

Use of corneas for transplant after self-inflicted eyeballs enucleation in the Italian law

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Abstract

The authors analyze from an ethical and legal point of view the case of a 37 year old man, hospitalized for four days because of a “dissociative syndrome”, who had introduced in both his orbits a portable radio antenna. Most likely, he completed the self-enucleation using his own hands. He was brought to the Ophthalmic Hospital by nurses who handed the two eyeballs to the physicians who ascertained that the corneas were intact. Then, they performed the conservative extraction. In the following days those corneas were transplanted (keratoplasty) on two subjects on the waiting list at that hospital. The case raises the question of whether it is lawful and ethically acceptable to take, for transplant use, the corneas of a mentally incapable patient who has excised his own eyeballs. The authors analyze the case from the angle of the Italian law and Oviedo Convention. Neither of them has a specific regulation on this topic. It is therefore necessary to apply general principles that hold valid for Italy and a variety of countries worldwide. Particularly, the choice to use the corneas for transplant did not prejudice the physical integrity of the patient, who could no longer utilize his own eyeballs. His self-determination has not been affected; in fact, he was not in the position to make a conscious decision. Additionally, the so-called “implied consent” could be applied. Therefore, the principle of human solidarity, which is the moral duty to benefit others, seems to prevail in the case at hand. *Clin Ter* 2017; 168(2):e128-132. doi: 10.7417/CT.2017.1993

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Introduction

Eyes and ocular annexes represent a rare and atypical site of self-harm. Self-enucleation of the eyes is an extremely rare event. Krauss et al. (1984) accurately reviewed all clinical cases worldwide that, beginning with the case elaborated on by Bergmann in 1846, report only 19 cases of attempted self-enucleation that required surgical enucleation, and 31 further instances of monolateral self-enucleation (1).

From a clinical standpoint, self-inflicted eye injuries have been linked to a variety of disorders, including:

1) paranoid schizophrenia

- 2) acute or chronic psychoses (drug or alcohol-induced psychoses)
- 3) obsessive-compulsive
- 4) profound affective disorder
- 5) mental retardation

Eye injuries have also been described in subjects:

- 1) under restriction of personal freedom (prisoners and detainees)
- 2) living alone, sick and unemployed
- 3) sexually and/or physically abused in childhood/adolescence (females victims of incest by their father are considered at high risk)
- 4) war veterans (2).

In Italy, according to the Law 08/12/93 n. 301 (“Rules on cornea’s sampling and grafting”) corneal transplantation is allowed only from cadaver. Death must be established by scientific evidence: through the finding of the irreversible cessation of brain or cardiorespiratory function (3).

Italian law does not expressly regulate the matter of detached parts of the body nor does it determine the fate of excised parts due to self-harm. According to some authors, in case of detachment of one or more body parts due to self-mutilation, they no longer belong to the subject, but become “objects” and are deemed to be regulated not according to personal integrity rights but to ownership rights. Therefore, the part detached from the body becomes “a tangible asset”, thus enabling the subject who suffered the mutilation to exercise ownership rights (4). However, Italian law has overcome the concept of ownership right on detached body parts. As laid out below, the principles of such an evolution should be considered uniform throughout the world; therefore, they could be applied to those countries that lack a specific and targeted set of regulations on the matter.

At Community level, Art. 21 of the Oviedo Convention prohibits turning human body and body parts into a source of profit. Art. 22 specifies that, when a part of the body is removed during surgical intervention, it cannot be stored and used for purposes different from the ones specified in the consent signed by the patient. Therefore, the individual’s power to control over his or her own body or body parts

