Additive manufacturing in the biomedical field: current status and future prospects

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Abstract

Additive manufacturing is currently used in many sectors and industries, and research continues into its potential for a variety of applications. Compared to traditional manufacturing processes, it is based on the addition of material and allows the production of intricate geometries and customised designs.

In the biomedical field, the seven additive manufacturing processes categorized by the ISO/ASTM standard are applied in the production of implants and prostheses adapted to patients, surgical models for the study of diseases, and medical devices and instruments. In addition, a further technique, bioprinting, allows the production of tissues and organs from living cells.

This paper analyses the current situation of this technology, looking its origins and presenting the future prospects for the sector.

Keywords: 3D-printing, Additive Manufacturing, biomedical applications, biomedicine, bioprinting

1. Introduction

Additive Manufacturing (AM) is a technology that evolved from rapid prototyping techniques. It is based on adding material in solid, liquid or powder form, layer by layer, in a defined space, using electronic means.[1] AM processes involve the use of computer software, a 3D printing or manufacturing machine, and the materials of which the part is composed.[2] This manufacturing process is shown schematically in *Figure 1*.

ISO/ASTM 59000 standard distinguishes seven different AM techniques:[3] Material Extrusion (ME), Powder Bed Fusion (PBF), Vat-Photopolymerization (VP), Material Jetting (MJ), Binder Jetting (BJ), Direct Energy Deposition (DED) and Sheet Lamination (SL), all with varying applicability in the biomedical field. *Figure 2* illustrates each of these techniques.

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Additive manufacturing processes for elements with biomedical applications do not usually consider a single technique on its own, but rather use the one that is better suited to each specific situation.

Some authors also include a complementary technique, bioprinting.[4] It typically involves the deposition of cells using nozzles like material jetting. The deposition is not direct, as the cells are contained in a material called bioink, so that small volume droplets containing living cells are placed. This technology achieves microscopic resolutions.

In this review, key aspects of additive manufacturing in the field of biomedicine will be explored, aiming to answer the following questions:

1. Origins of additive manufacturing in biomedicine
   a. What are the historical foundations of additive manufacturing in the field of biomedicine?
2. Conventional AM techniques in biomedicine
   a. What is the significance of convention al AM manufacturing techniques in biomedicine?
   b. What are the potential growth prospects associated with these techniques?
3. Advancements and expectations in bioprinting
   a. How has bioprinting evolved and what are the current state-of-art developments?
   b. What are the existing limitations that must be overcome for further advancements in bioprinting?

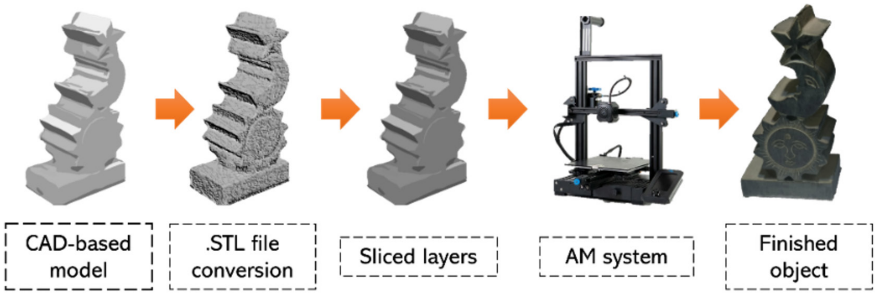

Figure 1. Additive manufacturing process

	Material Extrusion (ME)	Vat Photo-Polymerization (VP)	Material Jetting (MJ)	Binder Jetting (BJ)	Powder Bed Fusion (PBF)	Direct Energy Deposition (DED)	Sheet Lamination (SL)
DESCRIPTION	Material is selectively dispensed through a nozzle	UV initiated polymerisation cross section by cross section	Droplets are selectively deposited	Liquid bonding agent selectively deposited to join powder materials	Thermal energy selectively fuses regions of a powder bed	Focused thermal energy fuses materials as deposited	Sheets of material are bonded to form an object
SETUP							

Figure 2. Additive manufacturing techniques

By thoroughly exploring these questions, it is intended to provide a comprehensive understanding of the origins, growth prospects, and limitations of additive manufacturing techniques in the field of biomedicine.

