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To cite this article: A K Puppala *et al* 2020 *J. Phys.: Conf. Ser.* **1495** 012021

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Additive Manufacturing for VADs and TAHs - a Review

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Abstract. Heart disease or Advanced/Congestive Heart Failure (CHF) is one of the serious causes of death. Due to availability of low volumes of donor hearts, there has been an ongoing development of Mechanical Circulatory Support (MCS): Ventricular Assist Devices (VADs) and total heart replacement by Total Artificial Hearts (TAHs) for over 60 years. MCS systems had seen three phases of advancement. The first generation were largely mechanical devices and had pulsatility in their action, but were highly cumbersome, unreliable due to fatigue cracks and required an external pneumatic power and control. Smaller and continuous flow devices are the second generation MCS devices. Because of compact sizing they were suitable for implantations and were more durable than the first generation devices. Problems like pump thrombosis drove the development of motors with levitating or hydrodynamic rotors, leading to the development of third generation devices. Manufacturing of these electromagnetic devices for implantation has to adhere to the constraints of compatibility, space and weight. With the advent of new biomaterials, additive manufacturing is reportedly playing a significant role. Additive manufacturing reported for electromagnetic and electronic components had yielded considerably good performance. This paper reviews materials in electrical and electronics and also in bio medical sector suitable for Additive Manufacturing. An attempt is made to identify the materials that may be suitable for VADs and TAHs and the challenges to use AM techniques that complement each other to create next generation integrated-VADs and integrated-TAHs.

1. Introduction

Due to the less availability of donor hearts [1], there has been an on-going development of Mechanical Circulatory Support (MCS) as VADs and as total heart replacements by TAHs for over 60 years as bridge to transplant or as a destination therapy [2-6]. Natural myocardial performance when replaced by MCS in pre-transplant patients was shown to improve post-transplant rates of mortality [7-9].

Mechanical circulatory frameworks had seen three phases of advancement. The first generation mechanical circulatory support devices were largely mechanical devices, which were highly cumbersome, unreliable due to small fatigue cracks and required an external pneumatic power and control. These devices had Pulsatility in blood flow. Smaller and continuous flow devices are the second generation MCS devices, which were electro-mechanical. They were more reliable and compact than the first generation. The lifetime was limited to 1-2 years, but failed to get pulsatility in flow. Diminished nature of pulsatility increased the pressure gradients on the aortic valve; left ventricular recovery rate got slower [10]. Problems like pump thrombosis prompted the development of non-bearing type of devices leading to the development of third generation devices, where the rotors/pumps magnetically/hydrodynamically levitate, thereby providing better hemocompatibility [11]. Manufacturing of these electromagnetic devices for implantation has to adhere to the constraints of space and weight apart from being bio-compatible. Researchers are trying to understand why the blood interacts with the artificial surfaces of the pumps to cause clotting and inflammation and thereby develop surfaces that avoid the same [13].

Longevity, hemocompatibility issues combined with predicted increasing demand for heart valve replacements has evoked the search for alternative fabrication methods of heart valve replacements [14],



Similarly, intricate design and implementation of VADs and TAHs have to search for alternative fabrication methods. The authors of this paper mathematically implemented an algorithm to introduce pulsatility in continuous flow devices and reviewed the electrical motor and pump assemblies in VADs and TAHs [12]. This work not only reviews alternative manufacturing technique viz., additive manufacturing for the electric motors and pumps for VADs and TAHs, but also study the materials in electrical, electronics and biomedical industry for additive manufacturing.

2. Additive Manufacturing and materials in Electronics and Electrical Industry.

Researchers involved in AM have long focused on creating exteriors of a product namely, thermoplastics, metals and ceramics. However, of late, the focus is now turning towards working with/on materials that are required for a product's internal circuitry. These materials include conducting inks: toners loaded with charged particles that build live circuitry [13]. Conductive inks in combination with base materials, printers can 3D-print electronic objects as a single, continuous part, effectively creating fully functional electronics that require little or no assembly, offering the following advantages.

