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## TRANSPLANTATION IS NOT ENOUGH..., OR ON THE CONCEPT OF XENOTRANSPLANTATION

**Abstract.** The paper presents the emergence of the concept of xenotransplantation which is a relatively new issue in the literature on the subject. It is due to the fact that transplants of animal organs are currently in the experimental phase. The main current problem of transplantology is the shortage of organs; hence, the search for new solutions has become an everyday challenge. If a way for the human body to tolerate animal organs could be found, transplant medicine and humanity would be in a completely different place. The authors introduce the concepts of transplantation and xenotransplantation and their origins, then they raise ethical issues related to this type of organ transplantation. Finally, the authors conclude that xenotransplantations have a chance to be “incorporated” (back again) in the “transplants” category when the experimental phase of xenotransplantation shifts to the implementation stage. Time will tell whether it will be possible.

*Keywords:* transplantation, xenotransplantation, heterotransplantation, medical experiment.

### Introduction

The current key problem of transplantology is the deficiency of organs. By virtue of the fact that “nature abhors a vacuum” and it initiates on its own various actions to fill that void, people, drawing on familiar ways of coping in such cases, as for example filling the void in their own stomachs, undertake the idea of filling other “voids” in their own bodies, for example in the place of a sick kidney, with parts of animal bodies. If animals can be eaten (without taking into considerations the beliefs of vegetarians and vegans) in order to build the human body, then perhaps they can / should also be used to heal or rebuild it? “Recalling the history of mankind, it can be observed that the existence and development of humanity from the

beginning were conditioned by the possibilities of a gradual subordination of nature. It seems that between the distant times and today there is only a difference in the way, not in the purpose” (Zmyslowski, 2016: 14 – translation mine).

### **The concept of transplantation**

Transplantation is a treatment method that enables human life and health saving. It involves the replacement of diseased organs or parts thereof with healthy ones. The etymology of the term “transplantation” is derived from Latin, where the verb “transplantare” is translated as an act of uprooting and moving, grafting (Guzik-Makaruk 2008, p. 29). According to Roman Góral, transplantation is “a surgical removal of the tissue or the entire organ (graft) in case of specific disease conditions from one place to another within the same individual or from one person (donor) to another (recipient), which is intended to complement a loss or restore a function” (Góral, 1987: 154 – translation mine). An important way of addressing the issue of transplantation can be found in the Resolution of the Sejm of the Republic of Poland of 13 June 2008 stating that transplantation “is a necessary, effective and safe method of treatment, which represents for many patients the only chance to prolong life” (Resolution of the Sejm of the Republic of Poland of 13 June 2008 on approving transplantation as a treatment method, 11.01.2017). A compatible understanding of transplantation is indicated in the definitions provided by European Union documents, i.e. Directive of the European Parliament and the Council of 2004, which reads that “(t)he transplantation of human tissues and cells is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases” (Directive 2004/23/EC, 07/04/2004: 0048–0058, 11.01.2017). Władysław Kopalinski emphasizes that “transplantation means grafting, displacement of an organ or a part thereof within a single individual or from one individual to another, within the same species or between different species” (Kopalinski, 26.06.2017 – translation mine). This definitional approach incorporates xenotransplantation (also referred to as xenogeneic, xenogenetic, heterogeneous, heterologous transplantation, or heterotransplantation) – a type of transplantation where the human is the recipient and the animal is the donor. In the discussion on the concept the definition presented by G. Kaiser is worth considering. The author in the definition of transplantation presented in 1960s states that to carry it out parts of a deep-frozen human body can be used (Kaiser, 1966). Taking into account

aspects of a moral, ethical and legal nature of this controversial definition, at the same time it should be emphasized that the purpose of transplantation, i.e. treatment, does not exclude experiments. Therefore, in the future, these futuristic (from today's perspective) assumptions made by G. Kaiser can become real and, thus, modify the current interpretation of what transplantation is.

### **Xenotransplantation – extracting the concept**

According to the U.S. Public Health Service, “(a)ny procedure that involves the transplantation, implantation, or infusion into a human recipient of either (1) live cells, tissues, or organs from a nonhuman animal source, or (2) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs cells, tissues or organs” (Smorağ, Słomski, 2005: 133; Cooper, Kemp, Reemtsma, White, 2012) is defined as xenotransplantation.

