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Ethical Challenges of 3D-printed Organs: Allocation Fairness and Risks in Long-term Use

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Abstract. No matter what era people are, they are pursuing immortality. Although the life expectancy of human beings is getting longer, the development and exploration of the medical field are very limited. Nowadays, with the rapid development of 3D-printed technology, 3D-printed organs have been taken into practice from the theory. This not only shows the advances in medicine and technology, but also provides new hopes for patients with terrible organ failure. However, the application of the technology has raised a double ethical dilemma: on one hand, the limited amounts of printed organs cannot be distributed evenly, which face controversies over the allocation criteria of "severity of illness" and "ability of payment"; On the other hand, there are several legal and technical gaps in the safety and responsibility in the long-time use of the printed organs. The article combines technical principles and policy cases from home and abroad to analyse the challenges and propose some systematic solutions, aiming to provide the reference to balance technological innovation and social ethics.

Keywords: 3D-Printed Organs, Ethical Challenges, Allocation Fairness and Risks in Long-time Use

1. Introduction

1.1. Technical background and research objectives

3D printing organ technology builds organs with physiological functions (such as the heart and kidneys) by stacking cells and biomaterials layer by layer. The principle of 3D printing is theoretically simple and clear; the achievement rate of this technology has always been low. Between July 2014 and July 2019, a research team carried out 69 procedures to retrieve organs from donors after circulatory death (DCD). Out of these retrieval efforts, 49 hearts were selected for connection to an ex-situ normothermic cardiac perfusion system—a device designed to maintain heart function outside the body. Following evaluation, 17 of these perfused hearts were ruled unfit for transplant, with the remaining 32 proceeding to successful orthotopic transplantation in DCD cases. Over a 5-year follow-up period, the survival outcomes for patients who received DCD hearts showed strong results: 96% at 1 year, 94% at 3 years, and 94% at 5 years. For comparison, recipients of hearts from donors after brain death (DBD) demonstrated lower survival rates across the same time frames, at 89%, 83%, and 82% respectively. In terms of post-transplant

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complications, 31% of DCD heart recipients needed temporary support from extracorporeal membrane oxygenation (ECMO) immediately after surgery to manage delayed graft function. Importantly, when compared to a parallel group of patients who received hearts from standard-criteria DBD donors during the same period, the rate of rejection in DCD recipients showed no statistically significant difference [1]. However, rapid technological development raised some significant ethical controversies. The first question is about fairness of distribution: “How to avoid printed organs only belonging to the rich and powerful people?” The second one is in relation to the safety in long-term use: “Does the biocompatibility and cell stability of printed organs meet the conditions for long-term clinical use?” This essay explores solutions to the above two issues by analysing 3D technological principle, medical ethics literature and legal norms.

2. Methods

This study uses a comprehensive approach including technical analysis, ethical and legal research to systematically address the ethical challenges of 3D - printed organs.

2.1. Technical analysis

Use the peer - reviewed journals, technical reports and patent documents related to 3D bioprinting from 2013 to 2025. Collect some data on clinical applications. Quantitative analysis was used to compare the current gap between supply and demand in traditional organ transplantation with the potential of 3D - printed organs.

2.2. Ethical and legal research

Constructed a double - framework analysis of medical need and payment ability to assess the fairness in allocation. And also examined the existing organ transplant laws in domestic and aboard to identify drawbacks in them.

By following these kinds of methodology, the study ensures rigor in analysing ethical challenges and also provides a new framework for future research in medical technologies.

3. Overview of 3D-printed organ technology

3.1. Technical principles and development history

3.1.1. Technical principles of 3D bioprinting

There are many types of technologies for 3D printing, and over time, 3D printing has also been divided into various types of technologies for various purposes. When people want to use 3D printing technology, they can choose the one that is most suitable for the current situation and conduct research. Figure 1 shows the classifications of 3D printing production techniques [2]. Nowadays, because of the rapid development of 3D-printed technology, this technology is starting to help solve various problems in various fields, such as 3D bioprinting. 3D bioprinting is a branch of additive manufacturing, which can construct three-dimensional biological structures through layer-by-layer biomaterials and living cells. 3D bioprinting has gone through four stages, from using non biocompatible materials to being able to use live cells and proteins now. There are several strategies in the tech of 3D bioprinting, such as extrusion based, spray based, photopolymerization based, and magnetic bioprinting [3]. The core workflow involves digital modelling, bioink preparation. And the

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printing techniques involves extrusion-based bioprinting, spray-based bioprinting, photopolymerization-based bioprinting and magnetic bioprinting.