2. Methods

The review process took place from November 2022 to January 2023. The steps followed were as described below:

1. Identifying the subject matter
   Analyse the development of additive manufacturing techniques in the field of biomedicine and their expected growth.
2. Search for relevant literature
   The search engines used were Google Scholar, Springer Link and Scopus. The keywords used for the search were: "additive manufacturing", "3D-printing", "biomedicine", "biomedical applications", "bioprinting", in general, and others on specific materials or technologies.
3. Selection of studies
   Inclusion criteria: the selected articles involved systematic reviews and specific studies published in recent years, in either English or Spanish.

   a. Exclusion criteria: given the speed of change in the field of additive manufacturing, articles prior to 2016 were rejected. However, relevant content from earlier dates was included if it was deemed valuable and not covered in more recent references.
   b. Boolean operators such as AND and OR were used to further refine the search results.
4. Data extraction
   To proceed with the selection, abstracts and, if necessary, full articles were reviewed to decide whether the information they contained was related to the study's objectives. The analysis also encompassed examining the bibliographic references of selected articles to identify additional studies that could potentially be included in the review.

Using this method, a total of 20 articles and reviews relating to this topic in the period 2016-2022 have been directly analysed. In addition, 13 additional articles have been indirectly reviewed.

Based on the information extracted, an analysis has been carried out in order to both, confirm the studies already published on the subject, and summarize the new knowledge available. Attention has been focused on the additive manufacturing techniques on which a greater number of articles are being published in the biomedical sector.

3. Results and discussion

3.1. Conventional additive manufacturing techniques

The main biomedical application of additive manufacturing is the creation of customised implants. Surgical interventions of this type long precede the development of additive manufacturing. The first implants date back to 2500 BC, when Egyptian teeth bonded with gold wire have been documented. However, it was not until the last quarter of the 20th century that the first AM technologies emerged.[5]

Charles Hull introduced stereolithography in the 1980s, a concept very similar to what is nowadays classified as photopolymerization. Subsequently, the techniques of material extrusion and powder bed fusion were conceived. Then, the remaining technologies appeared.[6]

It was not until 1994 that an additive manufacturing technique was used for the first time to create a part whose insertion rectified a cranial defect.[7] To understand the novelty of

these techniques in the biomedical field, it is sufficient to notice the different nomenclature and classification of AM technologies used in articles published less than a decade ago[8,9], and the references about the necessity of standardization.[10,11]

Despite their newness, the development of additive technologies in the biomedical field has been massive. Today, implants are produced using these techniques to correct problems in any part of the human body, including the knee, hip, femur, clavicle, or teeth, among others. Even the reconstruction and replacement of bone pieces in animals has been reported.[12] The main advantage of additive manufacturing in implants and prostheses is the possibility of customisation to the needs of each patient. Bibliography also refers to a wide range of applications, including the creation of medical instrumentation, anatomical models, customised drugs, and devices like glasses or hearing aids.[13]

Although the overall growth of the sector has been significant, it has not been the same for all available technologies. While some technologies are well established and likely to grow, others are limited to specific applications, and others have proven to be sterile. *Table 1* shows the techniques cited in each article reviewed as a first approach to the usefulness of each method. To estimate this suitability, a mention ratio was calculated as the quotient between the number of articles referring the technique and the number of articles reviewed.

Not all techniques are of the same interest. Three groups are presented, proving the classification by Salmi, 2021:[11] those that are well established, those that are little used, and those that are rarely appropriate.

The most employed techniques are powder bed fusion, material extrusion and vat-polymerization. PBF is the most widely used technique. Its widespread usage is consistent with the fact that the first biomedical application of additive manufacturing was the creation of implants. They are usually made of metallic materials, and PBF allows the creation of 3D structures from titanium, stainless steel, cobalt, aluminium, copper, and nickel alloys.[15] However, some technologies within the PBF group also allow polymeric and composite structures production.[9] In fact, the manufac-

Table 1. Mention in the articles reviewed of the use of additive manufacturing techniques in biomedicine

Article	Additive manufacturing techniques						
	ME	PBF	VP	MJ	BJ	DED	SL
Rodríguez-Hernández & Reinecke, 2020[4]	X	X	X	X	X		
Kim et al., 2016[7]	X	X	X	X	X		
Liu et al., 2017[9]	X	X	X				
Bozkurt & Karayel, 2021[12]	X	X	X	X	X	X	
Sheoran et al., 2019[13]	X	X	X				
Ahangar et al., 2019[14]	X	X	X	X	X	X	X
Dhavalikar et al., 2020[15]	X	X	X	X	X	X	X
Kumar et al., 2021[16]	X	X				X	X
Talib et al., 2021[17]	X	X	X	X	X	X	X
Tom et al., 2022[18]	X	X	X		X		
MENTION RATIO	1.0	1.0	0.9	0.6	0.7	0.5	0.4

ture of pills with various dimensions and geometries and with patient-specific doses has been reported.[19] Pieces obtained with PBF have good characteristics in terms of strength, great resolution, and properties similar to those of the bone structures they are supposed to replace.[16] The only disadvantage is the cost and the need for post-processing.[14]

