15 minimum requirements to protect patients throughout the procedure and in the long-term, whether it is successful or fails, the Royal College has rightly made the well-being of the patient its primary concern.

The Report recognises that, after assessing all the risks and benefits of a full face transplantation, some patients may now choose to undergo it even given the “very high known and unknown risks” of the procedure especially in relation to immunology. *Changing Faces* fully supports the College's insistence that in this circumstance, it is the responsibility of Research Ethics Committees to maintain the highest ethical standards to ensure patient protection.

In particular, we are pleased that the College has stressed the following:

- the imperative that patients should have the fullest information possible about the risks and benefits of full face transplantation and of all alternative treatments including conventional reconstructive surgery and psycho-social interventions
- the importance of ensuring that patients have the chance to discuss their future treatments objectively with people who are not within the clinical team
- the need for clinicians to provide detailed plans for providing psycho-social support for the patient, their family and the donor's family after the transplant and in the long run, including in the event of graft failure.

Changing Faces hopes that the Royal Free Hospital's Research Ethics Committee will review its decision to give the go-ahead for a full face transplant research project to ensure that the Royal College's minimum requirements are fully met.”