



# Bioethical analysis of face transplantation in Brazil

## *Análise bioética do transplante de face no Brasil*

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### ■ ABSTRACT

**Introduction:** This update on bioethical aspects of face transplantation reviews the literature on the current status of organ and face transplantation, the significance of the human face, and the human face as a vital organ. **Methods:** This was a narrative bibliographic review, with documentary analysis of face transplantation in the last 10 years. **Results:** A search of the PubMed database identified 8,259 papers with the keyword face transplantation, 28 articles with the keywords face transplantation and bioethics, and 4,877 papers with the keyword organ transplant ethics; documents related to legislation were found in the Brazilian Association of Organ Transplantation (Associação Brasileira de Transplantes de Órgãos - ABTO). **Conclusion:** The experience of countries where face transplantation has been performed has shown that this is a viable option for the reconstruction of severe facial lesions. However, face transplantation is considered an experimental procedure with high risk of complications and costs, and requires a multidisciplinary team and the lifetime use of immunosuppressants. To date, this procedure is only indicated for a small group of patients. From a bioethics standpoint, it should be noted that, despite providing consent, the level of risk acceptable to the recipient must be assessed. Who will be responsible for the costs related to the procedure? When can public resources be used to justify individual rights over public rights?

**Keywords:** Face transplantation; Brazil; Face; Bioethics.

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## ■ RESUMO

**Introdução:** Atualização sobre os aspectos bioéticos do transplante facial. Estudo de revisão da literatura sobre a situação atual dos transplantes de órgãos e de face, a importância da face humana, e a face humana como órgão vital. **Métodos:** Revisão bibliográfica narrativa com análise documental acerca dos transplantes de face nos últimos 10 anos. **Resultados:** Na base de dados PubMed foram encontradas 8259 publicações com a palavra-chave *face transplantation, face transplantation and bioethics* em 28 artigos e *organ transplant ethics* em 4877 publicações; documentos relacionados à legislação encontrados na ABTO (Associação Brasileira de Transplantes de Órgãos).

**Conclusão:** A experiência dos países com o transplante de face demonstrou que é uma opção viável para reconstrução de graves lesões faciais, entretanto, é considerado um procedimento experimental com alto risco de complicações, altos custos, envolve equipe multidisciplinar e a necessidade do uso vitalício de imunossuppressores. Até o momento, é indicado para um pequeno grupo de pacientes. Do ponto de vista bioético, vale contextualizar que, apesar da obtenção do termo de consentimento, é necessário avaliar qual é o nível de risco aceitável para o participante da pesquisa. Quem será o responsável pelos custos relacionados ao procedimento? Quando os recursos públicos podem ser utilizados para justificar os direitos individuais em detrimento dos direitos públicos?

**Descritores:** Transplante de face; Brasil; Face; Bioética.

## INTRODUCTION

Face transplantation is described in the Bioethics literature on emerging procedures, and is considered a scientific advance, but must incorporate assumptions of social values and expected outcomes of specific policies. The challenge is to create opportunities for the development of emerging protocols in Brazil, where social inequalities are striking and the healthcare system consists of a public and a private network, in which the public sector subsidizes the private sector, while simultaneously investing little in the healthcare sector as a whole.

In 1965, the kidney was the first organ transplanted in Brazil. In 1991, the Organ Notification, Procurement and Distribution Center (Central de Notificação, Captação e Distribuição de Órgãos e Tecidos - CNCDO) was created. Fifty years later, Brazil is among the countries with the highest number of organ transplantations, primarily kidney, liver, and cornea, among others. Brazil has the largest public transplantation program, according to the National Transplantation System (Sistema Nacional de Transplantes - SNT).

In 2011, 23,397 organ transplantations were performed in Brazil, according to the SNT. However, thus far, no face allotransplantation has been performed.

Allotransplantation is performed between genetically non-identical individuals of the same species<sup>1</sup>.

The regulation of organ transplantation differs between countries<sup>2,3</sup>. In Brazil, Laws 9.434/97 and 10.211/2001, decrees, ministerial directives, and normative resolutions provide for organ harvesting for transplantation purposes<sup>1</sup>. The family decides whether or not the organs should be donated<sup>1</sup>.

