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The Impact of Additive Manufacturing on Biomedical Engineering

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ABSTRACT

A comprehensive review is conducted to examine the advancements and prospective opportunities of stem cell therapies in the field of regenerative medicine. Investigation of stem cells, including those obtained from embryos, adults, and induced pluripotent cell lines, has unprecedented potential in the management of many diseases such as diabetes, neurological disorders, and cardiovascular disease. Despite the current challenges, including ethical considerations and regulatory restrictions, stem cell therapies have already shown effectiveness in clinical environments. The review analysed current developments, ongoing research, and ethical concerns, while also outlining the anticipated future advances in stem cell-based medicines that might significantly revolutionise healthcare.

Keywords: Additive Manufacturing (AM), 3D Printing, Biomedical Engineering, Bioprinting, Patient-Specific Implants.

INTRODUCTION

Additive Manufacturing (AM), also known as three-dimensional (3D) printing, encompasses several technologies and processes utilized to fabricate materials layer by layer based on Computer-Aided Design (CAD) models. AM processes use various materials, including metals, polymers, and ceramics. AM technologies find extensive applications, not limited to biomedical and biomedical engineering fields, in industries such as aerospace, automotive, and consumer goods [1]. AM technology emerged in the late 1980s and became widely adopted in the 1990s. In the biomedical arena, AM technology began to generate interest for tissue engineering applications in the early 2000s. Since then, research has rapidly expanded, resulting in commercially available AM systems and bioprinting technologies. Currently, AM technologies are used in various biomedical engineering fields, including medical device development, personalized medicine, and regenerative medicine. This manuscript provides an overview of AM technology in biomedical engineering, including its impact on applications and future prospects. Advancements in imaging technology and the development of research tools, such as organ-on-a-chip platforms, biosensors, and laboratory-on-a-chip devices, will also be discussed [2].

ADVANTAGES OF ADDITIVE MANUFACTURING IN BIOMEDICAL ENGINEERING

Additive manufacturing (AM) has gained attention in biomedical engineering. Many research papers and patents have been published, and AM processes are used in various applications. This has attracted interest and investment from oil and gas companies, medical and dental organizations, and original equipment manufacturers. The COVID-19 pandemic has further increased the use of AM, including for PPE manufacturing. This study discusses the advantages of AM in biomedical engineering and provides examples of its applications [3]. Hierarchical structures and cellular materials allow tailored performance, including weight savings and energy management. Traditional methods have limited complexity, while AM technology allows for complex designs. Biomedical engineers can leverage AM processes for more complicated custom designs [4]. Some pharmaceuticals and therapy agents are often designed to be nanometer-sized; their performance, bioavailability, and toxicity are closely related to their shapes and morphologies. The fabrication of such bio-nano devices with control over shape and size is a great challenge. The development of specialized AM processes and innovative design concepts to address the potential impact on biomedical engineering devices in various applications, including bio-nano processes, bone scaffolds, macro-channels for biomedical devices, and multi-material implants, outlines many fascinating opportunities for the field of biomedical engineering [5].

CHALLENGES AND LIMITATIONS OF ADDITIVE MANUFACTURING IN BIOMEDICAL ENGINEERING

The rapid growth of additive manufacturing in the biomedical field has created game-changing technologies like bioprinting and synthetic organ production. However, the challenge is translating these technologies into market-ready, FDA-approved products quickly. Careful examination of each technology's capabilities, limitations, biopolymers used, and safety concerns is necessary for successful implementation [6]. For any additive manufacturing technologies being developed, it is imperative to explore the fundamental and optimal material of construction. Extensive studies have been executed by various groups to investigate the mechanical properties, porosity, biocompatibility, degradation rates, shaping devices for printing such as molds, and morphological feature sizes. Scaffolds were deemed an important facet of developing technology. The scaffolds must be porous (or made of hollow geometries) so as to allow nutrient and gas diffusion across the devices. These systems need rigorous testing, design, and simulation before undertaking any experimental work to ensure success [7]. Before starting development, it is essential to assess safety concerns with different polymers in-house and in existing literature. Researchers should conduct a comprehensive literature review to gather as much information as possible on safety hazards and their mitigation, following SOP. Failure to comply with safety regulations can pose risks and hinder research progress. A strong grasp of additive manufacturing technologies and materials is crucial for a successful implementation [8].