Material extrusion follows PBF in terms of interest. Thanks to its widespread use in all industrial and scientific fields (including amateur modelling), it has been established as an accessible, low-cost, and easy-to-use technology. These three characteristics have also made ME useful in the biomedical sector, despite certain disadvantages such as the slowness of the manufacturing process, the anisotropy, and the poor surface finish of the pieces.[14] It is applied in structurally unresponsive implants made of polymeric materials, but also in novel procedures such as the production of personalised medicines.[13] Its potential for the manufacture of composite pieces for the creation of multi-material splints and prostheses is currently being explored.[11]

Lastly, within this group of techniques of interest is vat-photopolymerization. Its main difficulties were the scarcity of biocompatible materials. Nevertheless, this situation has improved thanks to the development of new polymers that include this property and are also biodegradable, such as urethane dimethacrylate or diisopropylacrylamide.[14] VP can be used to produce pieces with a resolution of 20 μm with a nice surface finish. However, they lose their mechanical properties over time, so that, like ME, they are not very suitable for the production of parts with high responsibility.[12] The manufacture of surgical models that allow the study of diseases or the preparation of subsequent interventions is under research. In this context, the fabrication of a heart model for the study of congenital heart disease has already been reported.[15]

The second group, corresponding to those that are rarely used because they are very specific, is integrated by material jetting and binder jetting technologies. MJ is a complex technique because the material must be extruded through multiple small nozzles simultaneously. However, due to its high precision and the opportunity to make full-colour structures, it is used in the creation of surgical models.[12] BJ produces structures with very limited resistances, so its application to medical devices or implants is low, although there are some examples of prostheses produced with it. Once again, its current application involves the creation of surgical models with high chromatic reproduction. The manufacture of metal parts that can be used in the production of implants or medical devices is being studied.[14]

The last group comprises both, direct energy deposition and sheet lamination, with seldom use in biomedicine. DED produces parts with very limited quality in terms of precision and surface finish and is also quite complex and expensive.[15] Moreover, it is largely circumscribed to metal fabrication, where techniques such as PBF are more interesting. Some articles suggest its application for the repair of parts, although this sector is restricted by tough regulations.[11] SL is only used to produce surgical models, where there are also more interesting techniques such as MJ or BJ. In the biomedical sector, SL presents many difficulties, such as the low availability of laminated material or the limited supply of industrial machines based on it. Even though its chances of survival in the sector are low, some authors cite SL interest in the production of multi-material parts, thanks to the possibility of creating composite sheets, and DED value in repairing damaged structures, if the legal problems are solved.[16]

A summary of the conclusions drawn is shown in *Table 2*.

3.2. Bioprinting

Bioprinting combines the principles of tissue engineering and additive manufacturing.[12] There is not clear standardisation of the parameters and the procedures governing bioprinting. Current literature tends to classify it as an additional AM technique, although it is based on a combination of conventional techniques. However, this temporary classification makes sense if there are considered the dissimilarities in the equipment and materials used.

Bioprinting origins date back to 1988. In that year, Robert Klabe presented Cytoscribing, which allowed the creation of synthetic tissues using a classic inkjet printer. With a modified cartridge full of fibronectin he managed to write some words.[20] Simultaneously, tissue engineering began to develop, and much research was performed on the creation of the scaffolds needed for cells to be deposited and form tissue. In 2002, scientists at Wake Forest University created the first bioprinted organ, a small kidney.[21] In 2003, Chris Wilson and Thomas Boland patented the first inkjet bioprinter.[22] Meanwhile, engineers at the University of Freiburg created the first microextrusion bioprinter.[23] The development of bioprinting techniques began to accelerate. In 2007, the first specialized laboratory Organovo, was founded, and three years later it printed the first blood vessels from a single donor's cells.[24] In 2019, a new milestone was reached when a mouse-sized human heart was printed in Israel.[25]

The main technique used in bioprinting is inkjet, in which bioink is deposited similarly to MJ. Another well-established procedure is laser-assisted bioprinting, in which a high-energy laser light causes the biological material to change into a vapour state, and to be deposited as small droplets on the substrate. Another technique is microextrusion, in which small droplets with a volume of picolitres with cells inside are placed on fibres with high precision. The fibres are cross-linked between deposition and deposition to achieve three-dimensional structures.[4] Photopolymerization is also used as a bioprinting technique. *Figure 3* illustrates the techniques described.

