

State of the Art in Medical Additive Manufacturing

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Abstract: Additive manufacturing technologies have been gradually gaining importance over the past two decades, and their relevance in industry is being increasingly reinforced by countless feasibility studies. The medical industry is one of the most potent application fields for additive manufacturing, since the freedom of design such technologies allow for using a wide array of materials makes previously unimaginable devices feasible. The integration of these technologies into healthcare systems offers numerous advantages, including the customization and personalization of medical devices, pharmaceuticals, and equipment, enhanced cost-efficiency, and improved training methodologies. In this review, a scoping literature overview was conducted in order to identify the most important use cases, limitations and future directions of additive manufacturing in the domain of digital medtech.

Keywords: additive manufacturing; medical 3D printing; rapid prototyping; medical technology development; digital health tools

1 Introduction

Conventional manufacturing methods are predominantly subtractive, making them cost-effective primarily for large-scale production of identical items due to process optimizations. In contrast, Additive Manufacturing (AM) has significantly enhanced the affordability of small-batch customized production and prototyping.

AM refers to a class of manufacturing technologies wherein materials – such as powders, plastics, or metals – are deposited layer by layer to construct a 3D object from a computer-aided design (CAD) model [1]. Unlike traditional subtractive methods, such as CNC machining which removes material to shape an object (e.g., implants), AM builds structures by the successive addition of material. Formally, AM can be defined as the selective deposition or fusion of materials to fabricate components in a layer-by-layer fashion based on digital models, typically 3D CAD files. This definition underscores the key distinction between AM and conventional manufacturing approaches, which include subtractive or machining techniques (e.g., CNC turning), forming methods (e.g., forging), and bulk solidification processes (e.g., casting) [2]. AM is often referred to as 3D printing (3DP), rapid prototyping (RP), solid freeform fabrication (SFF), rapid manufacturing, stereolithography. Medical applications of AM are unfolding rapidly across various domains and are expected to revolutionize some aspects of healthcare in the coming decades. The production process of 3D printed objects can be implemented on site, saving both time and money on shipping. In-house manufacturing gives end users (surgeons, doctors) the possibility to participate in the development of a product, rapidly create prototypes and evaluate them [3]. In this review, the terms ‘3D printing’ (3DP), ‘additive manufacturing’ (AM) and ‘rapid prototyping’ (RP) are interchangeable, but AM is preferred.

2 Methods

The review was based on the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses, prisma-statement.org) principles. At first, related publications already available in the authors’ database (part I in the below table) were selected. Secondly, a methodical search was conducted on Google Scholar for the time range of 2008-2022 with keywords: ‘medical 3D printing’ (part II in the below table) and ‘medical additive manufacturing’ (part III in the below table). No citations or patents or website articles were considered, only original publications [4]. The details of the search are visible in Table I.

Table I
Details of the literature search

	part I	part II	part III	total
abstract read	40	100	100	240
full text read	25	67	46	138
searched keyword	-	medical 3D printing	medical additive manufacturing	-
selected for inclusion		-		75

Then the selected articles were grouped into the following use case categories:

- surgical planning and education;
- implants, prostheses, bioprinting;
- surgical and diagnostic tools;
- pharmaceuticals.

Exclusion criteria included the lack of scientific content, inappropriate source, language (any other than English), relevance and lack of access. In addition, general review articles falling into the area were added manually [5, 6]. Our conclusions relied on the employed technologies and the number of examples.

3 Results and Key Findings

In general, AM, including 3D printing, raises significant safety and security concerns, particularly due to its potential misuse for producing prohibited items – such as weapons – within the regulatory frameworks of regions like the European Union. As a result, there is a possibility that stringent regulations may be proposed and enacted, potentially limiting the use of 3D printing technologies to an extent that could hinder or preclude their applications in the medical field. Even in the absence of such restrictions, the clinical adoption of 3D printed medical devices requires not only the approval of the final product but also comprehensive validation of the entire AM process. Regulatory approval often necessitates extensive randomized controlled trials, which are both time-consuming and resource-intensive, representing a substantial barrier to market entry. Additionally, AM has been subject to various forms of IP protection – including patent, industrial design, copyright, and trademark laws – since its inception. For instance, the commercial distribution of a 3D printed replica of a patented object requires explicit authorization from the patent holder; otherwise, such distribution would constitute a violation of patent law [3]. The currently widely available AM technologies that are most used in the medical domain are the followings:

- Stereolithography (SLA);
- Digital Light Processing (DLP);
- Selective Laser Sintering / Melting (SLS/SLM);
- Direct Metal Laser Sintering (DMLS);
- Electron Beam Melting (EBM);
- Fused Filament Fabrication / Fused Deposition Modeling (FFF/FDM);
- Binder Jetting (BJ);
- Photopolymer Jetting (PJ).

3.1 Technical Variations

AM is increasingly utilized in the fabrication of various medical models and components. The dimensional accuracy of these models can vary significantly depending on the materials used, the specific AM technologies employed, and the operational parameters of the machines. Salmi *et al.* evaluated the accuracy of three AM technologies – SLS, BJ and PJ – in producing anatomical skull models [7]. To facilitate precise measurements, reference spheres were affixed to each model, and coordinate data were acquired using a Coordinate Measuring Machine (CMM). The spatial coordinates of the spheres' centers were measured and compared to the corresponding coordinates in the original digital CAD model by calculating interspherical distances. Among the evaluated technologies, PolyJet demonstrated superior accuracy compared to both SLS and BJ [7, 8].