Digital modelling is using medical imaging to create 3D models of target organs for patient specially. Bioink bioprinting means formulate bioinks composed of stem cells to support cell survival and tissue formation [3]. Extrusion-based bioprinting deposits bioinks through a nozzle under mechanical pressure, suitable for constructing thick tissues. Spray-based bioprinting uses aerosol droplets to precisely place cells, used in delicate structures like vascular networks. Photopolymerization-based bioprinting puts light to crosslink bioinks into solid structures, enabling use high-exact fabrication of complex geometries. Magnetic bioprinting utilizes magnetic fields to guide cell-laden microcarriers into predict shapes, enhancing the control over tissue architecture [3]. But overall, 3D-printed organs are just like a printer based on layered design, using computer scanning to obtain patient organ data as files, and using stem cells, growth factors and so on as ink to print organs layer by layer.

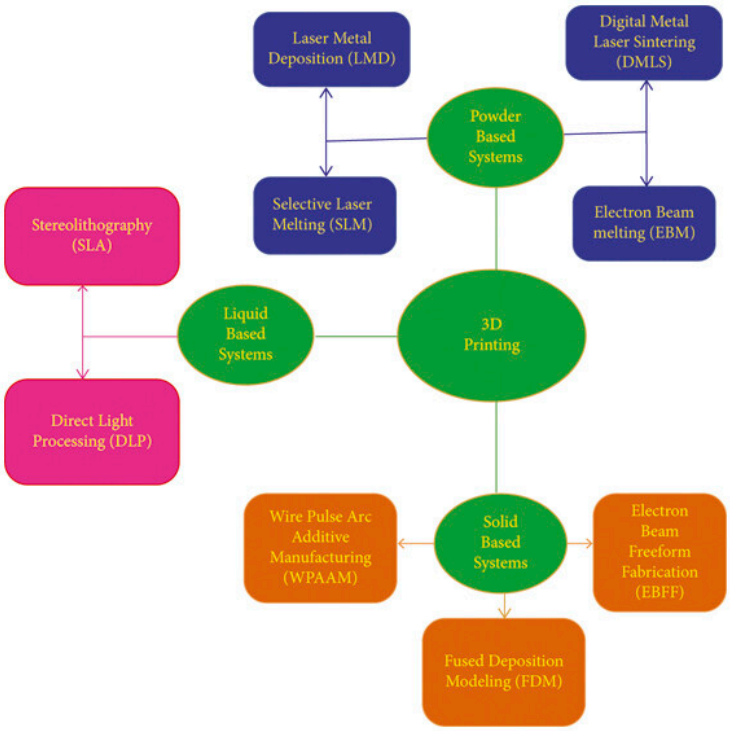

Figure 1. Classifications of 3D printing production techniques

3.1.2. The history of the 3D printing technology

The technology has developed through five phases, which develops from non-living to living building blocks:

Based on the properties of raw materials and the characteristics of printed products, the evolution of 3D printing technology in biomedical applications can be categorized into five distinct stages. As illustrated in Figure 2, these stages progress sequentially from the utilization of non-living materials to the incorporation of living building blocks [3].

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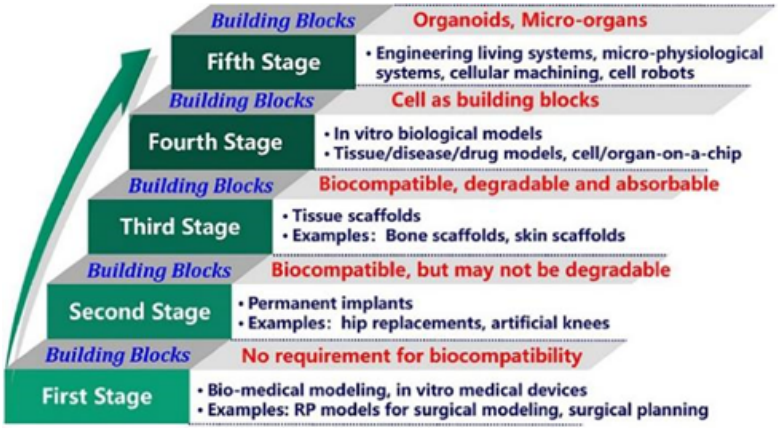

Figure 2. 3D printing technology's advancement in biomedical applications is categorized into five stages, with the classification based on the properties of the building blocks involved

Phase 1 (Pre-2010): The first stage is to print appliances that serve as surgical models and in vitro medical devices that do not come into contact with the human body and therefore do not need to be biocompatible [4]. Primitive non-biocompatible materials were used to fabricate anatomical models for surgical planning, lack of biological functionality.