The documented history of attempts to treat people with animal transplants dates back to the early 20th century (Deschamps, Roux, Sai, Gouin, 2005: 01.09.2016). Piotr Marciniak citing the first scientific reports of performed xenotransplantations as their precursors, indicates Jaboulay from Lyon (1906) and Unger from Vienna (1910), who carried out renal grafts from goats, pigs and rhesus monkeys, but with patients surviving only 2–3 days (Morciniec, 2001: 173). –185). From a scientific perspective, as P. Morciniec points out, “only the experiments conducted in the 1960s by the teams led by the American professors Reemtsma and Starzl are worth noting. The patients survived with chimpanzee and baboon kidneys for up to several months (9 months the longest). The results were surprising because they were achieved without immunosuppression. Reemtsma claimed in connection with the experiments that chimpanzee kidneys are no more rejected than analogous human organs. The successful attempts to transplant hearts of non-human primates were recorded in 1968 by professor Barnard in the Republic of South Africa” (...) [it is worth emphasizing that it was Ch. Bernard who made the first allogeneic heart transplant in man] “whose patients survived a few days” (Morciniec, 2001: 174 – translation mine).

The most commonly cited story in the context of xenotransplantation involves transplantation of a baboon heart to a 15-day-old baby with congenital heart disease. Baby Fae – initially the true identity of the girl was not known and the world media called her so (Janicki, 2012: 14.09.2016).

Stephanie Fae Beauclair was born on October 14, 1984, and her heart congested with hereditary hypoplasia consisted only of the right part, resulting in the inevitable death of a newborn within a maximum of several weeks. Leonard Bailey undertook the pioneering transplantation of a young baboon heart. “The operation took four hours. The new girl’s heart began to beat, and over the next few days, her condition gradually improved. The doctors emphasized that before she was breathing hard, whereas now she behaved like a normal healthy child: she cried, wept, yawned and cuddled to her mother.” (Janicki, 2012: 14.09.2016 – translation mine) The child died on the 20th day after transplantation. The medical environment, as it was then, is now divided on evaluating this procedure. Many accuse Leonard Bailey of ambiguity: “For years he had dreamed of making a breakthrough in medicine. So far, he had experimented only with animals, transplanting one organ taken from another and watching how much time would pass before they die. For a large part of the medical community he was considered a pariah” (Janicki, 2012: 14.09.2016 – translation mine). One remarkable comment came from one of his colleagues: “Dr. Moneim Fadali, a cardiologist at the University of California, Los Angeles, hotly commented that the whole operation was merely an example of irresponsible bravado, and that a human heart rather than an animal one should be searched for the child. Bailey replied that the chances of getting such an organ in the required time were minimal. In fact his team did not do anything in that direction. The most controversial news was that on the day of the surgery another hospital reported to Loma Linda that they had a potential donor. The message was simply ignored.” (Janicki, 2012: 14.09.2016 – translation mine) Kamil Janicki’s article on this memorable transplant ends with a quote from a publication published in 2012: “Stephen and Thomas Amidon, authors of the book «The Sublime Engine: A Biography of the Human Heart», summarize: The team of surgeons were accused of entrusting false hopes that the human organism would adopt an organ of another mammal. At present, most physicians treat xenotransplantation, i.e. inter-species organ transplants, as a blast and bypass it from afar. Fortunately!” (Janicki, 2012: 14.09.2016 – translation mine). Scientists found that it was rather a blood type incompatibility rather than a strong reaction of the transplant rejection that was the cause of the infant’s death. The first kidney liver implantations to human recipients in the last stage hepatitis B were performed by Thomas Starzl (1993), informing the scientific community that patients died 1 and 2 months after the transplantation. The swine liver transplants conducted in the 1990s in California and the swine heart transplants performed in Poland ended with an immediate rejection and the deaths of the patients.

(Morciniec, 2001: 174). In 1989 Zbigniew Religa, due to the lack of human organs, undertook a xenogeneic transplant. He transplanted a heart of a pig. Although the surgery did not save the patient's life, "in Religa's opinion, even if the chance of success was only ten percent, it was worth a try" (Mateja, 2016: 86 – translation mine). The attempts continue, emotionally stirring, causing the need to systematize the problem and define its key concept.