CURRENT APPLICATIONS OF ADDITIVE MANUFACTURING IN BIOMEDICAL ENGINEERING

Additive manufacturing or 3D printing has gained attention in biomedical engineering due to new technologies allowing fabrication of patient-specific designs. Medical imaging techniques generate CAD data and STL files of anatomical structures as input for additive manufacturing. Examples of commercial products include cranial implants and titanium lattice scaffolds. Bioprinting of tissues and organs using living cells is also of interest [9]. Patient-Specific Implants and Prosthetics: Patients now receive customized implants and prosthetics that fit perfectly. Examples include cranial plates, mandibles, orthopedic implants, and dental applications made from biocompatible materials like titanium. Anatomics and Oxford Performance Materials' OsteoFab technology have developed commercially available products. Additionally, 3D printing aids in creating patient-specific prosthetics, such as Limbitless Solutions' PE prosthetic arm for Ibrahim [10]. Bioprinting is 3D printing with living cells or biomaterials. It uses bio-inks, like hydrogels with biological components. Techniques include 3D bio-plotting, 3D bioprinting, FRESH, and Kenzan. Most are still in research labs, but some companies offer commercial bioprinters. Organovo's bioprinter has printed liver tissue models. regenHu's 3D bio-printer combines bioprinting with ceramic printing for orthopedic use [11].

PATIENT-SPECIFIC IMPLANTS AND PROSTHETICS

Medical implants and prosthetics are vital components of modern healthcare. Medical implants can replace or support damaged tissues, while prosthetics restore body functions or aesthetics. However, designing and fabricating these devices is challenging due to complex geometries, biocompatibility requirements, and individual variability. In recent years, additive manufacturing (AM) has emerged as a promising solution for biomedical implants and prosthetics. AM, also known as 3D printing, is a layer-by-layer fabrication technique that can create complex structures from computer-aided design models (CAD). AM offers several advantages for biomedical applications, such as design freedom, customization, biocompatibility, and improved functionality. This section focuses on the advances of AM in patient-specific biomedical implants and prosthetics [4]. Many companies develop patient-specific AM implants and prosthetics for various human applications, such as bone defects, tooth loss, and cranial deformities. An example is the treatment of bone defects with 3D-printed implants. In one case, a man suffered a traumatic work accident that shattered his femur, leaving a 17-inch deficiency. Researchers created a personalized 3D-printed bone implant with ceramic and PEEK polymer. The implant, designed based on CT reconstruction data, improved nutrient flow, mechanical strength, and biological activity. Simulations showed the metal device was 2.5 times more rigid than the polymer implant. The implant fostered osseointegration, regaining load-bearing capacity and aiding biological remodeling. This case showcased the global potential of AM biomedical implants [12]. AM is utilized for esthetics and function restoration following cancer treatment. A 50-year-old female patient had a partial right maxillectomy due to sarcoma.

A customized porous implant was necessary to restore contour, function, and speech. The team used mesh software to reconstruct the skull mathematically and generate a CAD model. Numerous trials were conducted to achieve satisfactory results. The final model was fabricated using a laser sintering machine. The implant was successfully fixed, showcasing AM's effectiveness in maxillofacial rehabilitation. This case demonstrates AM's efficiency and flexibility for medical implants [13]. A third application involves an elderly woman with severe tooth loss in both dental arches, leading to maxillary atrophic resorption. Biomedical engineers designed a customized patient-specific prosthesis based on patient anatomy and individual needs. Through 3D scanning and modeling techniques, a highly aesthetic design of a titanium framework prosthesis was created, enhancing anatomic compatibility, stability, and occlusion function. The patient's satisfaction increased significantly following the surgery, indicating that AM prosthesis procedures provide good quality biocompatible prototypes. This clinical case raises the possibility of globally applying AM prosthesis technology [14].