Phase 2 (2010–2015): The second phase involves 3D printing permanent implants such as hip replacements and artificial knee joints. These implants require some degree of biocompatibility, but not necessarily degradability [4]. Transition to biocompatible polymers and the first try to incorporate non-living cells, leading to some simple tissues like skin grafts.

Phase 3 (2015–2020): The third stage involves typical scaffold-based tissue engineering – the 3D-printed structure acts as a scaffold for cell growth and tissue formation. Ideally, the materials used to fabricate tissue-engineered scaffolds should be biocompatible, biodegradable, and resorbable to fit the process of native tissue formation and infiltration [4]. Breakthrough in vascularization and multi-cell type integration, exemplified by Organovo's mini liver tissue (2016), which exhibited partial metabolic function [5].

Phase 4 (Post-2020): The fourth stage is to print living cells directly as building blocks to build biomimetic tissues or organs. 3D bioprinting enables the direct fabrication of in vitro biologics for use in regenerative medicine and pharmaceuticals [4]. Focus on functional organogenesis, including the development of perfumable blood vessels and innervated tissues, as seen in the CALEC technology trial for corneal regeneration [6].

Phase 5(2020-Nowadays): Lately, 3D printing technology applied in the biomedical field has progressed to the fifth stage. In this stage, organoids or micro-organs are engineered and assembled to produce complex in vitro living systems or micro physiological systems [4].

In the historical research of 3D printing, there have also been some key breakthroughs, for example: an American company named Organovo successfully printed mini liver tissue with a depth of 0.5 millimetres and a width of 4 millimetres in 2016, which has partial liver function [5]. At the same time, the CALEC technology clinical trial developed by Massachusetts Eye and Ear Hospital and Harvard Medical School in the United States used autologous corneal limbal tissue cells, and the patient's vision recovery rate was maintained 92% in 18 months after the treatment [6].

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3.2. Clinical application prospects

In the world, there are over 3 million patients waiting for organs transplantation [7], and this technology can solve the shortage of traditional organ transplant donors in theory. However, at present, the production of printed organs has some significant issues: Printing a complex organ, such as the heart, will take more than 72 hours and the success rate is only 35%, in addition, the cost of printing a single kidney is very high about $250000, far more than traditional organ transplant surgery [8]. Compared with traditional transplantation, although the donor availability is unlimited and the immune rejection risk is much less than the high risk of traditional transplantation, the surgical complexity and long-term safety of 3-D printed organs are not clear. It requires a lot of specialized bioprinting expertise, while traditional transplantation has established surgical protocols. Otherwise, the long-term safety of traditional transplantation is well-documented in decades of follow-up, while the long-term safety of 3-D printed organs are unknown limited by less clinical data.

4. Results and discussion

4.1. Ethical challenges of fairness in allocation

Nowadays, organ allocation is mainly based on the "end-stage organ failure score", which means if you have a severe condition, you will be given priority to a transplantable organ. For example, the figure below is that Figure 3 of one study illustrates the ability of pCLIF-SOFA scores to distinguish between PELD/MELD scores in predicting the risk of death in paediatric patients with acute liver failure (ALF) in Figure 3 [9]. According to the score, we can get the basic organ failure degree and then allocate the organs to different kinds of patients.

