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Human Fabrication: An Ethical Viewpoint

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ABSTRACT

3D bioprinting of tissues and organs for the treatment or replacement of diseased body parts is widely recognized as key driver of the so-called 4th industrial revolution. Indeed, 3D bioprinting has the potential to play the role of a game changer in current and future biomedical practices by dramatically impacting on regenerative medicine and surgery and influencing the socio-economical field as a new business model. In spite of the numerous benefits that the 3D bioprinting seems to give to patients and broadly citizens, the fabrication of body parts (or human bio-fabrication) raises several concerns from ethical, legal and social perspectives. In this brief commentary the most prominent issues are considered by making a distinction between new (or renewed) questions - like the need to define the nature of the digitalized human body – and "old" issues as confidentiality, informed consent, intellectual property rights.

Keywords

Engineered tissues, Artificial organs, Human digitalization, Ethics.

3D bioprinting of tissues and organs for regenerative medicine is one of the most fast developing and promising areas of biotechnology [1]. The quick and successful development of 3D bioprinting leads to consider it as key driver of the so called "4th industrial revolution" [2] and encourages to see optimistically the future treatment of several diseases through the regeneration or transplantation of engineered tissues and organs.

Now entering the stage of "evangelism", after dispelling doubts on its efficacy, 3d bioprinting looks at currently the final and challenging goal to make available in the routine medical practice customized organs for successful transplants.

The bioprinting approach has already been used to address problems in transplantology. In 2006, Atala and colleagues performed the first successful transplant of a bio-fabricated bladder [3] and most recently, in 2022, the transplantation of a 3d bio printed ear was conducted by using engineered patient stem cells. The application of 3d bioprinting is not limited only to regenerative surgery but it extends to the field of reproduction [4], pharmacology research for drug and toxicity testing and cosmetology [5,6].

Successes in the field of bioprinting announce the promising possibility for a future replacement of cartilage, blood vessels, internal organs like heart, liver, kidney and they show how this technology can contribute dramatically to the development of a new paradigm in personalized medicine. However, the bio fabrication raises several ethical, legal and social issues that need to be considered now and as this technology evolves. 3d bioprinting is opening new ethical horizons and putting into discussion "old" concepts and categories by raising pressing questions. One of the most prominent refers to the need to think (or re-think?) carefully the "human nature" in light of the effects that this technology has on the human body and its ontological nature. In other words, how should we define a body formed from bio printed organs and tissues? Considering that bio printed organs are developed based on digital model, often using CAD software's, how should we call the assemblage of natural and "digital" body parts? Which kind of moral, legal and social categories and approaches should we use to define the human body, once bio fabricated organs or tissues are implanted inside it?

Furthermore, to which extent should we consider the 3d bioprinting

a therapy and from which point should we see it as "human enhancement"? According to the ethical utilitarian approach, while this technology is largely justified when it improves the health and the quality of life of individuals, it becomes critical when it poses the risk of human nature changes (e.g., enhancement, transhumanism). Again, there is the need to distinguish between bioprinting as medical treatment and as human improvement [7].

Although the issues related to the potential impact of bio fabrication on the very human nature embraces the core of the ethical and regulatory debate on this technology and let see, on the ground, critical questions associated with the potential development of a fabric of humans, other ethical problems cover this process like confidentiality, informed consent, intellectual property rights. Before the 3D bioprinting technology spreads and becomes widely available in the clinical practice, more traditional ethical and regulatory aspects should be considered. First of all, there is a need to develop specific models of informed consents for donation, material manipulation, storage and further use including for commercial and research purposes. Moreover, it is necessary to develop requirements for safety, quality and efficiency of technological procedures. Furthermore, it is of great importance to establish committees for developing regulations and legislations governing this technology by securing the confidentiality of donors and patients like the clear property of these data. Last but not least, it is essential to set regulations for limiting the commercialization of 3d bioprinting and establishing sanctions for illegal traffic of artificial organs.

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