3.2 Overview of Typical Medical Use Cases

3D printing has emerged as a clinically valuable visualization tool for both preoperative and intraoperative planning across a wide range of surgical procedures. High-resolution imaging data acquired from modalities such as multidetector computed tomography (MDCT), magnetic resonance imaging (MRI), or echocardiography can be utilized to fabricate life-sized anatomical and pathological models, as well as patient-specific implants and surgical guides. These printed models are applicable in planning both open and minimally invasive surgeries, offering several advantages, including improved surgical outcomes, reduced perioperative risk, and the facilitation of novel surgical techniques.

In thoracic surgery, for instance, AM is employed to evaluate tumor invasion into critical structures and to aid in the diagnosis and management of upper and lower respiratory tract conditions. Compared to conventional 3D image visualization, physical 3D models enable more efficient assimilation of anatomical information, support optimal surgical decision-making, and contribute to reduced operative times. The introduction of patient-specific 3D printed implants is also expected to significantly influence both aesthetic and life-saving interventions in the future [9].

In diagnostic radiology, advanced visualization is essential for diagnosis and interdisciplinary communication. Yet, there is still a need for standardized use of 3D printed models derived from DICOM (Digital Imaging and Communications in Medicine) datasets. Integrating 3D printing into radiological practice presents challenges, including the need for specialized training, suitable materials and equipment, and clear operational guidelines. To justify investment in AM infrastructure, clinical benefits must outweigh costs. The use of AM-generated models from DICOM images – for procedural planning and implant fabrication – is expected to grow significantly. Radiologists should therefore gain foundational knowledge of AM, including available technologies, materials, documented clinical applications, and related benefits to patient care [10].

3.3 Imaging and Patient Data Issues

To fabricate any patient-specific component using additive manufacturing, a 3D model of the patient's anatomy is essential. The acquisition of high-quality medical imaging data is a critical step in the generation of accurate 3D representations, as the fidelity of the resulting models is directly dependent on the quality of the input data. The DICOM standard is the globally recognized protocol for the transmission, storage, retrieval, processing, and display of medical imaging information. Imaging modalities such as MDCT, MRI, and echocardiography are the most commonly employed techniques for acquiring detailed data of both soft and hard tissues [11].

A noteworthy software platform in this context is the 3D Slicer (www.slicer.org), an open-source toolkit designed for image registration, segmentation, and visualization, with full support for DICOM standards. Although it is not certified for clinical use, 3D Slicer remains one of the most widely adopted tools for post-processing medical images in additive manufacturing applications for healthcare.

3.4 Material-Related General Issues

Biocompatibility is a critical criterion in the selection of materials for medical applications. Upon contact, foreign materials typically interact with human tissues, which may lead to adverse effects. These interactions can result in rapid degradation of the material or, conversely, damage to surrounding biological tissues. Therefore, materials chosen for medical use must exhibit high biocompatibility, ensuring minimal tissue reactivity and controlled or extremely slow degradation rates.

In the context of orthopedic and dental implants – where integration with the patient's bone is required – an essential material property is the porosity. Porous structures serve several purposes: (1) they replicate the trabecular structure of bone, increasing the implant's surface area and facilitating osseointegration by promoting bone in-growth; (2) they allow adjustment of the implant's mechanical properties, such as the elastic modulus and stiffness, to better match those of native bone; and (3) they reduce the overall weight of the implant. AM techniques are particularly well-suited to produce such porous structures, as their layer-by-layer fabrication process enables the creation of gradient porosity and complex internal architectures [1, 12, 13]. Controlled porosity is also crucial in tissue engineering (TE), where scaffolds must support cell proliferation and tissue development.

Recent advancements include the development of novel methods for quantifying the porosity of 3D printed medical devices using microcomputed tomography. For instance, Asghari Adib et al. investigated GelMA-based biomaterials for intracorporeal additive manufacturing of TE scaffolds, using this imaging modality for detailed structural analysis [14, 15].

Among the most commonly used biocompatible metal materials for AM-fabricated porous orthopedic and dental implants are titanium alloys, particularly those compatible with SLM or DMLS processes [16-18]. Recently, there has been growing interest in the application of zirconium, tantalum, and their respective alloys in biomedical implants [19-22]. According to Kunčická *et al.*, zirconium alloys demonstrate superior biocompatibility compared to titanium, due to lower biocorrosion and reduced immunogenic response [21]. Additionally, Kulkarni and Kakandikar highlight unique advantages of zirconium alloys in biomedical contexts, including the formation of a bone-like apatite layer, enhanced biocompatibility, and low magnetic susceptibility, which is particularly beneficial in MRI diagnostics [22].

Despite their advantages, these metallic materials are refractory and expensive, as is the specialized equipment required for their processing via selective laser melting — the primary technique for manufacturing patient-specific, porous implants such as hip joint cups, intervertebral discs, and dental implants (Fig. 1).