BIOPRINTING OF TISSUES AND ORGANS

Bioprinting is a specialized form of additive manufacturing (AM) that uses the same layer-by-layer techniques to build complex three-dimensional (3D) constructs, but with living cells and biological materials instead of plastic or metal. Such constructs have the ability to replicate the functions, structures, and properties of natural tissues. Bioprinting has opened a whole new realm of possibilities for potentially endless biomedical applications that were hardly imaginable until recently. Such applications include personalized tissue and organ grafts, tissue microarrays for drug testing, bio-inks for the fabrication of complex scaffolds for tissue engineering, and low-cost organs-on-chips for in vitro physiology studies and toxicology assays [15]. Tissue and organ grafts made from bioprinted constructs that are composed of a patient's own cells can overcome the problems of donor organ shortage and tissue rejection. Bioprinting can be utilized to generate tissue grafts with a pre-defined geometry for replication of critical shapes such as ears, noses, and bone segments, or to reconsolidate large defects that occur after cavernous malformation or gunshot injuries. In terms of functional reconstruction, bioprinted multi-tissue constructs are needed, such as the generation of vascularized cardiovascular grafts or bioprinted liver tissues that eliminate the side effects of synthetic drugs [16]. To date, all bioprinted tissues and organs have been built using a human cell type (usually fibroblasts, keratinocytes, or smooth muscle cells), along with the incorporation of other ECM components, such as collagen, alginate, gelatin, and fibrin. The sole in situ bioprinting of hydrogels to accelerate tissue repair has also been demonstrated. Although these bioprinted tissues have shown promise in vitro under highly controlled conditions, no functional bioprinted tissues have yet been implanted into humans. The scale-up of such bioprinting processes is critical for future surgical outcomes [17]. Additive Manufacturing (AM) as a technology that can fabricate patient-specific 3D structures - adequate size and shape - based on digital information from high-resolution images. It focuses on Layer-by-Layer procedures and advances from prototypical models to the generation of end-use parts. AM has important healthcare applications, mainly focused on low-weight and customized devices, tools, and implants, which improves surgical procedures and helps rehabilitation [18]. Patient-specific (or personalized) additive manufactured implants or prostheses is a concept that implies the fabrication of structures tailored to individual patients and the need for predictive and optimized numerical methodologies for manufacturing processes. The idea of creating custom-tailored implants can be extended to the reconstruction of large bone defects customized manufacturing of patient-specific titanium mesh. Computer-assisted design tools have remarkably changed the production of orthopedic and craniofacial implants [19].

FUTURE DIRECTIONS AND INNOVATIONS IN ADDITIVE MANUFACTURING FOR BIOMEDICAL ENGINEERING

As the technology continues to advance, the potential for additive manufacturing to revolutionize biomedical engineering will only increase. Over the next five years, the additive manufacturing of final-use medical devices is expected to grow more than 21 percent annually, one of the fastest-growing sectors of the industry. Research continues into improving materials, both in terms of biocompatibility and performance, and exploring the use of new materials, such as ceramics or metals that meet regulatory requirements [20]. Several major advancements in additive manufacturing technology are anticipated, such as enhancing the precision and quality of manufactured parts by two to five times; integrated real-time monitoring capabilities; and, eventually, the ability to add multiple materials during the same build. Combinations of two or more of these technologies are expected to emerge in the next five years to offer competitive advantage in niche markets in the business [21]. Areas of research and development in additive manufacturing that will focus on healthcare applications are advancing to develop manufacturing for medical implants that are bioresorbable and stimulate new bone growth or smart scaffolds that release drugs or growth factors in a controlled manner. There is interest in designing and evaluating trials to use 3D-printed dummies for surgical procedures, enabling rehearsals and reducing the need to practice on real patients. Current trials include cranial surgery on craniosynostosis patients, heart surgery on pediatric patients, and laparoscopic surgery on kidney tumors. Such trials illustrate how additive manufacturing fits well with a developing trend toward proactive and personalized healthcare [22]. As the technology continues to grow and mature, there will be a focus on the regulatory aspects including safety considerations, failure modes, and associated manufacturing controls. Attention to these important aspects will play a crucial role in determining the sector's long-term growth and success, as companies learn from past mistakes with other technologies [21].

CONCLUSION

Additive manufacturing (am) has significantly influenced biomedical engineering, enabling the creation of complex, patient-specific devices and advancing the fields of personalized medicine and regenerative therapy. Despite the remarkable progress, challenges such as material biocompatibility, regulatory approval, and the scalability of bioprinting technologies remain. As research continues to push the boundaries of am, future innovations will likely enhance the precision, functionality, and safety of am-produced biomedical devices. This will not only improve patient outcomes but also contribute to the broader adoption of am in healthcare. The ongoing development of new materials and techniques, coupled with a focus on regulatory standards, will be crucial in realizing the full potential of am in biomedical engineering.

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