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Editorial

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3D Printing of Biomaterials: Is It Disruptive or Destructive?

Muhanad M. Hatamleh

Department of Applied Dental Sciences, Faculty of Applied Medical Sciences, Jordan University of Science and Technology, Irbid 22110, PO Box 3030, Jordan

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1. Introduction

3D printing represents a new era in the field of digital manufacturing, finding its applications in many industries, such as healthcare, automotive, and aerospace. In particular, 3D printing has the potential to completely revolutionize the manufacturing process for implants, medical equipment, and even human tissues within the healthcare industry. The rapid rise of 3D printing raises fundamental questions i.e., Is this technology truly revolutionary, or does it perhaps take us in a direction other than we might expect? This editorial aims to consider the dual-edged nature of 3D printing, with particular respect to biomaterials, and argue for a more selective and responsible approach in using it. Furthermore, the importance of regulatory frameworks in ensuring the safety and effectiveness of 3D printing for healthcare applications cannot be overlooked. While such frameworks are well-established in the EU, UK, and USA, they are notably absent in the MENA region.

2. The Promise and Peril of 3D Printing in Healthcare

3D printing is offering unparalleled opportunities in healthcare, from designing patient-specific implants to bioprinting tissues, and more. The capability for the manufacturing of complex geometries and custom parts on demand can have the potential to improve patient outcomes while economically reducing costs to a great extent. According to a report by Grand View Research, the global healthcare 3D printing market is going to augment to a valuation of $6.08 billion by 2027, due to gains in biocompatible materials and increased demand for personalized medicine [1]. This tremendous growth also brings up a couple of ethical and practical issues.

One of the main issues could be considered as how much 3D printing is overapplied. The enthusiasm toward what it can accomplish oftentimes translates into indiscriminate use or making applications without adequate thought to whether it really provides advantages over conventional ways of manufacturing. With regard to customized parts, 3D printing does very well; however, for every application, it is not always the most efficient and cost-effective alternative. Traditional manufacturing processes, such as injection molding and CNC machining, are more applicable to mass-produced and standardized medical devices.

3. Guidelines for Adopting 3D Printing in Healthcare Workplaces

Ensuring the responsible and effective use of 3D printing in healthcare requires adhering to the set of guidelines meant to assess intended use, comparative advantage, time efficiency, ease of use, and cost.

1. Intended Use Assessment: The primary use of 3D printing should be focused on applications requiring personalization, such as patient-specific implants or prosthetics, as well as anatomical models that assist surgeons in planning surgical procedures. If the intended use does not involve such customization, traditional manufacturing may be more appropriate [2].
2. Advantages over Manual Production: It should be justified with apparent advantages when using 3D printing over conventional manual production. It is particularly useful for creating complex geometries and intricate designs that are difficult or impos-

Corresponding Author:
Muhanad M. Hatamleh, Department of Applied Dental Sciences, Faculty of Applied Medical Sciences, Jordan University of Science and Technology, Irbid 22110, PO Box 3030, Jordan, muhanad.hatamleh@gmail.com

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sible to achieve manually. However, if a task is simple and can be performed manually with precision, 3D printing will not have many advantages for such cases [2].

3. Aid in Time Efficiency: In healthcare, saving time is of essence and directly related to patient benefits. Despite the fact that 3D printing for some customized devices cuts down on the time spent in production, there is a need to consider the entire flow right from design through printing to post-processing for an actual time benefit [3].
4. Ease of use: The main focus at a healthcare workplace with regards to the adoption of 3D printing should be to ensure ease of use. Facilities have to select the solutions for 3D printing that are accessible by clinicians and technicians, requiring minimum training so that the chances of error will be at a minimum [4].
5. Analyze Cost-Effectiveness: The aspect of cost is often an overriding factor in healthcare. While 3D printing is relatively cost-effective for certain applications due to the elimination of mold requirements and minimal material waste, this may not be the case universally. Thus, a cost-benefit analysis must be performed to tell if long-term benefits justify the initial investment [5].