The history of face reconstruction is old; however, the first facial transplant was performed in France in 2005, in a patient with von Recklinghausen's disease, after project approval by the French Ethics Committee (Comité Consultatif National d'Ethique - CCNE). The Committee concluded that this was a clinical research study, conducted in a public hospital, indicated for a case of complete loss of facial units, describing the need for cadaver, immunotolerance, and immunosuppression studies, similar to hand transplantation research, in the position paper<sup>4</sup>.

Since then, these studies have been conducted worldwide. Researchers seek to offer a near-normal facial appearance and restore identity, autonomy, and human dignity, with recommendations on the informed consent form for the recipient and donor, the need to create a mask of the donor's face for use in the funeral, and other mechanisms respecting the donor's dignity<sup>4</sup>.

The discussion about facial transplantation raises many questions, such as the vital significance of the human face, the adverse effects of using immunosuppressants, and the benefits of the procedure, for example. How can autonomy, confidentiality, and privacy be guaranteed? Who would be responsible for paying for the procedure and immunosuppressive drugs? This review aims to conduct a bioethical analysis of these issues.

## OBJECTIVE

This bioethical analysis aims at describing the status of face transplantation worldwide and in Brazil, the significance of the human face, and the human face as a vital organ.

## METHODS

Documentary research was conducted to search for information from the last 10 years in the PubMed and Virtual Health Library databases. The keyword *face transplantation* was found in 8,259 papers, *bioethics* in 28 articles, and *organ transplant ethics* in 4,877 papers. Article on ethical issues related to organ transplantation and the status of organ transplantation in Brazil were selected.

## Theoretical Framework

### 1. Current status of organ and face transplantation

Researchers who have performed face transplantation have advocated the procedure to improve the quality of life of individuals with disfigured faces, and to mitigate psychological effects and promote social wellbeing. They consider the face a vital organ due to the serious psychological problems caused by facial trauma. Face transplantation refers to allotransplantation from a donor diagnosed with brain death<sup>5-10</sup>.

Kidney transplantation was the first organ transplantation, and was performed over 60 years ago; since then, several other organs have been transplanted. Progress in immunological research reduced the number of rejections, and transplantations are now performed worldwide<sup>1</sup>. In the 1960s and 1970s, drugs with improved immunosuppressive action emerged, albeit with side effects. In the 1980s, new immunosuppressants emerged and multiple organ harvesting from cadaveric donors and the use of methods for harvested organ preservation were standardized<sup>1</sup>.

The first face transplantation was performed in France<sup>4</sup>. Previously, healthcare professionals considered the procedure unethical, although they regarded the face as the main organ of body esthetics, taking into account

the stigma caused by trauma and the importance of the identity of the transplanted face<sup>10</sup>.

Face transplantation is only appropriate when conventional methods are insufficient, according to the American Society of Plastic Surgeons and the American Society for Reconstructive Microsurgery<sup>5</sup>. The number of organ and tissue transplantations has increased over the years, as well as the demand for these procedures, which currently exceeds the available supply, thus requiring regulatory and ethical mechanisms, according to Caplan<sup>11</sup>.

Several potential beneficiaries are unsuitable as organ recipients, including the elderly, drug users, those with severe mental disability or a criminal record, or who have no access to appropriate follow-up healthcare. There are also financial obstacles to accessing the transplant waiting list.

From the technical standpoint, face transplantation has proven feasible, although this is a complex procedure, requiring a multidisciplinary team and lasting from 8 to 36 hours. The authors showed the viability of microsurgical revascularization by conventional, end-to-end arterial anastomosis, preferably between the external carotid arteries and their branches and between the external maxillary and facial arteries; venous anastomosis between the external jugular vein, the facial vein, and the thyrolingual trunk; and neural anastomosis of the trigeminal and facial nerves.

Identifying vascular pedicles and facial nerves is often a difficult task due to anatomic distortion, fibrosis, and tissue retraction, requiring magnetic resonance, angiography, and Doppler imaging resources and surgical team skills<sup>1</sup>.