In response to cost and equipment challenges, recent studies have explored alternative methods such as thermal plasma spraying of refractory material powders or wires to create bioactive coatings on implants. For example, Kalita *et al.* demonstrated the successful clinical use of titanium implants coated with 3D bioactive plasma-sprayed titanium, validated in canine models [23]. Similarly, Kussaiyn-Murat A. *et al.* employed an industrial robotic arm for microplasma layer-by-layer deposition of tantalum coatings onto titanium implants, guided by 3D scanning data of the implant surface to achieve high-precision application [24].

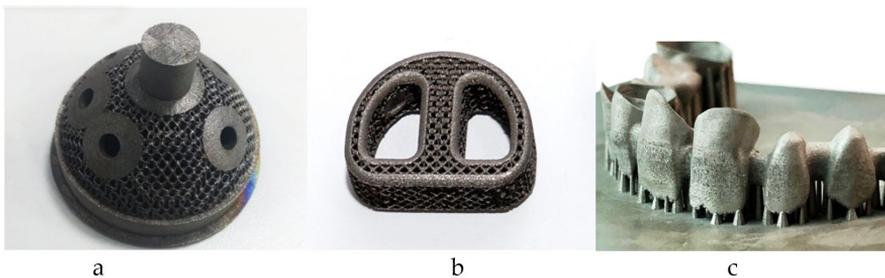


Figure 1

Samples of implant parts obtained by authors using selective laser melting of Ti6Al4V (Grade 5) titanium alloy powder: (a) hip cup, (b) intervertebral disc, (c) dental bridge

Regardless of the technology producing the implant itself, AM can be included in the process at the design stage of the model. Based on data from either computed tomography (CT) or magnetic resonance imaging (MRI), a 3D bone image can be reconstructed and a 3D model can be developed that accurately represents the patient's anatomy. Using the AM reverse engineering technique, the missing part of the bone can be created. Then the individual patient's implant can be produced from biocompatible materials using, for example, CNC machines (Fig. 2). A plastic

physical model of the implant can be pre-printed, which allows better understanding of the situation and is suitable for simulation operations.

Shape memory alloys (SMAs) are a class of materials capable of undergoing significant deformation while retaining the ability to return to their original shape upon exposure to a specific thermal stimulus. The most commonly used SMA in biomedical applications is nickel-titanium alloy (NiTi or Nitinol), due to its shape memory effect, super-elastic properties, and biocompatibility. Nitinol has been applied in various orthopedic contexts, including guide wires, staples, and anchors, and is currently under investigation for use in large bone trauma cases. Additive manufacturing technologies such as SLM and DMLS have been used to produce Nitinol implants [3].

Biodegradable metals represent a promising category of materials that gradually degrade within the body after fulfilling their intended function. This property supports tissue regeneration and allows the implant to eventually disappear, which is especially beneficial in orthopedic, cardiovascular, and pediatric applications. The use of degradable implants can eliminate the need for costly and invasive secondary surgeries and is especially advantageous for young patients who are still growing. Currently, magnesium-based and iron-based alloys are the most studied biodegradable metals. Although these materials show promise in meeting clinical demands for resorbable implants, available *in vitro* (laboratory-based) and *in vivo* (within a living organism) studies yield mixed results regarding their reliability [3].

Polymer materials have also been employed in the medical industry for over 30 years. A wide range of biodegradable and non-biodegradable polymers have gained approval for human use from regulatory agencies such as the Food and Drug Administration (FDA). As polymer science has advanced, applications have expanded significantly, encompassing uses such as sutures, catheters, and ligament replacements [3].



Figure 2

Sample plate for the pelvic bone (with screws) machined by authors from titanium alloy on a CNC machine and 3D plastic model of the pelvic bone obtained by 3D printing using X-ray images

4 Major Application Domains

4.1 Preoperative Planning and Surgical Education

Surgical training modules that utilize inanimate objects, cadavers, or animal models can reduce the initial learning curve for trainees; however, they often fall short of providing fully realistic surgical experience. In comparison to *in vivo* simulations using porcine or cadaveric models offer superior anatomical accuracy and the benefit of living tissue perfusion, making them highly effective educational tools. Nonetheless, these methods are constrained by high costs and ethical considerations. AM, specifically 3D printing, presents a compelling alternative by enabling the creation of anatomically accurate, patient-specific models that replicate clinically relevant organ systems [25].

Over the past decade, a wide range of applications for 3D printing in surgical disciplines has been demonstrated. Clinically, 3D printed models offer both visual and tactile feedback, allowing for the simulation of complex anatomical movements, such as articulation of the temporomandibular joint, which are difficult to replicate using virtual software alone. These models have been shown to improve preoperative planning, resulting in shorter operative times, reduced exposure to general anesthesia, minimized wound exposure, and decreased intraoperative blood loss. 3D printed models have been successfully employed in various specialties: orbital and mandibular reconstruction in maxillofacial surgery; craniofacial, skull base, and cervical spine planning in neurosurgery; prefabrication of fixation plates and lesion excision planning in orthopedic surgery; mapping congenital heart defects and tracheobronchial variations in cardiothoracic surgery; vascular interventions for aortic aneurysms and dissections; partial nephrectomy in urology; frontal sinus reconstruction in otolaryngology; and liver resection and transplantation in general surgery [26].