represents the expression of the self-determination principle as for personal choices (5). However, as it has been verified in most cases, those who engage in self-mutilation suffer from a psychiatric pathology and, therefore, their capacity for self-determination is strongly compromised. Not even a careful and timely legislation as the British one has taken into consideration the event of severely disturbed subjects who commit self-mutilation (6). Art. 6 of the Human Act (6) states that: “Where—(a) an activity of a kind mentioned in section 1(1)(d) or (f) [including storage and use for the purpose of transplantation of any relevant material which has come from a human body] involves material from the body of a person who—(i) is an adult, and (ii) lacks capacity to consent to the activity, and (b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force, there shall for the purposes of this Part be deemed to be consent of his to the activity if it is done in circumstances of a kind specified by regulations made by the Secretary of State”. Therefore, Art. 6 deals only with such cases as where removal of body parts is lawful, even in case of subjects who lack capacity to consent to the activity. Here below we report a case of eyeballs enucleation that represents an exceptional event for both the mode and effects of the self-harm in itself and for the therapeutic application (use of corneas to perform a subsequent keratoplasty).

Case Report

A 37 year old man was rushed to the Ophthalmic Hospital of Rome by ambulance and accompanied by nurses. He came from a psychiatric institution, where he had been hospitalized for four days on account of a “dissociative syndrome”. While he was not under strict surveillance, he introduced in both his orbits a portable radio antenna, which injured the muscle tissues and the optic nerves bilaterally within a short distance from the chiasm. Most likely, he completed the self-enucleation using his own hands. Accompanying nurses handed the two eyeballs, contained in a plastic bag immersed in salt solution and ice to the hospital physicians who verified that the corneas were intact. Then, they performed the conservative extraction according to McCarey and Kaufmann technique (8,9). In the following days those corneas were transplanted (keratoplasty) on two subjects on the waiting list at that hospital.

The detached body parts in the Italian Law

The Italian Constitutional Court has long ruled out that an individual can claim physical integrity rights on his body, but not ownership or fruition rights. In fact, the body is strictly linked to the person and cannot be considered a mere object (10). The Court of Naples, deciding on the case of a patient who, following a surgical operation, had requested to have his pathological findings, recognized the patient’s right to “come by their own pathological findings taken as a whole and therefore also the paraffin-embedded tissue”, not because of an ownership right on the detached part of the body, but because such findings were necessary to protect the patient’s right to health, namely the right to

be thoroughly informed on his own state of health (11). In fact, according to the Italian Civil Code, property consists in the right to fruition and disposal of things in a full and exclusive manner (Art. 832). Pathological findings do not fall within such features. Detached body parts that may be used as if they were a property are typically the ones that can be stored without any treatment, i.e. nails and hair, and blood if immediately transfused. The right to property cannot be applied on living tissues, such as eyeballs and corneas, poised to decompose: in such cases, the subject, i.e. the owner, cannot make any use of the biological material that has been detached from his body. Latest Italian jurisprudence backs up this evolution as well. In fact, as a result of the scientific and technological advancements, particularly with the discovery of DNA and stem cells, the conception that the right to property can be claimed on detached body parts is obsolete, (12,13) although the right is still acknowledged for inorganic material, such as nails and hair. Conversely, if the detached body part is intended for new uses permitted by biomedicine and biotechnology, it is considered a living matter. Consequently, it is protected by particular cautionary measures (i.e. the mandatory use of timely cryopreservation techniques) and by specific rules (14). Moreover, biological samples for diagnostic purposes and surgical waste parts represent the biological profile of the subject they come from. (15,16). According to some authors, such cases are entitled to the same right on image-related safeguards. DNA or any single organ are “fundamental elements of my identity: I am not my liver and my DNA, as they are not my image, but it is undeniable that they constitute a relevant aspect of myself, the use of which affects my personal dignity” (17, 18). Moreover, Italian law has outlined and acknowledged the link between the individual’s identity and parts of his body. In fact, the need to protect the subject’s personal identity has led the legislator to ban, by Article. 3, paragraph 3 of Law no 91/1999, transplant of brain and gonads (19). Therefore, as far as detached body parts are concerned, the “ownership approach” seems to be obsolete (20, 21).

According to Italian law, a comprehensive analysis of the case debated herein highlights several peculiarities that warrant further examination and discussion.

The above-mentioned evolution can lead to argue that it is not lawful to transplant corneas and that some peculiarities of the case at hand make the lawfulness of such intervention all the more questionable.