Brazil has hospital departments with teams of plastic surgeons and microsurgeons prepared to perform the procedures. However, it is not known with certainty what the general population thinks about face transplantation, and the opinions of surgeons and researchers is also unclear. In Brazil, total face allotransplantation has not yet been performed. However, similar to most countries, a strict law on organ transplantation is in force<sup>1,2,12</sup>.

The main articles of the law include the accreditation requirements for hospitals and surgical teams, permission for the use of deceased donor organs, diagnosis of death, consent forms, permission for the use of living donor organs, restrictions on the use of unrelated living donor organs, prohibition of organ trade, and penalties for infractions.

Regulations state that organ transplantation can only be performed in a public or private healthcare facility by a medical-surgical team previously authorized to perform organ harvesting and transplantation by the agency of the Unified Health System (Sistema Único de Saúde - SUS), after screening for infections and

infestations, as required by the Brazilian Ministry of Health (Ministério da Saúde - MS)<sup>12</sup>.

There are 18 Ministerial Orders (Portarias) regarding transplantations, and Article 2º of Ministerial Order (Portaria) 3407/98 is particularly important. The procedures regarding organ transplantation in the public healthcare network are funded by the SUS. Organ transplantation may also be performed in the private healthcare network, although health insurance plans do not cover the procedures.

Patients waiting for a compatible organ donor to be located are included in a single, national list, meeting severity criteria, among others. Allocation is coordinated by the National Transplant Center (Central Nacional de Transplantes - CNT) according to state guidelines and cooperation with the CNCDO<sup>12</sup>.

The following are prerequisites for performing organ transplantation: a) a physician with this medical specialty; b) a surgeon with at least 6 months of experience in surgery related to the transplanted organ. New types of organ transplantations should be preceded by protocol approval by the ethics committee of the healthcare facility and permission from the CNCDO<sup>12</sup>.

Face transplantations, although not vital, are important for the quality of life of the organ recipient. The face must only be harvested from a living donor diagnosed with brain death, cannot be stored, has gender and age particularities, and requires trained teams, as face harvesting and transplantation, among other issues, makes donation unpredictable. With such limitations, unpredictability prevents patients and relatives from planning and burdens the healthcare system<sup>1</sup>.

There are also issues regarding the refusal to perform transplantation. In a survey, 15.7% of organ donations were refused, 48.6% of which were refused because the wishes of the donor were unknown, 23% because the donor expressed opposition to organ donation, 17.6% because the family wanted to maintain the body intact, 1.4% for religious reasons, and 9.4% for unknown reasons<sup>13</sup>.

## 2. Importance of the human face

The human face is a component of a person's personality and body image, and is important for relationships and quality of life. The face expresses the appearance, provides information on age, sex, ethnicity, and emotional state, and helps to form the body image, which is crucial for social interaction<sup>14</sup>.

Anatomical and facial expression studies by Bell, Darwin, and Ekman described the human face as the most exposed part of the body throughout life, important for the psychosocial development of the individual. As complex, unique and individual systems, no two faces are alike.

However, there are common facial behavior patterns, influenced by culture and passed between generations<sup>15</sup>. Facial expression is an adaptation to the environment in which the person lives.

Researchers question whether the face represents a genetic code that is decoded throughout life and through social sharing. Studies with photographs of people from various regions of the world enabled definition and classification of facial expressions and the *Facial Action Coding System*<sup>14</sup>, wherein more than 10,000 thousand facial expressions are shown.

In the 1950s, studies showed that facial expressions and hand gestures varied with culture. Magalhaes<sup>15</sup> stated that facial expressions are not only a cultural product, but also show emotions and act as catalysts between our behavior and the environment. They are a preparation for actions, playing a key role in the development of learning.

Emotions are formed by conscious experiences, physiological reactions, and expressive behavior, and consist of cognition, facial expressions, and the autonomic nervous system. Expressions are determined by emotional experiences and may be inhibited or disguised. The face is an instrument at the service of social interactions, important for expressing feelings and communicating, and affects human feelings<sup>14,15</sup>.

## 3. The human face as a vital organ

Disfigurement and loss of expression can affect personal identity, which is vital to humans. Studies on the psychological problems faced by people with disfiguring facial trauma found that 10-70% of patients had depression, anxiety, aggression, suicidal tendencies, and social, marital and professional problems. Higher unemployment and alcohol consumption rates, lack of treatment compliance, lower education level, and less social support were also found among these patients<sup>16</sup>.