The medical and social issues associated with xenotransplantation treatments, in an unwilling way, brought them to the point of isolation from the whole matter of transplantation. Thus, the concept of xenotransplantation, which had so far functioned in internal specialist communications, came into being in the common language. Of course, it still referred to very specialized medical treatments, but they slowly became common.

### **Forced (?) ethical peregrinations of transplantologists**

The compilation of cells, tissues, and organs of humans and animals is not just a futuristic vision, but the idea deeply ingrained in the history of mankind – the possibility of interspecies connection, which we now admire by studying ancient myths and legends. Greek mythology is full of such human-animal crossbreeds, but also close to our hearts is the tale of the Warsaw mermaid. Apart from myths and legends, the fact is that the development of medicine is largely based on research conducted on animals. Do we have the right to experiment on animals? Looking for answers, or rather what could be argued, Piotr Morciniec's words considering directly transgenic studies can be quoted: "Basically these things do not differ much from other animal experiments, and certainly their utility is much greater in this case (saving lives) than, for example, in the generally accepted eating of animal meat. At least the minimum condition, that we deal with a forced (final) solution due to a lack of human organs, must be proved" (Morciniec, 2001: 184 – translation mine). Piotr Zmyslowski, considering the legal and ethical issues of animal transplants, explains that "(...) the order of the natural world imposes the ratio of subordination between individuals better and less adapted to environmental conditions. Humanity as the absolutely dominant species would never have developed so well without that dependence. So progress is not being pursued to equate the status of people and animals, but to make it less painful for the subordinate and to use the evolutionary position in a rational way. The normalization of such a relationship with regard to xenotransplantation experiments is the establishment of such

procedures which will aim at minimizing, not eliminating, animal sacrifices, and limiting their suffering.” (Zmyslowski, 2016: 119 – translation mine). The quoted author also points out that the law on xenotransplantation itself, both at the national and international levels, is “in the experimental phase”. Adding to that, this fact should lead both to caution and to increased research. (Zmyslowski, 2016: 121).

Is the “industrial breeding” of animal donors an answer to the shortage of graft organs? If yes, which animals are taken into account? Scientists point to many species. Owing to the size and the vertical posture of the body the kangaroo is mentioned as a potential human organ donor, and, because of genetic similarity, also the dolphin. However, they indicate that the use of apes seemingly being “the closest to humans” (the primates and of lower orders) for transplantation would be unacceptable due to the preservation of the species (Morciniec, 2001: 177). They also emphasize the difficulties associated directly with the breeding of most species, i.e. its nuisance and the most essential free reproduction. “As a result of previous research, it has been found that the most useful donors (...) may be domestic animals, particularly domestic pigs being most favoured. However, the possibility of using a properly reduced horse or an enlarged sheep, goat or dog as a part of planned breeding is not excluded” (Morciniec, 2001: 177 – translation mine).

In 1992, researchers from the little-known British biotech company Imutran bred a genetically modified (transgenic) breed of pigs. “Due to inserting certain genes into the genetic material of these animals, the properties of their tissues were changed to deceive the human immune system and avoid over-rejection.” (Łęski, 1999: 24.02.2015 – translation mine). In 1995, in *Nature*, the Imutran scientists presented the results of the experiment confirming the assumptions of their research. “Hearts of the transgenic pigs transplanted to monkeys worked for as long as 60 days, which was considered as evidence of overcoming the barrier of over-rejection. The new technology is ready for human trials,” said David White, the Medical Director of Imutran” (Łęski, 1999: 24.02.2015 – translation mine).

