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ETHICAL CONCERNS OF 3D PRINTING IN MEDICINE

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ABSTRACT: *3D printing, or additive manufacturing, powers the production of three-dimensional objects from digital files, showing significant utility in various fields, including medicine. Within healthcare, 3D printing has brought about revolutionary advances, particularly in the creation of patient-specific medical devices and implants, thus enhancing personalized patient care. A major application of this technology in the medical field is the formulation of prosthetics, enabling the fabrication of custom items tailored to individual patient anatomies, providing increased comfort and a natural fit. Additionally, this technology promotes cost-effective production and accelerated turnaround time compared to conventional manufacturing processes. Additionally, 3D printing is useful in creating surgical guides and models, thus facilitating medical professionals in meticulous pre-surgical planning and trial using accurate models of organs and body parts. At the same time, the generation of precise surgical guides increases the accuracy of surgical efforts. As the footprint of 3D printing technology expands, the ethical concerns that arise regarding its application require diligent attention. Therefore, it is imperative that medical professionals, regulators, and society navigate these ethical considerations, ensuring the safe, equitable, and beneficial use of this technology across all patient demographics.*

KEYWORDS: *ethics, standards, healthcare, 3D printing, additive manufacturing, effectiveness.*

INTRODUCTION

Introduction: The advent of 3D printing in medicine has markedly transformed approaches to patient care, enabling a new era of personalized and efficacious treatment modalities. However, this innovative technology, while groundbreaking, engenders significant ethical quandaries that demand scrutiny and address [1]. Critical concerns pivot around patient privacy, informed consent, intellectual property rights, and quality control of printed medical devices and implants. When constructing patient-specific items, questions loom regarding ownership and access to design files and patient medical data. Additionally, issues pertaining to the accuracy, safety, and potential unauthorized reproduction of copyrighted medical devices utilizing 3D printing technology arise, necessitating meticulous consideration to safeguard the ethical application of this technology.

In recent years, a surge in research and dialogue surrounding the ethical implications of 3D printing in medicine has manifested, resulting in a plethora of books and scientific publications delving into this subject [2]. This body of literature explores a spectrum of ethical dilemmas, spanning from the creation of potentially unregulated and hazardous medical devices to the exacerbation of existing health disparities and ethical matters enveloping the 3D printing of human tissues and organs. Numerous publications emphasize the pressing need for comprehensive regulatory frameworks and oversight to ensure the safety and efficacy of 3D-printed medical devices, alongside a call for amplified collaboration among medical professionals, regulatory bodies, and society. Such collaborative efforts are pivotal to navigate and address ethical concerns judiciously, assuring the safe, equitable, and ethical deployment of 3D printing technology across patient care domains.

ETHICAL CHALLENGES OF 3D PRINTING IN MEDICINE

Ethical Dilemmas in Medical 3D Printing

One paramount ethical conundrum in 3D printing within medicine centers around informed consent. Achieving comprehensive patient understanding of the risks and benefits, especially regarding devices or implants

crafted using live cells or tissues, is crucial. This encompasses disclosing technological limitations, such as possible device failures and potential long-term health impacts.

Quality control represents another ethical hurdle, accentuating the necessity to formulate and adhere to standards and guidelines for generating 3D-printed medical devices and implants, especially pertinent in bioprinting, which fabricates structures using living cells[3].

Intellectual property also surfaces as a critical concern, highlighting worries regarding patent infringement and unauthorized reproduction of copyrighted designs. Addressing these issues necessitates clear regulations and guidelines, promoting transparency, accountability, and ethically considering 3D printing during design and development phases. It is pivotal to examine the utility, beneficiaries, and associated risks of 3D-printed medical devices or implants during the design phase. Evaluations should embrace safety, efficacy, and potential societal impacts, considering the direct influence on patient health and well-being.

List of Ethical Challenges:

Quality Control and Safety: Safeguarding the safety and efficacy of 3D-printed devices.
Informed Consent: Assuring patients comprehend the risks and benefits of 3D-printed devices before consent[4].
Intellectual Property: Aligning intellectual property protection with innovation and affordable healthcare accessibility.
Privacy and Confidentiality: Protecting patient privacy and confidentiality.
Equity and Access: Confirming equitable access to 3D-printed devices without worsening healthcare disparities.
Transparency and Accountability: Ensuring transparency in material sourcing and accountability for adverse events in 3D printing use.
Social and Cultural Considerations: Acknowledging cultural sensitivity and potential disruptions to social norms and practices.
Positive Ethical Aspects:

Improved Patient Outcomes: Customized implants and surgical tools from 3D printing enhance patient outcomes and life quality[5].
Increased Accessibility: It potentially makes medical devices more accessible and affordable, especially in developing regions.
Faster Production and Reduced Waste: Minimizing production time and waste compared to traditional manufacturing.
Enhanced Surgical Planning: Facilitating detailed patient anatomy models for comprehensive surgical preparation and risk reduction.
Advancement in R&D: Accelerating the development of new medical devices and treatments, potentially catalyzing healthcare breakthroughs.

"Surface Roughness: Ethical and Technical Perspectives in Implant Making"

Exploring the dual domain of 3D printing and CNC machining opens a dialogue on the precision and customization achievable in the medical device manufacturing sphere, especially concerning surface roughness in implants. The ideal surface finish is critical in medical devices to minimize bacterial adhesion, reduce the risk of infection, and enhance biocompatibility.