Patients undergo various reconstructive procedures with high emotional and economic costs. In the most extreme cases, patients progress to social withdrawal, which may result in "social death"<sup>15</sup>. Family support and culture are relevant to the social reintegration of these patients. A study showed that most facial trauma victims have low purchasing power; of 711 cases, 23% required specialized procedures, such as reduction of fractures and reconstruction with grafts or flaps<sup>16</sup>. Thus, this population has few resources, which increases social vulnerability resulting from facial disfigurement.

## RESULTS

The results of this narrative literature review were based on a documentary analysis of papers related to the ethical and bioethical aspects of transplantation, following a search and subjective selection by the author. The self-

identity of the donor, that is, the set of characteristics and traits specific to an individual, is among the ethical issues of face transplantation. Self-identity is the awareness of one's individuality in relation to other people.

From the standpoint of Maurice Merleau-Ponty apud Swindell<sup>17</sup>, identity is not only the mind, but also the body. The conscious being is the integration of body and mind, as shown by studies on phantom limbs, when people continue to feel the presence of the amputated limb after amputation. The body is a central part of personal identity. Thus, donating an organ is donating a part of oneself. Some people receiving organs describe the sensation of having someone inside them<sup>17</sup>.

Lock<sup>18</sup> stated that donated organs often represent more than mere parts of biological bodies; instead, the recipients experience a personified life. People receiving transplantations commonly worry about the sex, ethnicity, skin color, personality, and social status of the donor. Many believe that their way of being in the world could be changed by the donor; for example, they would not like to have organs from convicted criminals in their bodies, fearing a transformation due to characteristics stemming from the donor.

Sharp<sup>19</sup> observed that most people receiving organ donations expressed the feeling of rebirth, and often felt that they acquired emotional, moral, or physical characteristics of the donor. The symbolism of the organ affects identity and varies according to the transplant. Heart recipients have reported experiencing a greater identity transformation than that of kidney recipients.

The relatives of organ donors often think that their loved ones live in the other bodies, as if they were an extension of the donors' biographies. The identity issues underlying facial transplantation are not different from those involved in other organ transplantations, but rather supplemented with aspects related to the unique identity of the face and its meaning for personal identity.

The authors reported differences between the person who loses identity due to disfigurement, and those who receive facial transplantation. Facial transplantation recipients wished a different identity from that acquired in the trauma, which was unexpected and undesired. This does not mean that the person is unable to accept their change and form a new identity.

Furthermore, the donor could be identified in 2.6% of cases and the recipient in 66% of cases after facial transplantation. In addition, the experience thus far has shown that recipients accept face transplants well and do not feel a loss of identity with the new face.

Articles on ethics included 73 publications against, in favor of, or neutral regarding face transplantation<sup>20</sup>. Articles about face transplantation in 2008 expressed concerns about identity change and psychological effects

in 100% and immunosuppressive effects in 69.1%, with risks and benefits discussed in 64.8%; articles expressing concern about immunosuppression and identity appeared both before and after the first transplantation was performed. The following issues prevailed: patient selection, costs, and the inability of the disfigured person to have a normal life.

In 2012, all articles published were favorable to performing face transplantations. In 2004, Banis et al.<sup>21</sup> conducted a survey to promote philosophical and ethical discussion on face transplantation, with a focus on the need for public evaluation of innovative medical procedures before their application. This position would be defined as prophylactic ethics, according to Caplan<sup>11</sup>. He described, among other issues, the possible reasons for the failure of transplantation policies.

Other related ethical issues include publicity, invasion of privacy, face procurement for donation, the risk acceptance tool, the risks, the high rejection rate, the differences between face and solid-organ transplantation, the difficult functional recovery, and the psychological, economic, and social implications. The autonomy of participants, donors, or recipients is expressed in the consent process.

The importance of donor anonymity, donor family consent, the recipient's ability to consent, the respect for the privacy of recipients and donors, the need for review of the definition of brain death and the certainty of diagnosis, the treatment costs for society, the risks of performing the experimental procedure, and the respect for the dignity of everyone involved was identified in a survey conducted in France among 909 plastic surgeons<sup>22</sup>.