In one study, fifteen patients scheduled for laparoscopic splenectomy, nephrectomy, or pancreatectomy underwent creation of full-scale 3D virtual anatomical models reconstructed from contrast-enhanced MDCT scans, which were then prototyped using 3D printing. A group of thirty radiology professionals evaluated these models through a structured questionnaire. The study revealed that medical students exploited the most benefit from the models, followed by surgeons, radiologists [27].

A range of custom simulation models, or task trainers, have also been developed using 3D printing for procedures such as ocular foreign body removal, ultrasound-guided joint and nerve block injections, and various suturing or reconstructive techniques. These trainers are increasingly used in simulation-based training to address growing educational demands. The production cost of such models is a small fraction of that of commercially available simulation models, making AM a cost-effective option for low-volume, specialty-specific training tools [28].

Additive manufacturing has also contributed to research in vascular diseases. Abdominal aortic aneurysm (AAA), a permanent dilation of the distal aorta, has been studied using patient-specific 3D printed phantoms to improve screening and risk prediction. Cloonan et al. demonstrated the use of AM in fabricating AAA phantoms for ultrasound-based pulse wave imaging, illustrating the potential of these models to enhance both diagnostic imaging and computational analyses [29]. Similarly, Tam et al. utilized 3D printing to replicate aneurysms with complex neck anatomy, aiding in endovascular aneurysm repair planning [30]. Liew et al. reported the application of patient-specific 3D printed models to improve both patient consent and comprehension in posterior lumbar fixation procedures, as well as to enhance imaging interpretation skills among neurosurgery trainees [31].

Modern medical education increasingly relies on diverse educational resources to build clinical competence. However, acquiring these resources can be challenging due to financial, ethical, legal, and cultural barriers. Additive manufacturing has been successfully integrated into anatomy education in several academic institutions, contributing to long-term educational initiatives across disciplines including the medicine, the arts, and the sciences [32].

The anatomical fidelity of 3D printed models has also been evaluated. Fasel et al. compared whole-body CT-derived 3D printed models with cadaveric anatomy and found a high degree of anatomical accuracy [33]. In forensic medicine, Ebert et al. proposed the combination of medical imaging and 3D printing to generate physical models of forensic findings. These models were more comprehensible to laypersons than traditional volume-rendered or 2D reconstructions and were deemed useful for courtroom presentations and educational purposes [34].

Despite the growing adoption of simulation-based education, its use in teaching congenital heart disease has been limited. Costello et al. assessed the integration of 3D printed heart models into a simulation-based training curriculum for pediatric residents and found that the models improved understanding of congenital heart abnormalities and critical care principles [35]. In a case report, Son et al. described the use of a 3D printed heart model with a benign cardiac schwannoma located in the interatrial septum, which facilitated selection of the optimal surgical approach [36]. Ikegami and Maehara further emphasized the utility of 3D models in visualizing internal structures to assist with complex surgical decision-making [37].

Lim et al. conducted a comparative study on the effectiveness of 3D printed models versus cadaveric specimens in teaching external cardiac anatomy. Results indicated that 3D printing offered notable educational benefits and could serve as a valuable adjunct to traditional cadaver-based curricula [38]. In another application, 3D printed kidney models were generated from CT segmentations of renal parenchyma, vasculature, collecting systems, and tumors. These patient-specific models supported preoperative planning and simulation for robotic surgery [25, 39]. Additionally, 3D printed models have facilitated decision-making in lung tumor resection procedures by improving spatial understanding of tumor location and surrounding anatomy [40].

4.2 Surgical and Diagnostic Tools

Herrmann *et al.* evaluated the use of a low-cost FDM 3D printer to fabricate MRI-compatible components for laboratory experiments. All components were successfully produced and demonstrated compatibility with the MRI environment. The entire design and printing process was completed within a few days, and the resulting parts exhibited functional integrity, well-defined structural details, and high dimensional accuracy [41].

Rankin *et al.* investigated the feasibility of using 3D printing for the fabrication of surgical instruments. A standard Army/Navy surgical retractor was reproduced using an FDM printer and polylactic acid (PLA) filament. The estimated unit cost of the 3D printed retractor was approximately 10% of that of a conventional stainless-steel version. The printed retractor demonstrated sufficient mechanical strength to meet the functional requirements of the operating room [42].

Wong and Pfahnl assessed the feasibility of producing acrylonitrile butadiene styrene (ABS)-based surgical instruments using FDM 3D printing [43]. Their findings indicated that, provided proper attention is given to print orientation during the design process, the mechanical performance of FDM-printed instruments is comparable to that of injection-molded counterparts [44].

Beyond general instrumentation, 3D printing has also been widely employed in the development of patient-specific surgical templates and intraoperative guidance devices. These tools have demonstrated utility across multiple surgical specialties, including maxillofacial surgery, neurosurgery, orthopedic surgery, hand surgery, and general surgery [26].

In addition to manual surgical tools, additive manufacturing has shown potential in the production of certain components used in robotic surgical systems, expanding its application beyond traditional surgical instrumentation [45].

4.3 Regenerative Medicine and Bioprinting

Ghilan *et al.* [46] reviewed the fundamental principles of 3D bioprinting, highlighting its promising potential for tissue regeneration. 3D bioprinting, a subset of tissue engineering, involves the precise deposition of living cells and biomaterials—collectively referred to as bioink—into predefined templates to construct complex tissue architectures. A 3D bioprinter dispenses bioink according to a digital computer-aided design (CAD) model, allowing for the fabrication of structures with specific geometry and internal organization [46]. Following the printing process, the construction may either undergo maturation *in vitro* or be implanted directly into the patient.