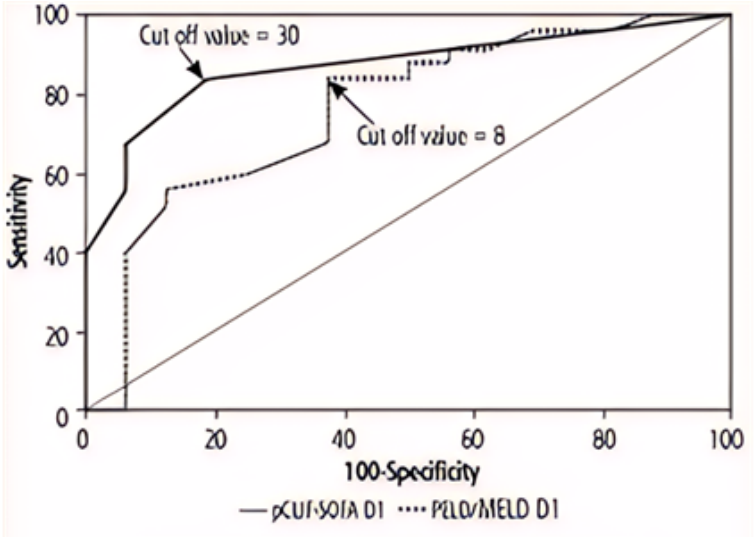

Figure 3. The discrimination ability of the pCLIF-SOFA and PELD/MELD score

However, 3D-printed organs face double standard controversies due to limited production of the printed organs. Some people support advocate for medical priority: critically ill patients, should be given priority access to transplantation opportunities, but it is hard to achieve because in every year, there are many new and potential patients in different kinds of degrees. If those patients have to wait until they become severe before treatment, it would violate the ethical principles of medicine. There

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are also another group of people emphasize the payment fairness. They believe that self-funded patients should be given priority than patients who receive treatment over medical insurance. However, if this is done, it will definitely lead to a phenomenon of "rich people first" in society, just like many movies where poor people cannot protect their hearts that should have been given to them, so they can only resist them with their lives. The World Health Organization [10] (WHO) also pointed out that “Without regulation, 3D printed organs may become a typical case of "biomedical technology privilege” [9].

4.2. Ethical and legal risks associated with long-term use of printed organs

4.2.1. Uncertainty of health risks

Due to the lack of perfect cases in 3D-printed organs so far, the biodegradability and immune rejection of printed organs still require long-term research and experiments. According to the United Network for Organ Sharing (UNOS) published in January 2019, there are 124,206 men, women, and children currently in need of a lifesaving organ. With barely 26,448 transplants performed annually and only 12,740 people registered as donors, this, unfortunately, equates to 8,000 individuals dying per year in the United States alone [10]. Besides, on an ethical level, doctors should consider that patients should be given right to inform consent, such as whether the patient can fully understand the meaning of “long-term risk unknown” and whether they can clarify the risks and side effects after transplantation. Secondly, another ethical issue, who should bear the responsibility if technical defects become apparent after transplantation?

4.2.2. Legal gaps and responsibility definition

Due to the lack of legal regulations and requirements for printed organs worldwide at present, no country can promise the consequences of surgery. And there is a report in 2023, a hospital in Germany experienced an infection after a printed organ transplant, and the patient sued the hospital, but he was rejected due to insufficient legal basis. Now, putting yourself in someone else's shoes and thinking about it. If someone needs 3D-printed organs but there is no legally protected hospital to help them with the surgery, they will be very desperate. So, the country should immediately establish some basic laws for manufacturers and hospitals of 3D-printed organs to protect the patients.

5. Domestic and international policies and case analysis

5.1. International experience

At present, many of the countries' policies on 3D printed organs are still in the process of continuous development and improvement. On one hand, it is wonderful to encourage technological innovation to solve organ shortages problems, and on the other hand, it is necessary to face to the ethical, legal, and safety challenges raised by the new technology. For example, in ethical part, it has issues like fairness in organ allocation and the privilege of technology; In terms of law, there is hardly no defined and clear regulation in legal and also no responsibility definition of 3D-printed organs; About safety, it is essential to establish the same standards to ensure the quality and safety of 3D-printed organs. However, overall, there are almost no country has yet built a regulate, comprehensive and complete policy system for 3D-printed organs.

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5.2. Domestic exploration

Since the successful development of China's first 3D bioprinter capable of printing biomaterials and live cells at Hangzhou University of Electronic Science and Technology in 2013, research on 3D-printed organs in China has made some rapid progresses. Otherwise, Tsinghua University and other prestigious universities in China have also started researching and inventing 3D printers, promoting the development of China's new bioprinting technology shown in Figure 4 [4].