Even if declared, the privacy of the recipient may be infringed because the media may acquire and publish information on the identity of donors and recipients, and the latter may develop severe psychological stress. Face transplantation is estimated to cost 80,000 dollars and the use of immunosuppressants costs approximately 600 dollars per month<sup>23,24</sup>.

The number of transplantations performed in Brazil increased 74.8% and the costs increased 163% because, in addition to the surgical procedure, the postoperative medication required is expensive.

Transplantation costs were approximately BRL 990 million in 2010, according to data from the MS, and Portal Brasil reports that kidney transplantation cost BRL 27.6 thousand in 2012. The costs are high, and increase in the case of living donor transplantations due to indirect costs also related to the organ donor. Furthermore, public investment in staff training, team formation, specialized laboratories, and medication, among others, is also required<sup>25</sup>. It should be noted that expenses related to transplantations in Brazil are borne by the SUS.

## REVIEW AND CONCLUSION

The subject of face transplantation has blurred the lines between research ethics, clinical bioethics, and minority ethics, especially when related to the protection of research participants or surgical patients. Other questions include who would be responsible for the costs of the research study, the procedure, or the lifelong immunosuppressants, and how would the transplantation waiting list be established, based on what criteria and who would make that call, because face transplantation has unique aspects regarding ethnicity, blood type, sex, race, and morphological facial features.

The fact is that some authors already consider face transplantation a procedure incorporated into healthcare practice and an option in the case of severe facial disfigurement. The analysis of current published discourse on face transplantation shows that social studies focus on disfigurement and the inability of the individual to socialize, and cognitive studies focus on scientific progress and physiological and psychological aspects resulting from disfigurement and the loss of quality of life.

Kalliainen<sup>26</sup> proposed a rationale based on the principles proposed by Beauchamp and Childress<sup>27</sup>. However, they are insufficient because patients with disfigured faces have reduced autonomy and are exposed to risks, including the use of immunosuppressants, adverse reactions, and lack of guaranteed privacy. Although performing face transplantation could be an option after other facial reconstruction options have been exhausted, how would the public health resources be distributed to promote social justice?

The Universal Declaration of Bioethics and Human Rights<sup>28</sup> addresses a key role in society, by protecting research study participants and by promoting concern for future generations. Thousands of people participate in research studies seeking new knowledge, diagnosis, prevention, and treatment.

Inevitably, they will be exposed to various risks, ranging from adverse effects, pain, and discomfort, to loss of time and even death. What would be the acceptable risk for participating in a research study involving complex surgical procedures and why are there ethical, legal, and professional norms and rules? The central standard for risk assessment is the principle of proportionality, that is, the risks are acceptable if there are possible benefits for the participant and future generations. This principle requires a balance between means and ends in which participants are not exposed to unnecessary, excessive, and unreasonable risks<sup>29</sup>.

Another issue for analysis is the principle of responsibility, proposed by Jonas<sup>30</sup>, in which the causal power is a condition of responsibility, that is, the agent must be responsible for his or her actions, although this topic merits discussion as to the limits of responsibility.

In the discussion on public management and allocation of public funds for transplantation, when could they be used to justify individual rights over public rights? The right to choose is meaningless without adequate resources to perform the procedure. According to utilitarianism<sup>31</sup>, a theory used for public management evaluation, decisions should be analyzed for their consequences, that is, the total sum of wellbeing for the largest number of people.

From the standpoint of Kant<sup>32</sup>, humanity should be treated as an end in itself, and not as a means. Regarding the basic question related to the political, moral, and social concepts of the 21st century, as opposed to specific aspects of individualism, in defense of civil society, who decides what is good?

The whole society can define its own norms, or, conversely, a single form of good society can serve as reference to other communities. Healthcare policies could analyze how to ethically address public health issues and how to organize human society by considering the concept of the value of human research subjects.

## COLLABORATIONS

- KTB** Conception and design of the study; writing the manuscript or critical review of its contents.
- EMFS** Writing the manuscript or critical review of its contents.

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