Several bioprinting techniques have been developed, including inkjet printing, laser-assisted printing, extrusion-based printing, and droplet-based methods

utilizing piezoelectric crystals. The latter approach, which employs acoustic waves to eject bioink droplets, was successfully demonstrated by Keriquel et al., who used this technique to deposit collagen and nanohydroxyapatite-loaded mesenchymal stromal cells in situ onto mouse skull defects, promoting bone regeneration [47].

Low-temperature 3D printing of calcium phosphate-based scaffolds has shown great promise for the fabrication of synthetic bone graft substitutes, offering improved biological performance compared to conventional grafting techniques [48]. In the context of auricular reconstruction, 3D printing has also enabled the regeneration of auricular cartilage and adipose tissue. In the study [48], polycaprolactone (PCL) and cell-laden hydrogels were printed together, while polyethylene glycol (PEG) was used as a sacrificial support material. This approach demonstrated the feasibility of regenerating ear tissue through the spatially controlled printing of chondrocytes and adipocytes.

Calcium silicate (CaSiO_3 , CS) ceramics have attracted attention in bone tissue engineering due to their *in vitro* bioactivity, including apatite mineralization. Wu et al. used 3D printing to fabricate uniform CS scaffolds with tunable pore structures and high mechanical strength, confirming their suitability for bone regeneration [49].

Cox et al. systematically characterized bone scaffolds produced via 3D printing with hydroxyapatite (HA) and polyvinyl alcohol (PVOH) composite powders. This method supports osteo-conduction and osteo-integration *in vivo*, making it promising for bone tissue engineering [50]. The aortic valve's complex geometry and mechanical demands pose major challenges in cardiovascular tissue engineering. Hockaday et al. developed a novel 3D printing technique to fabricate heterogeneous aortic valve scaffolds using photo-crosslinked hydrogels, demonstrating rapid engineering of constructs with suitable biomechanical properties and spatial heterogeneity [51]. Despite such advances, major limitations persist in bioprinting—most notably, achieving complete vascularization within printed tissues. Developing vascular networks across scales, from large vessels to microcapillaries, remains one of the field's most critical challenges [52]. A partial breakthrough occurred in 2019, when researchers printed a small bioartificial heart using patient-derived cells and basic vascular networks. However, clinical viability still requires advances in cell functionality and scaling up printed structures to human-relevant sizes [53].

4.4 Combining Bioprinting and Robotic Surgery

The integration of tissue engineering (TE)-based AM, known as bioprinting, with robot-assisted surgery (RAS) holds significant potential to enhance the clinical application of regenerative medicine through *in vivo* bioprinting techniques [54]. This innovative approach replaces the conventional open surgical implantation of externally fabricated TE constructs with minimally invasive, endoscopic

bioprinting systems capable of printing directly onto tissue defects within the body (Fig. 3a,b). Utilizing endoscopic AM, synthetic tissue structures can be printed directly inside the body via standard minimally invasive surgical ports (Fig. 3c), thereby reducing surgical trauma and improving clinical workflow.

Recent studies have explored in-vivo bioprinting using minimally invasive techniques [55]; however, major limitations persist due to the intrinsic invasiveness of the procedures and the restricted structural complexity achievable by current TE fabrication systems. A notable advancement in addressing these challenges was reported by Simeunović *et al.*, who developed a surgical robotic platform for intracorporeal additive manufacturing of TE structures [54]. Their system mimics the architecture, kinematics, and fluid dynamics of commercially available robotic surgical systems. A central innovation of this endoscopic AM platform is a novel material dosing system, capable of generating low extrusion pressures comparable to desktop bioprinters. This design enables cell-friendly material deposition, preserving cell viability and proliferation within the printed TE constructs.

An imaging-based comparative analysis between scaffold structures printed using the intracorporeal system and those produced with conventional desktop bioprinters revealed that the former exhibited approximately fivefold lower spatial accuracy in its current iteration. Nonetheless, the achieved resolution was deemed adequate for TE applications [54]. While this proof-of-concept successfully demonstrated the feasibility of combining bioprinting with RAS under laboratory conditions, further research is required to address challenges posed by the interaction between surgical tools and dynamic, deformable soft tissues. These interactions currently hinder stable and repeatable bioprinting outcomes in vivo.

The field of robotic surgery continues to advance rapidly [56-58], which enhances the feasibility and appeal of merging TE and RAS technologies. Such integration could revolutionize regenerative medicine by enabling precise, real-time fabrication of biological constructs within the operative field, potentially transforming the management of complex tissue defects.