Inkjet printing uses machines like those used commercially for typical AM applications, but suitably modified to be able to use biological material. Three possible methods are used: thermal, piezoelectric, and electrostatic.[26] The first one employs a heating system that generates air bubbles which, when exploded, generate the necessary pressure to expel the bioink. The second uses a piezoelectric material which, when excited by an electric current, generates a mechanical impulse to expel the bioink. Finally, electrostatic bioprinters apply a voltage to a plate, which deforms and allows the bioink to be extruded. Laser-assisted bioprinting was first successfully applied in 2004.

Table 2. Additive manufacturing techniques

Technique	Status	Current applications	Applications under research
ME	Versatile	Implants, models	Multi-material parts, customised drugs
PBF	Highly versatile	Implants of any type and material	Customised drugs
VP	Versatile	Implants	Surgical models
MJ	Specific usage	Models	Metal pieces
BJ	Specific usage	Models, some implants	Metal pieces
DED	Infrequent usage	Part reparations	None
SL	Infrequent usage	Models	Multi-material parts

One of its main limitations is the possible thermal damage to cells that occurs in the nanoseconds it takes for the laser to vaporise the bioink molecules. However, laser-assisted bioprinting allows high resolutions and is compatible with viscous bioink.[27] Microextrusion uses deposition systems driven by pneumatic or mechanical energy. Since the deposited droplets are very small in volume, resolutions close to 100 μm are achieved.[14] Finally, photopolymerization can be used to obtain high-resolution structures suitable for bioinks of any viscosity. Its main problem, however, is that UV light can produce significant alterations in the cellular systems obtained, such as cancer. It also presents additional problems like the need for large quantities of material and the long production time.[28] Among them, the technique that achieves the lowest resolutions is the laser-assisted. However, the production time is quite long. To accomplish shorter times, microextrusion can be used, although it has a low cell survival rate.[16]

The reviewed articles also mention unusual techniques that include magnetic bioprinting, acoustic bioprinting, and bioplotting.[27] The first involves magnetic flotation, in which magnetic fields are used to deposit the cells. In the second method acoustic waves are applied to provide the necessary impulse for the bioink deposition. The third one allows the extrusion of tubes or spheroids of materials through a syringe and using UV light, as in the case of photopolymerization. Stereotactic bioprinting, implemented with robotic technologies, has also been reported. It employs a three-dimensional coordinate system to eliminate the anisotropy typical of 3D printing processes. Even so, it is not widely used in practice.[29] All these techniques are still in the testing phase. In fact, given the novelty of bioprinting, even the more established ones are still being improved.

The development of bioinks is also under research. Bioinks must meet five basic conditions for their application:[15,16] rheological, relating to viscosity, and shear thinning; cross-linking, concerning its consistency; hydration, its water content; mechanical, dependent on the above; and biological, selected to promote cell