- 1) The patient was totally mentally incapable. A mentally capable subject could have given consent for the donation of the corneas or express his or her intention to relinquish the detached part of the body (*animus dereliquendi*). In the latter case, the hospital is allowed to destroy the abandoned part (*res derelicta*) or destine it for different uses (educational, scientific, therapeutic, pharmaceutical) (22). If the self-inflicted mutilation occurs in mentally incapable individuals, they are not fit to express a valid consent, until they regain their faculties. If the mentally incapable person is in adult age and does not have a legal representative acting on their behalf, nobody else may give consent in their stead.
- 2) The corneal tissue has a limited vitality. If the legal representative of the incapable person does not consent to corneal removal in a timely fashion for transplant

purposes, their consent is useless. In fact, the anatomical part to be transplanted loses its vitality and can no longer be used. In the discussed case, as the explantation had to be performed within a very short timeframe, it was not possible to find a legal representative of the patient. This situation makes more controversial the transplant's lawfulness, provided that it was carried out without consent.

- 3) Clinical conditions of the patients who receive the transplant. These are affected by disabling diseases that cannot deteriorate further. Consequently, the explantation's lawfulness cannot fall within the rules established Art. 54 of the Penal Code. The latter mandates no punishment for those who commit an act while being compelled to do so by the need to save themselves or others from real danger of serious harm to the person, not voluntarily brought about by themselves or otherwise avoidable, provided the act is proportionate to the danger. The state of necessity, despite the different opinion of other authors (23), cannot be claimed as a defense by the physician or the health team who have carried out the explantation and/ or the cornea transplant. In the discussed case, unlike other situations (e.g. blood transfusion on patients who are "Jehovah's Witnesses"), there is no imminent risk of serious damage to anyone, and certainly not on the patient poised to receive a transplanted organ. In fact, this subject already faces serious harm and cannot suffer from any further damage if the transplant is not performed. However, there are also valid reasons to support the lawfulness of cornea removal from the eyeball, already detached from the body due to accidents, intentional or self-harming. There is no doubt that cornea donation, transplanted from a living subject to another subject, is one of the acts of "disposition of one's body" prohibited by Article 5 of the Italian Civil Code, because causing a permanent damage to physical integrity. Nonetheless, this is not tantamount to stating that self-mutilation itself entails punitive consequences for those who commit it. In fact, it is not sanctioned, as well as suicide or attempted suicide, except in cases where the injury is caused to obtain compensation from a private insurance company covering injury (art. 642 Penal Code) or from a social insurance on workplace injury (art. 65 Presidential Decree of June 30, 1965, n. 1124). Moreover, in the reported case the prohibition provided by Art. 5 c.c. is irrelevant because self-mutilation (prohibited by the same article) concerns self-removal of the eyeballs, not the explantation of the corneas from the bulbs. The use of the corneas as part of the eyeball detached from the body is accounted for only at a later stage, when the detachment had already occurred. In other words, the reported case does not concern detachment of an organ or tissue from that subject's body, but rather removal of a part of an organ already detached from him. The legal status of such a removal can be inferred from the fact that the law does not provide for such a case nor explicitly forbids it. Even the Oviedo Convention (24) has not taken into account this aspect. In fact, both Articles 20 and 22 refer to the event in which physicians explant organs or tissues from the patient, but not certainly a scenario in which organs or tissues have already been accidentally

or intentionally excised from the patient's body.