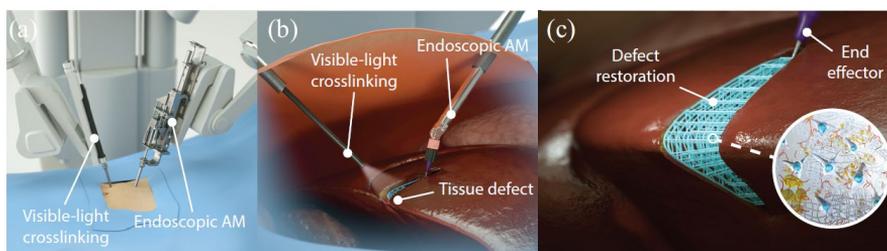


Figure 3

Concept of intracorporeal tissue engineering with Endoscopic AM. (Based on [47])

4.5 Implants and Prostheses

3D printing has facilitated the rapid and cost-effective production of customized, patient-specific implants. Researchers have developed bespoke mandibular implants in maxillofacial surgery, cranial vault implants for cranioplasty in neurosurgery, hip implants in orthopedic surgery, and bioresorbable airway splints for the treatment of complex trachea-bronchomalacia in pediatric cardiothoracic surgery. As modern medicine advances toward increasingly individualized treatment strategies, the high degree of customizability inherent in 3D printing has the potential to transform prosthetic manufacturing into an accessible and affordable process across clinical domains [26].

Importantly, in 2016, the FDA removed regulatory restrictions on 3D printed implants within the 510(k)-approval system class. This policy shift enabled the incorporation of 3D printed materials into conventional surgical workflows, accelerating their clinical integration.

3D printing technologies are capable of producing implants with intricate microarchitectures, including specified pore size and geometry, which support postoperative tissue integration and regeneration [59, 60]. For example, Wumanerjiang et al. reported reduced iatrogenic damage to surrounding vasculature during 3D printed hip replacement surgery, a notable advantage in anatomically vascular regions such as the hip joint [61]. Xia et al. provided an overview of current advancements in orthopedic applications of 3D printing [62], while Okolie et al. reviewed biomaterials suitable for the fabrication of hip joint implants and other orthopedic devices [63]. Both reviews concluded that 3D printed scaffolds significantly enhance implant functionality and clinical outcomes.

Silva et al. evaluated the dimensional accuracy of selective laser sintering (SLS) and binder jetting (BJ) models for replicating cranio-maxillary anatomy. Both methods produced models with acceptable precision for clinical application in maxillofacial surgeries [64].

The emergence of biocompatible, stimuli-responsive materials has introduced a new paradigm in implant design—referred to as four-dimensional (4D) printing. This involves 3D printed structures engineered to change shape or function over time in response to environmental stimuli such as tissue growth, resorption, or other physiological conditions. Morrison et al. demonstrated the use of 4D printing to fabricate airway splints that accommodate natural growth of the pediatric tracheobronchial tree while preventing collapse, with progressive bio-resorption and favorable long-term outcomes [65].

Li et al. investigated the application of 4D printed shape memory polymers (SMPs), which can retain a temporary shape and return to their original configuration upon external stimulation. These "smart" materials have potential use in aneurysm occlusion, dental applications, and suture implants [63, 66, 67]. SMPs can respond to a range of stimuli including temperature, humidity, pH, electric fields, and

magnetic fields. However, challenges remain regarding the identification of SMPs that are simultaneously biocompatible, biodegradable, and exhibit appropriate thermal properties. Okolie *et al.* [63] noted that material selection software such as CES EduPack may assist in narrowing down suitable candidates, though further research is needed to optimize SMPs for biomedical 4D printing applications.

Custom 3D printed implants have been successfully utilized in the reconstruction of various bone structures, including pelvic, femoral, and tibial hemiarthroplasties. At the Mayo Clinic, surgeons performed bilateral total hip arthroplasty using 3D printed implants for a patient with dwarfism, whose anatomy was unsuitable for standard implants. Similarly, in 2015, Chinese surgeons replaced a segment of cancerous cervical vertebrae in a 12-year-old patient using a 3D printed titanium implant [68].

CAD/CAM-based AM techniques have found numerous applications in the near-net-shape production of complex metallic components with tailored mechanical properties. Advanced technologies such as electron beam melting (EBM) and direct metal laser sintering (DMLS) have driven progress in replacing traditional materials for medical implants. Parthasarathy *et al.* proposed a design framework using EBM to fabricate periodic cellular structures optimized for biomedical use [69].

3D printing is also increasingly used in dentistry [70, 71]. While selective laser melting (SLM) is a key breakthrough, it is not the only promising method for dental manufacturing. Traditional casting has improved with plastic-based rapid prototyping for lost-wax techniques. Similarly, digital milling – like SLM – is fully digital, with certified dental materials available for both. When material cost is critical, especially with gold-based alloys, SLM offers advantages due to minimal material loss and significantly reduced waste compared to milling or casting. SLM is particularly effective for producing complex components like multi-part dental bridges or partial dentures, which are difficult to fabricate using conventional methods [72].

4.6 Pharmaceutical Products

Khaled *et al.* used 3D extrusion printing to create a multi-active solid dosage form, or polypill, integrating five compartmentalized drugs within a single tablet. The formulation featured two independently controlled and well-defined release profiles, demonstrating that complex medication regimens can be consolidated into a patient-specific oral dosage form. Polypills hold strong potential to improve medication adherence through convenient single-tablet administration and optimized dosage and release kinetics for each drug [73].

In a related study, Skowrya *et al.* investigated the use of FDM-based 3D printing to produce extended-release tablets. They successfully fabricated solid, elliptical tablets containing prednisolone by loading polyvinyl alcohol (PVA) filament with

the drug. This method demonstrates the potential of FDM 3D printing for the personalized production of controlled-release pharmaceutical dosage forms [74].