The research concerning genetic modification of pigs to create transgenic organisms conducted in Poland (Smorag, Słomski, 2005: 142–143), also brought optimistic results. “Within the framework of the commission of the Ministry of Science and Information Technology, the Polish project on xenotransplantation is being implemented, involving 11 research teams representing various scientific specializations such as molecular biology, embryology, virology, immunology, and transplantation surgery. The main goal of the project is to obtain transgenic pigs for the gene constructions that lower

the immune barrier between human and pig (...). As a result of the work, the transgenic boar TG1154 was obtained. This is the first transgenic pig in Poland whose genotype was modified for the purpose of xenotransplantation” (Smorag, Slomski, 2005: 142–143 – translation mine). At the next stage of the Polish research, “transgenic pigs with 4 transgenes modifying their immunogenicity and also double transgenic pigs with two variants of transgenes were obtained. The produced (...) transgenic pigs are used by cooperating medical teams, inter alia as donors for the development of cardiovascular heart valves (*Fundacja Rozwoju Kardiochirurgii* – the Foundation for Cardiac Surgery Development, Zabrze) and skin biotech dressings for treatment of patients with severe burns (*Centrum Leczenia Oparzen* – the Burn Treatment Center, Siemianowice Slaskie)” (Smorag, Slomski, Jura, Lipinski, Skrzyszowska, 2011: 15.09.2016 – translation mine).

Assumedly, donors bred in this way (to call a spade a spade – ultimately: for organs, tissues and cells) make it possible to overcome the human immunological barrier, which is of great importance in successful receiving of transplanted organs. “This is because animal cells and tissues containing human proteins are not recognized as being alien. Although the genetic backbone of donor animals remains alien to human, it can be made similar to the one of the potential recipient” (Morciniec, 2001: 176 – translation mine). Regarding other advantages of pigs as transgenic organisms, P. Morciniec writes: “Apart from all the advantages, rapid growth and easy breeding of pigs (many animals in a litter, short pregnancy, and rapid maturation) are particularly important. Thus, in the case of successful experiments, healthy animals of sufficient size, age, and gender would be available, which means that grafting might be planned in advance, unlike in the case of human organs, most often obtained after the sudden death of a donor. In the era of rapidly rising costs of medical treatment it is also to be considered due to the very low cost of breeding pig donors, which American breeders estimate at a level comparable to the production of animals for consumption” (Morciniec, 2001: 177 – translation mine). But what is at the root of the idea of genetic modification of animals should be kept in mind! “It is not about increasing the number of organs as such, but to make it possible to save the lives of the sick in this way. Such an objective based on the fundamental norm for the protection of human life is indisputable” (Morciniec, 2001: 181 – translation mine). However, one must not forget that both shortage and excess can become a factor of social risk and problems. The possibility of an unrestricted supply of organs of animal origin could for example exert pressure to “use only animal organs cheaper than human ones. Such a form of demand entails the temptation of treating the organs

as a commodity to offer, also in the case of diseases where the therapeutic pathway is not justified (fetuses, newborns, too old patients, etc.). It may lead to too hasty decisions and choices without sufficiently comprehensive consideration of risks and expected benefits” (Morciniec, 2001: 182 – translation mine).

The conducted research not only represents the medical potential for the development of transplantology. It seems to be an opportunity for patients with diabetes, (Reichart, Niemann, Chavakis, Denner, Jaeckel, Ludwig, Marckmann, Schnieke, Schwinzer, Seissler, Tönjes, Klymiuk, Wolf, Bornstein, 2015: 31–35), “multiple sclerosis, haemophilia, AIDS, Alzheimer’s disease, Parkinson’s disease, Huntington’s chorea, where modern medicine cannot help in a comprehensive way” (Zmyslowski, 2016: 109). “High hopes are also associated with brain cell transplants for the treatment of central nervous system disorders: Multiple Sclerosis, Alzheimer’s, Parkinson’s, or Huntington’s Chorea. Cells for these treatments have been extracted many times from human fetuses after abortions. Due to tremendous ethical controversy, the use of swine cells for transplants brings hope. Such experiments are also already being conducted” (Łęski, 1999: 24.02.2015 – translation mine).