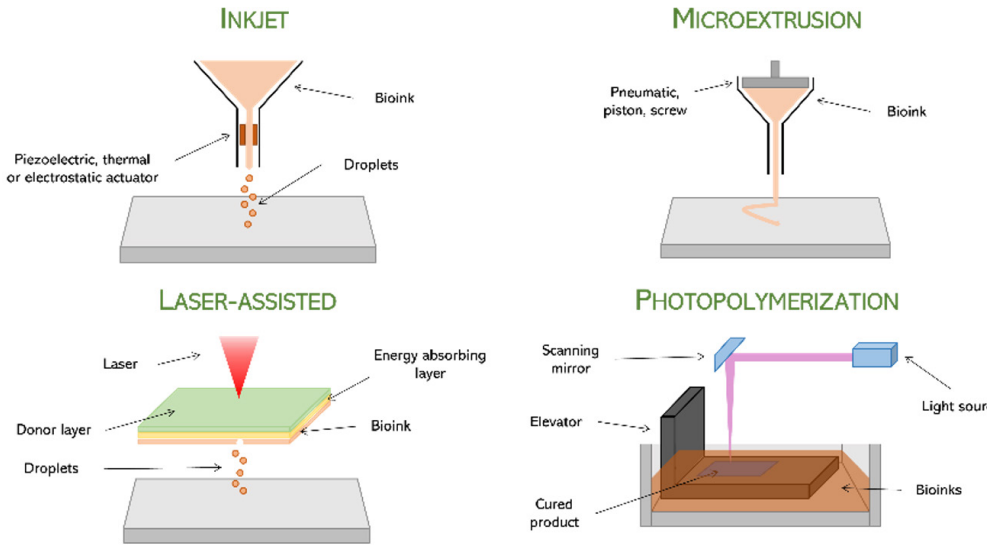

Figure 3. Scheme of the main bioprinting processes

survival. The most common bioinks today are alginate and gelatine, although a wide variety of materials are available including agarose, collagen, fibrin, hydroxyapatite, hyaluronic acid and polyethylene glycol.[14,16,30,31]

The reviewed sources suggest that bioprinting will continue to develop. The following research opportunities or challenges are recognised:[29,32,33,34]

- Customisation. The future lies in adjusting medical treatments to each patient's situation rather than imposing generalist approaches. An objective is to produce artificial organs that can be transplanted and accepted by subjects without any problems.
- Generalisation of the technique. Although the bioprinting of corneas, cartilage, bones, and skin has already been reported, there are still cells such as liver, nerve, and pancreatic cells with difficulties in terms of their growth and development outside of humans. Another challenge is the vascularisation of organs, as although bioprinted objects resemble real organs and their outer cells can live for a while, the inner ones often die quickly.
- Clinical trials. In bioprinted organs and systems with identical characteristics to those of a real human being, the efficacy and safety of medical treatments could be tested without any risk.
- Ethics. Although bioprinting holds great promise, the costs of manufacturing an organ may not be affordable for the entire population, with some experts warning of the "stratification of biofabrication". In addition, bioethicists argue about what bioprinted tissue is, and whether it should be classified as a native transplant, a biological therapy or a medical device, and the ethical consequences of its inclusion in each of these groups.

4. Conclusion

This review has provided new insights into additive manufacturing processes for biomedical applications. The recent introduction of these technologies in the field has been successful, as it has provided innovative solutions at reasonable cost and excellent properties in many areas such as implant and prosthesis manufacturing, production of surgical models and medical devices, and biofabrication of tissues and organs. The products obtained have the advantage of customisation, which is a general trend in biomedicine.

All AM technologies are applied in the sector, although some have proven to be more interesting than others. PBF, ME and VP are the most effective techniques with the highest expectations for industry permanence and/or growth. MJ and BJ have demonstrated to be useful technologies for specific applications such as surgical modelling, but there is growing interest in other areas of biomedicine such as implant manufacturing. In contrast, SL and DED have not yet fully established themselves and the literature is torn between their disappearance and the exploration of new applications where they may be useful.

Bioprinting, the eighth additive manufacturing technique, has been developed to create living structures. Many aspects of this technology are still in the research phase, but the results are very promising. Experts believe that fully functional and customised bioprinted organ transplants will become common in the future. However, the number of available biomaterials still needs to increase and the technique, successful with certain cellular systems, needs to be extended to others where results have been inconclusive.

To sum up, AM is still developing in the biomedical field, but studies suggest that it will

be fully integrated into the industry in the future.

The present review is subject mainly to two limitations. Firstly, the rapid pace of change within the sector renders information quickly obsolete. Thus, it is crucial to conduct regular reviews on the subject, such as this one, to ensure the preservation of up-to-date insights.

Secondly, the review's scope is constrained by the number of articles analysed. However, a rigorous analysis of the most relevant articles published in recent years has been undertaken, ensuring that the conclusions drawn align with the current state of the sector.

The primary contribution of this review lies in establishing a comprehensive framework for additive manufacturing in the biomedical field. It consolidates considerations on the origins, current status, future expectations, and limitations of both conventional techniques and bioprinting within a single work. Furthermore, the review validates hypotheses from previous articles concerning the state of the art of the technique and shed lights on significant issues that demand attention and require solution.

Author contributions: DDL conducted the search for relevant sources, reviewed the existing literature, analyzed the latest advancements in the field, organized the gathered information, and wrote the manuscript. GGV conceptualized the study idea, reviewed and confirmed the results, and provided feedback on the written work, which was supervised by him. Both authors have read and agreed to the final version of the manuscript.

Conflict of interest: None

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