Consider an illustrative case of manufacturing a hip joint implant, diving into the nuances of 3D printing and CNC machining. Utilizing a 3D printing method, such as selective laser melting, can provide intricate and tailored geometries crucial for producing patient-specific implants. These are potentially advantageous in ensuring optimal integration with the patient's anatomy. Nevertheless, the initial surface roughness of the printed implant might necessitate further post-processing (like polishing), which could introduce additional steps and costs into the production. (6)

Contrastingly, CNC machining might offer more direct control over the surface finish, producing smoother surfaces right off the machine, albeit with potentially more limited capabilities in crafting complex internal geometries. The ability of CNC machines to achieve a superior surface finish might sometimes be offset by its limitations in customization, especially when compared to 3D printing. The deliberation becomes complex when considering the additional post-processing steps that might be imperative for 3D-printed components to ensure adherence to biomedical standards.(7)

Weighing the ethical implications within this technological context becomes pivotal. The intersection of patient safety, device efficacy, and equitable access to these technologies brings to light an array of questions regarding affordability, insurance paradigms, and regulatory navigation. Addressing these questions is fundamental in fostering an environment where innovations in both 3D printing and CNC machining continue to coalesce and evolve, thereby aligning technological advancements with ethical manufacturing practices.(8)

In a field where both technologies present their unique merits and limitations, a synergistic approach that harnesses the customization capabilities of 3D printing with the precision of CNC machining could pave the way towards optimized medical device production. The careful integration and ethical application of both technologies will undeniably sculpt the path ahead for medical device manufacturing, ensuring it is steered towards more comprehensive, patient-centric solutions.

"Precision in Medical Manufacturing: Navigating Surface Quality and Accuracy

Surface quality and dimensional accuracy stand as pivotal pillars in the realm of medical device manufacturing, intrinsically linking technical specifications to patient safety and device efficacy. The significance of these parameters transcends technological considerations, entwining with ethical concerns and directly influencing the performance and biocompatibility of medical devices and implants.(9)

High-caliber surface quality is crucial, mitigating the risk of bacterial adhesion and thereby, reducing potential post-implantation infections and enhancing wear resistance. Conversely, dimensional accuracy ensures that medical devices, especially patient-specific ones, adhere precisely to design specifications, preventing malfunction and the subsequent need for additional interventions, which present both risks and costs.

In the context of 3D printing and CNC machining, each presents distinct advantages and challenges related to surface and accuracy. While 3D printing excels in creating intricate, custom geometries, managing surface finish can be a hurdle. CNC machining often yields superior surface finishes and tight tolerances but may be constrained in creating complex structures.

EXAMPLES OF ETHICAL CHALLENGES

CASE NO.1: In 2019, a 23-year-old woman in the Netherlands underwent surgery to replace her entire lower jaw with a 3D-printed titanium implant. The implant was designed using computer-aided design (CAD) software and printed using an electron beam melting (EBM) technique. The surgery was performed at the University Medical Center Utrecht, and the implant was manufactured by LayerWise, a Belgian company that specializes in 3D printing medical implants.

While the surgery was successful, there were concerns about the quality control and regulation of 3D-printed medical devices. The implant was the first of its kind in the Netherlands, and there were questions about the safety and efficacy of using a 3D-printed implant for such a complex and critical procedure. Some experts raised concerns about the lack of standardized regulations and guidelines for 3D-printed medical devices, which could lead to inconsistencies in quality control and potential safety issues for patients.[10]

Despite these concerns, the patient was reportedly satisfied with the results of the surgery, and the implant was functioning as expected at the one-year follow-up. This case highlights the need for ongoing evaluation and regulation of 3D-printed medical devices to ensure their safety and effectiveness in clinical practice.

Unique collaboration: The 3D lab and head and neck surgeons of the Netherlands Cancer Institute have worked for years on this groundbreaking innovation together with the Dutch company Mobius 3D Technologies (M3DT). This application is expected to be more widely applicable in 2023/2024. In the meantime, research is underway to further expand these techniques for implants elsewhere in the face and skull. Health Holland has made this development possible by granting an innovation grant.

Fig.1. With 3D Printed titanium Lower jaws.

CASE NO.2:

In 2018, a team of doctors at Phoenix Children's Hospital in the United States used 3D printing technology to create models of a patient's heart to assist with a complex surgical procedure. The patient was a six-year-old girl with a rare congenital heart defect that required a highly specialized surgical approach. The doctors used the 3D-printed heart models to create a customized surgical plan, which allowed them to visualize the heart in three dimensions and to practice the surgical procedure beforehand. While the use of 3D-printed heart models was successful in this case, there were concerns about the cost and accessibility of 3D printing technology for medical use. 3D printing technology can be expensive, which may limit its accessibility for some hospitals and patients. Additionally, there are concerns about the regulation and oversight of 3D-printed medical devices, as there are currently no specific regulations in place to ensure their safety and effectiveness.[11]

Despite these concerns, 3D-printed heart models have the potential to revolutionize surgical planning and improve patient outcomes. As the technology becomes more advanced and accessible, it will be important to address these ethical challenges and establish clearguidelines and regulations for the use of 3D printing in medicine.

Fig.2 Heart Models Help Save Children's Lives, Phoenix Children's Heart Center (Source)

CONCLUSION

The impact of 3D printing has transformed the healthcare industry by providing customized medical solutions, faster production, and reduced waste. However, ethical challenges must be addressed to ensure the safety and effectiveness of 3D-printed medical devices. To overcome these challenges, regulations, guidelines, and standards need to be established to promote transparency and accountability. It is essential to consider the ethical implications of 3D printing to ensure that it benefits patients and society at large. However, it is crucial that we address the ethical challenges associated with 3D printing to ensure that patient safety and well-being remain our top priority. In summary, the ethical considerations of engineers in the field of 3D printing in medicine are crucial to ensure that patients receive safe and effective medical care. Engineers must uphold high ethical standards and consider the impact of their work on patient health and well-being.

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