5 Additional Considerations for 3D Printing

5.1 Economic Evaluation of 3D printing in Surgery

When comparing AM technologies with traditional manufacturing methods, several distinct advantages emerge. As noted by Tilton et al. [1], AM offers economic feasibility for the production of small batches – ranging from a single unit to several – particularly for complex geometries. It also enables high productivity, minimal material waste, and reduced dependency on specialized tooling, thereby facilitating both mass and individualized medical production. Moreover, AM supports design flexibility, allowing for innovations that would be challenging or impossible with conventional methods.

However, the adoption of AM is associated with notable limitations, particularly regarding cost. The total expenditure includes not only the hardware and software costs but also skilled personnel for operation and maintenance, as well as costs related to materials and design. Another challenge involves the time required to fabricate physical models, which vary depending on the complexity and size of the object, as discussed by Javaid and Haleem [2].

A systematic review by Serrano et al. [75] evaluating the cost implications of 3D printing in surgical practice found insufficient economic evidence to confirm its cost-effectiveness. This is largely due to the absence of comprehensive economic and organizational analyses that account for the multifaceted impact of implementing 3D printing technologies in clinical settings.

However, several studies indicate strong potential for operational cost savings and improved efficiency. King et al. [76] showed that *in situ* 3D printing and preoperative adaptation significantly reduced surgical time in mandibular fracture management. Similarly, Ballard et al. [77] reported cost savings in orthopedic and maxillofacial surgeries, primarily due to reduced operating room time using 3D printed anatomical models and templates. Witowski et al. [78] also demonstrated the cost-effectiveness of personalized 3D printed liver models for preoperative planning in laparoscopic hemi-hepatectomy for colorectal cancer metastases.

While evidence points to potential cost and clinical benefits, the limited scope of economic research remains a barrier for policymakers and healthcare administrators aiming to adopt these technologies. Still, ongoing standardization and the rise of open-source software are helping to lower incremental costs and improve clinical access to 3D printing. For example, Scerrati et al. [79] successfully developed a

workflow for producing physical 3D models of cerebral aneurysms using only free and open-source software for computer-aided design (CAD) and 3D printing. Similarly, an open-source surgical fracture table was developed under a public design license, allowing for unrestricted modification, use, and distribution [80]. This initiative, a collaboration between Western Engineering (Ontario, Canada) and Michigan Technological University (Houghton, Michigan, USA), outlined a step-by-step methodology for the low-cost fabrication of surgical table components using a desktop 3D printer. Although this contribution was published as an online resource rather than a peer-reviewed article, and financial data were not reported, it nonetheless illustrates the trend toward reducing the cost of surgical equipment through decentralized digital manufacturing technologies such as 3D printing.

5.2 AM Deployed to Mitigate the COVID-19 Pandemic

The COVID-19 pandemic highlighted the critical role of rapidly producible items [81], particularly personal protective equipment (PPE) and diagnostics [82]. Worldwide, many conventionally manufactured products were redesigned for 3D printing to meet urgent needs. In this context, Radfar *et al.* examined various 3D printed designs adapted during the pandemic and demonstrated how AM can support global healthcare in both current and future crises [83]. Their analysis of protective, preventive, treatment, and diagnostic tools – such as face masks, shields, swabs, hands-free handles, and ventilators – concluded that one of the earliest impactful outcomes was the 3D printing of nasal swabs, developed through collaborations between universities and 3D printer manufacturers [84]. Meanwhile, manufacturing often wastes 80-90% of raw materials. A major limitation was the lack of standardized safety regulations.

Kumar and Pumera [85] also reviewed the contributions of 3D printing to the medical sector during pandemic-related supply chain disruptions. They highlighted AM applications in PPE, ventilators, specimen collectors, safety accessories, and isolation chambers. Their review underlines the advantage of AM in emergencies, particularly due to the rapid mobilization of individuals, researchers, and companies into a global 3D printing network. The authors stress that even post-vaccination, virus mutations and outbreaks persist — underscoring the continued relevance of 3D printed safety products and the need for a global AM consortium.

McCarthy *et al.* report that in 2020, several government agencies and private groups launched the Covid 3D TRUST initiative, which created:

- (1) a digital repository of 3D printed PPE and medical models with ratings from Veterans Affairs' testing and analysis;
- (2) digital health center: to provide efficiently healthcare needs and supply available manufacturers; and
- (3) a network of 3D printing and healthcare quality experts identifying and mitigating risks for workarounds for supply chain shortages [85].

The advancement of AM and collaboration between entities enabled the rapidly development and distribution of products beyond traditional ways, very efficiently. The wide spread of consumer-grade 3D printers has empowered small-scale manufacturers, hospitals, communities and individuals to produce PPE, diagnostic tools and accessories—supplementing the conventional supply chain [85].

6 Discussion and Future Directions for Research in the Field

This article overviews numerous examples showing that the application of additive manufacturing is a very influential and rising domain within the field of medical education and intervention planning, mostly making use of technologies with plastics, ranging from attention computing to surgical robotics [86, 87]. Figure 4 summarizes how many publications were cited in this review for each sub-domain of medical technology, which also indicates the relative importance of additive manufacturing in these fields. Models for preoperative planning and medical education seem to be the most dominant applications.