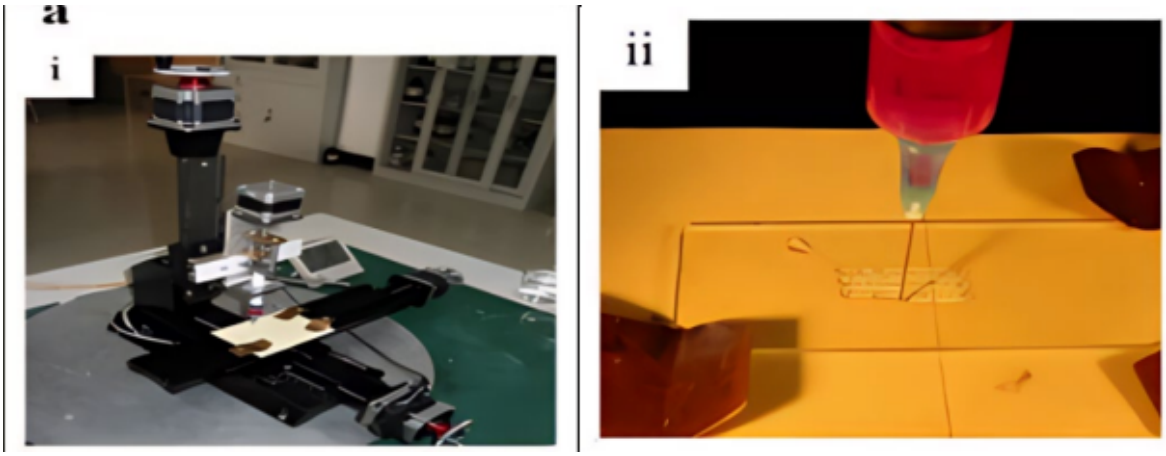

Figure 4. Notable early endeavours in extrusion-based 3D bioprinting include: (i) the first-generation cell assembly printer developed by Tsinghua University in 2002; (ii) the corresponding printing process

Domestic research teams have successfully printed various tissues and organ units using 3D printing technology, such as blood vessels, liver units, ear cartilage tissues, kidney units, etc. In 2015, the mass production of 3D-printed liver units with stable functions was achieved, which promoted the research and development of artificial liver and provided a new solution for new drug.

In terms of policies, like other countries, domestic policies on 3D-printed organs are also constantly developing and improving. Although some technological achievements have been made, it is still impossible to manufacture complex organs with complete functions that can survive for a long time, and there are also many shortcomings and problems. However, with the rapid development of technology, if live organ printing makes some breakthroughs in the future, it will face a series of ethical and legal issues, such as fairness in organ allocation and responsibility definition. The relevant policies and regulations should need to be further clarified and improved at that time.

6. Solutions to ethical challenges

6.1. Establish a transparent allocation mechanism

Organ sources and allocation processes should be recorded to ensure resource and a committee made up with medical experts, ethicists and patient representatives should be formed to develop the allocation standards. And the allocation criteria should take into account with both the severity of the condition and the ability to pay for the expenses. However, to avoid discrimination, a tiered financial assistance model can be incorporated, where patients with limited financial means can still

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access organs based on their medical urgency, with costs covered through a combination of government subsidies, charity funds and insurance policies.

6.2. Strengthen patient rights protection and informed consent mechanisms

Establish a standardized informed consent framework for 3D-printed organ transplantation, requiring medical institutions to provide patients with comprehensive information about technical risks, alternative treatment options and post-transplantation follow-up obligations. This framework should mandate interdisciplinary counselling teams—comprising transplant surgeons, ethicists, and psychologists—to assist patients in making autonomous decisions. Additionally, institute a post-transplantation patient rights protection mechanism, where medical teams are legally obligated to provide at least 5 years of free follow-up care and organ function monitoring, with costs shared by manufacturers and insurance providers. To prevent exploitation, establish a patient advocacy committee to mediate disputes between clinical teams and recipients, ensuring that vulnerable populations are not coerced into experimental procedures. Such measures would embed ethical safeguards in the patient journey, balancing scientific innovation with individual autonomy and welfare.

6.3. Improve laws and technical specifications

Develop the "3D Bioprinting Organ Law" to clarify the responsibility of manufacturers, medical institutions and research teams, in order to better divide responsibilities. At the same time, establish a "life cycle monitoring" system for printed organs, requiring companies to provide at least 10 years of tracking data to ensure that printed organs can be used for a long time and confirm the average usage cycle of organs.

7. Conclusion

The ethical challenge of 3D printing organ technology is essentially the conflict between the rapid speed of technological innovation and the slow development of social norms. In short term, a simplified management plan should be made through collaboration between subjects such as mechanics and ethics. In long term, global legal development should be promoted to ensure technological reliability and safety. In future research, every country should evaluate the ethical impact of 3D printed organs, to provide a basis and reference for policy-making.

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