### **Concerns supporting the conceptual isolation of xenotransplantation**

Xenotransplantation, as a controversial issue, besides strong positive emotions that may be regarded as the hope of people waiting for a transplant or the passion of scientists who want to (at least in the premise) change the world to better, is connected with eternal pessimism. The latter also resonates constantly in the world of science trying to hold off further experiments. The proverbial fly in the ointment of the scientific zeal and delight with the idea of animal transplantation was the call to stop xenotransplantation clinical trials for fair scientific reflection made by Fritz Bach and Harvey Fineberg of Harvard University (Bach, Fineberg, 1998: 10.10.2016). The scientists positively argued the existence of a real threat of zoonoses (ERVs/endogenous retroviruses) transmitted along with transplanted cells, tissues or organs. Animal pathogens, after being “transplanted” into the human body, could cause unknown illnesses that could spread within the human species in the course of an epidemic or even a pandemic. Discussion on the reality of this type of threat is not possible at the moment, as, on the one hand, there are theoretical warnings

expressed by scientists, and, on the other hand, the available research results (which prove the safety of this type of treatment) are not sufficiently evident. “The largest retrospective xenotransplant safety study conducted on 160 patients so far has not confirmed this risk. However, when evaluating the reliability of the results, it should be borne in mind that the study was commissioned by the Novartis company, which invests huge sums in the development of xenotransplantation experiments” (Morciniec, 2001: 176 – translation mine).

The concerns related to the innovative method involve not only medical (the threat of zoonotic diseases), moral (i.e. medical experiments on animals), or legal (it is not explicitly regulated in national and international law) aspects, but also social ones (Ravelingien, 2005: 88–90). It is noteworthy that the Xenotransplantation Subcommittee of the Central Ethics Commission of the Swiss Academy of Medical Sciences presented its position on xenotransplantation. It includes a compilation of ethical aspects that affect xenotransplantation, ranking them in three groups. The problems experienced “from the donor perspective were identified as: respect for the rights and dignity of the animal and its claim to health. The ethical interests of the recipient could be considered in the following aspects: the rights of the recipient, the assault on their identity, the clear consent, and the assessment of benefits and risks. The last perspective is defined as «family and society» including: the risk to the public, health, the costs and funding” (Morciniec, 2001: 181 – translation mine).

The social determinants of xenotransplantation as a matter of a particular nature are best reflected in the questions arising in the research space, starting from those relating to “the possibility of changing the identity of a human being by the integration of animal organs and cells. If these fears were confirmed in reality, not only individuals but all humanity would be at risk” (Morciniec, 2001: 179 – translation mine). The merging moral dilemmas e.g.: “Can one fully love with a pig’s heart if the heart is at least a symbol of love?; what will be the emotional reaction of the social environment?; how far will the lack of acceptance by the family affect the recipient’s well-being and their recovery?” (Morciniec, 2001: 180 – translation mine). In their reflections researchers unambiguously underline the social aspect of problems connected with xenotransplantation which must be sought and answered today! “It can be assumed that sooner or later the following research issues / questions will appear among others: will the recipient be mentally and spiritually burdened with the knowledge that his or her heart or kidney comes e.g. from a pig? Will such a person, owning animal organs, feel less valuable compared to other people – and to

what extent? What impact will transplantation of animal organs have on the self-identification of the ill person?” (Morciniec, 2001: 180 – translation mine).

## Conclusions

It is undoubted that xenotransplantation is a part of future medical therapy. “There are a lot of studies in the world now whose results, for obvious reasons, are still covered by mystery. Thanks to them, xenotransplantation has the opportunity to play a very important role in the future of the medical theatre of life.” (Zmyslowski, 2016: 108 – translation mine). At this point, it is necessary to ask whether as humans we have the right to use animals in such a way. Is the society ready for the benefits and risks that xenotransplantation can induce (like any other improperly used medicine)? Also in this case, as in a lens, it brings together multi-faceted interdisciplinary issues of transplantation. The social problem can be split into its problematic aspects: legal, ethical, moral, religious, and medical. The uniqueness and beauty of transplantation, as a means to save people’s lives and health, lies in the idea of an extraordinary gift that within their own free will one offers to another. In the case of xenotransplantation, this “holy principle” does not apply because “the animal ontologically is unable to make a gift from its organs, i.e. it cannot, unlike the human, be a free donor. Adopting such a formulation, it is another form of objectification of animals, from which man takes away tissues and organs without asking for the right to do so” (Morciniec, 2001: 184 – translation mine). The starting point for further consideration is the *a priori* assumption that human life and health are paramount. From this perspective, interspecies transplants appear as an opportunity for terminally ill patients, many of whom die waiting for transplants. The fact that xenotransplants are effective medical treatment will be evident when ... the concept itself will become extinct, “incorporated” (back again) into the term of “transplantation”.

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