These technologies also influence the ways different surgical tools and templates are manufactured. Regenerative medicine is a field which can greatly benefit from additive manufacturing in the future, even though present techniques are still in their development or clinical phases. Patient-specific prostheses and implants form a large and worldwide market, therefore additive manufacturing may become an invaluable toolkit for making the process cost-efficient. We could see that in the age of large-scale drug consumption, creating personalized pills to deliver a wide array of different agents is also a large potential for companies to improve their products and therefore the life quality of the patients. In this improvement, additive manufacturing might prove to be a disrupting technology. In situ bioprinting has enormous potential, directly supplying the equipment need of the operating rooms [88, 89]. Moreover, the potential to recycle the raw materials offer significant advantages from the sustainability point of view [82, 90]. The recycling of 3D misprinted models (i.e., waste management) has become a major issue recently [91], for which even startup companies have been established for better management and prevention (e.g., FilaMass Zrt., Budapest, HU).

A consolidated summary of the AM technologies is provided in Table II.

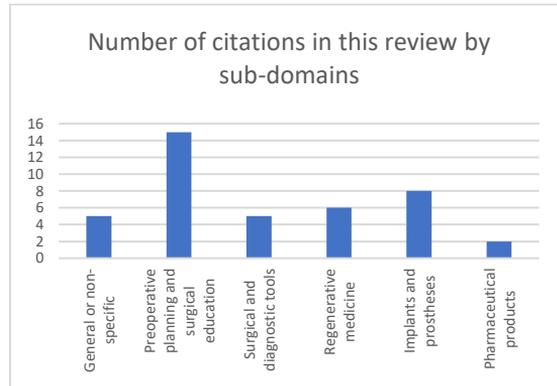


Figure 4

Number of publications in this review by sub-domains in medical technology

Table II

Additive Manufacturing Techniques in Medical Applications – a summary

AM Technique	Medical Applications	Key Advantages	Production Time	Relative Cost	Clinical Outcome Improvements
SLA/DLP	Anatomical models, surgical guides	High resolution, smooth surfaces	4-12 hrs	Medium	30% shorter surgical planning time
SLS/SLM	Orthopedic & dental implants, anatomical structures	High strength, complex geometry	6-24 hrs	High	Enhanced implant fit, reduced intraoperative risk
DMLS	Patient-specific metal implants (Ti, Zr, Ta alloys)	Excellent biocompatibility, osseointegration	6-24 hrs	Very High	Improved implant longevity, reduced reoperation rates
EBM	Load-bearing orthopedic implants	Low residual stress, complex lattice structures	10-30 hrs	Very High	Promotes faster bone integration
FFF/FDM	Surgical instruments, training models	Low cost, accessible, good for functional prototypes	2-10 hrs	Low	85-90% cost savings on training tools vs commercial
Binder Jetting	Anatomical and dental models	Color printing, low cost prototypes	5-15 hrs	Medium	Effective in medical education

PolyJet (PJ)	Maxillofacial & cranial models	Highest dimensional accuracy among plastics	6-12 hrs	High	High patient-specificity in reconstructions
Bioprinting	Tissue scaffolds, cartilage, vascular models	Living cell deposition, controlled architecture	6-48 hrs	Very High	Enables regenerative therapy, under active research

Looking ahead, several trends are poised to shape the next decade of medical AM. The convergence of AM with artificial intelligence, medical imaging, and robotic-assisted interventions will enable fully automated, feedback-driven fabrication of personalized therapeutic solutions. In situ bioprinting, in particular, represents a paradigm shift by allowing tissue structures to be printed directly into the body during minimally invasive procedures — eliminating the need for complex preoperative tissue culture and transplantation.

However, substantial technological and regulatory gaps remain. Most AM platforms are not yet certified for clinical use, and the lack of standardized protocols for quality assurance and biocompatibility validation continues to hinder widespread adoption. Furthermore, limitations in vascularization, mechanical strength, and functional integration of bioprinted tissues represent major research bottlenecks. Addressing these challenges requires interdisciplinary collaboration across material science, biomedical engineering, computational modeling, and regulatory science. Future research priorities should focus on:

- Scalable bioprinting technologies capable of producing complex, perfused tissues with embedded vasculature;
- Development of smart, stimuli-responsive materials for next-generation implants that can adapt to physiological conditions (i.e., 4D printing);
- Real-time imaging and AI-guided AM systems for intraoperative use;
- Economic and life-cycle analyses to support health technology assessment and cost-effectiveness evaluations;
- Regulatory frameworks and clinical trials that balance innovation with safety and efficacy validation.
- Quality Control, and certification of individual 3D model productions and post-application monitoring.

Conclusions

Medical Additive Manufacturing is emerging as a transformative enabler of personalized healthcare, offering unprecedented capabilities in producing patient-specific devices, implants, anatomical models, and bioprinted tissue constructs. The integration of AM into clinical workflows has already demonstrated improvements in surgical accuracy, reduced operative times, and enhanced educational outcomes.

Ultimately, the successful clinical translation of medical AM will depend on robust evidence demonstrating not only technical feasibility but also improved patient outcomes and economic sustainability. By addressing current limitations and aligning innovation with healthcare needs, AM has the potential to become a cornerstone technology in the future of precision medicine.

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