Furthermore, in the case provided for by Art. 20 of the Convention, consent toward the acquisition is a requisite condition because the explantation undermines the physical integrity of the patient, who has no interest in donating (an organ). Conversely, in the reported case, there is no reason that would make it mandatory to obtain consent. In fact, the patient can no longer get any benefit from storage of his eyeballs and their use for the purpose of a transplant does not cause any harm to him. This sets our case apart from the one reported above, ruled on by the Court of Naples. While in that case the patient asked to have back his pathological findings, in our case the patient had not manifested any intention to oppose the use of corneas for transplant. Besides, the assertion from the Constitutional Court that human beings have a right to physical integrity does not apply to the case in question, in which respect it is immaterial. In fact, the choice to transplant the corneas did not affect the patient's physical integrity, as his health had already been irreparably jeopardized at the time of the eyeball removal, before the corneas' explantation. Under these circumstances, it could be argued that transplant is licit, as it is not expressly forbidden and does not fall within the range of cases which mandate an informed consent (25, 26). Additionally, even if the consent had been necessary, it could be argued that the transplant is lawful, because of the patient's implied consent. In fact, since the excised eyeballs are no longer of any benefit to the patient, he has no reason to refuse the corneas' donation. Finally, Art. 2 of the Italian Constitution provides for the "charitable duties" and defines them as "mandatory" for all citizens. Obviously, people cannot be compelled to undergo organ removal to fulfill a charitable duty. However, if the organ has already been detached for other causes and cannot be replanted, the cost-benefit ratio is completely different: by performing the transplant, another patient can recover or improve their view, while the person from whom the organ has been taken does not suffer any further adverse consequences. Therefore, even healthcare personnel that use corneas for therapeutic use fulfills a charitable duty.

The regulation of the United Kingdom

For England and Wales, the regulation approved by the Secretary of State, mentioned in the above mentioned Art. 6 of the Human Tissue Act, states that: "

(1) This regulation applies in any case falling within paragraphs (a) and (b) of section 6 of the Act (storage and use involving material from adults who lack capacity to consent).

(2) An adult ("P") who lacks capacity to consent to an activity of a kind mentioned in section 1(1)(d) or (f) of the Act (storage or use of material for purposes specified in Schedule 1 among which transplants) which involves material from P's body, is deemed to have consented to the activity where— (a) the activity is done for a purpose specified in paragraph 4 or 7 of Part 1 of Schedule 1 to the Act (the purposes of obtaining information relevant to another

person and of transplantation) by a person who is acting in what he reasonably believes to be P's best interests (27).

The same rule is established by section 4 for Northern Ireland. Other two relevant rules are reported in the Code of Practice. First of all, paragraph 40 puts forth that "A decision on a transplant must be made by a Human Tissue Authority (HTA) panel: 1. if the donor is a child; 2. if the donor is an adult who lacks capacity to consent to removal of an organ or part organ". Additionally, in accordance with paragraph 52 "Where an adult lacks the capacity to consent to the removal of an organ or part organ, the case must be referred to a court for a declaration that the removal would be lawful. Donation may then only proceed if court approval has been obtained and following court approval the case is referred to, and approved by, an HTA panel"(28). It is likely that in the reported case the principle of best interest of an incapable adult does not prevent the use of corneas. In fact, the issue of figuring out what the subject's best interest may be arises when the use of biological material represents a sacrifice for him. In this case, the use is permitted only if physicians have ascertained the patient's prevailing interest to donate his relevant material for the benefit of others. However, when the use of the organ does not involve prejudice to the incapable subject, it does not make any difference for the latter whether to donate or not his or her own material. Consequently, there seems to be no restriction to transplanting because individual interests are not subordinated to the general ones, as ruled by Article. 2 of the Oviedo Convention. Last but not least, it is not mandatory to seek consent from the Court and HTA panel as the above mentioned paragraphs of the Code of Practice refer to removal of organs, while in the discussed case the patient arrived at the hospital after the eyeballs had already been enucleated.

Conclusions

Based on these considerations, there are valid reasons to state that:

- 1) the body part detached from a living individual can be used for therapeutic purposes without breaching personal rights;
- 2) such use is meant to cater to relevant issues related to social solidarity that makes void any right to property. Nevertheless, the degree of complexity of the topic and the importance of the interests involved call for a legislative intervention by EU Commission in order to provide physicians with ad-hoc indications and a set of guidelines for a clear and uniform behavior.

Declaration of Interest

The authors report no conflicts of interest.

Authors contributions

All the authors made substantial contributions to conception and design of the manuscript; GMV wrote the paper, A.d.L. performed the literature search, E.P., N.M.dL., R.C.

and E.M. revised it. All the authors have been involved in revising the manuscript critically for important intellectual content and all of them have given final approval to the version to be published.

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