4. The Need for Selectivity and Cross-Contamination Concerns

The key to optimizing the benefits of 3D printing lies in selectiveness—deciding what to print. While 3D printing offers significant design freedom, it also presents limitations in material compatibility and post-processing requirements. In the case of biomaterials, the opposite of this statement becomes even more important. Biomaterials are needed when implants and prosthetics have to safely interface with the human body, yet not all 3D printers can satisfactorily manage such materials [6].

Another key issue is the potential of cross-contamination. Most 3D printers today have the capability to print a number of materials simultaneously, which too often results in unintentional mixing and contamination. Trace amounts of non-biocompatible material could render a medical device inoperable inside the human body. In order to minimize this risk, strict handling protocols should be carried out along with running the printers dedicated to only biocompatible materials [7].

5. The Issue of Sustainability and Recyclability

The issue of sustainability and recyclability cannot be viewed as an issue of trifle insignificance while 3D printing is increasingly becoming an everyday thing. Most 3D printed objects are made from plastics, which again means contribution to plastic waste. In healthcare, where single-use devices are prevalent, the issue of waste is of paramount importance. Consequently, it is essential to develop recyclable 3D-printed models to address this concern. [8]. Some companies are only now looking into biodegradable materials for 3D printing, but even so, it is an uphill task to ensure that they are recyclable and suitable for the medical field in their application [9].

6. Regulatory Frameworks: A Critical Missing Piece in MENA

It is imperative to establish robust regulatory frameworks, as the technology is rapidly advancing in the healthcare sector.

The EU, UK, and US each have comprehensive regulatory frameworks that guide the application of 3D printing in the manufacture of medical devices, ensuring their safety and efficacy. The MDR, which took effect in May 2021, presents quite a strict set of regulations for the manufacturing and marketing of medical devices in Europe, to which 3D printing is no exception. Conformity assessments shall be performed by the manufacturer, as stated by MDR, along with detailed technical documentation and ISO standards compliance, especially for high-risk devices [10,11].

It has similarly laid guidelines concerning 3D printing of medical devices in the UK by the Medicines and Healthcare Products Regulatory Agency, and it emphasizes on risk management, material safety, as well as sterilization procedures [12]. The MHRA has established that any 3D-printed medical device must meet the necessary safety standards before being placed on the market [13].

The FDA has been at the forefront in the regulation of 3D printing in the United States. Technical considerations by additive manufacturing and quality system regulations should, therefore, be addressed by the FDA guidelines. This includes the necessity of an adequate Quality Management System (QMS) and adherence to UDI requirements, crucial for tracking and monitoring medical devices [10].

However, there is an evident lack of similar developed regulatory frameworks in the MENA region, which creates a threat to patient safety and product quality. Since standardized regulations are not imposed in the countries of MENA, 3D-printed medical devices are not as stringently tested and validated as under the regular use of EU, UK, and USA regulatory frameworks. In this respect, bridging this regulatory gap is very significant and important to ensure the realization of benefits in a safe and effective way of 3D printing for healthcare across the region.

7. Conclusion

In conclusion, while 3D printing in healthcare holds significant promise, it must be approached with caution and responsibility. The technology is disruptive and can be destructive if it is used irrationally. Being selective about what is being printed, ensuring materials are safe for the human body and biocompatible within established regulatory standards, and being oriented toward sustainable development will grant numerous benefits of 3D printing without falling into its trap. The future of 3D printing in health care is bright, but it needs consideration and guidelines for steps forward in ways that emphasize patient safety, cost effectiveness, environmental sustainability, and robust regulatory oversight. Whether 3D printing of biomaterials proves disruptive or destructive mainly depends on how it is being used. Going forward, informed decisions have to be made that balance innovation with caution so that 3D printing serves as a force for good in healthcare. Most of all, this will be addressing the regulatory gaps, especially those existing in regions like MENA, and will enable sustainable and responsible innovation.

List of Abbreviations

CNC	Computer Numerical Control
MDR	Medical Device Regulation
ISO	International Organization for Standardization
MHRA	Medicines and Healthcare products Regulatory Agency
FDA	Food and Drug Administration
QMS	Quality Management System
UDI	Unique Device Identification
MENA	Middle East and North Africa

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AI Declaration

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