- Printability on Non-flat surfaces.
- Customization, for not only mechanical parts but also electronic and electromechanical parts
- Lower material wastage and also lower part weight.
- Absence of harmful chemicals for “etching”
- Simplified process in the assembly line
- Probable reduction in the size
- Modular approach - in building products.

All of the benefits listed above are reportedly taking 3D-printed electronics to different sectors and pushing the frontiers in several industrial domains such as sensors and prototypes for aerospace and defence, mobile antennae for telecom, touch screen displays and transistors for consumer electronics, and solar cells for energy and utilities [14].

The technologies available to 3D print electronics are classified – based on the process of manufacturing electronics, into two broad categories viz., 3D printing the electronics separately from part production process while the other one being - integrating the 3D printing of electronics with the part production process as reported in [15]. Aerosol jet manufacturing reported in [16] could define a whole new way to create dense electronic board assemblies and potentially improve the performance and consistency of electronic assemblies.

2.1. AM in Electrical and Electronics Industry

Several types of motors and pump assemblies for VADs and TAHs were reviewed in [12]. Linear tubular switched reluctance motor for LVAD application was proposed in [17]. Line-start Synchronous Reluctance Motors, although solve low starting torque problem, needs complex rotor structure that is difficult to manufacture. Po-Wei et al [18] reported a Synchronous Reluctance motor with a squirrel cage rotor manufactured using 3D printing technology. Soft Magnetic Composites compliment the Selective Laser Melting (SLM) 3D printing approach resulting in a motor with low vibration and low rotor copper loss along with lower motor weight and volume [19-22].

2.2. Materials in Electrical and Electronics Industry

AM technologies also vary by the type of materials they can use for electronics. Fine aerosol of metal particles, including silver, gold, platinum, or aluminium were reportedly used to deposit onto a surface. Aerosol jet printers reported in [16] can deposit polymers or other insulators and can even print carbon nanotubes, cylindrically shaped carbon molecules that have novel properties useful in nanotechnology, electronics, and optics. Although the list of materials for 3D printing of electronics is limited, it is seemingly growing. Graphene, with its high electric and thermal conductivity is offering applications in integrated circuitry [15]. Nanoparticles of silver, copper and carbon nanotubes were reportedly used to build thin film transistors and RF antennas for cell phones [14, 23].

3. Additive manufacturing and materials in Biomedical Sector

Cardiac-aberrations, either congenital or non-congenital in the medical care/diagnosis are commonly being visualized using medical images obtained through computed tomography (CT), magnetic resonance (MR) imaging, and echocardiography (echo). Medical image post processing techniques are providing an attractive route for pre- and peri-procedural planning. However, 3D printing of patient-specific anatomical replicas, in true-to-life models are helping to reduce morbidity, mortality and financial burdens on the clinical environment [24]. These 3D printed models that morphologically represent and have tactile interaction are perceived to better prepare a clinician for a procedure. Surgeons and interventionalists were reported to benefit by knowing the shape, size and location of the defect [25-27]. Studies reported in [28-29] suggest a reduction in fluoroscopic exposure and cardiopulmonary bypass time which correspond to lower exposure to potentially harmful radiation as well as cardiac and cerebral events and overall medical costs [30]. A 3D printing technique using the personalized hydrogel as a bioink, when combined with the patient's own cells, the hydrogel reportedly was used to print thick, vascularized, and perfusable cardiac patches that fully match the immunological, biochemical and anatomical properties of a patient [33]. With these advantages, 3D printing is affecting significant advances in clinical care [24, 31]. However, 3D printed electrical machines or pumps for VADs or TAHs are not reported in literature.

3.1 Materials and AM methods in Biomedical Sector

Various biomaterials and their applications in biomedical engineering as reported in [34] are reproduced here in Table 1. Several AM technologies reported in the literature in the biomedical sector are Metal on Metal (MOM) [35], Electron beam melting (EBM) [36], Selective laser melting (SLM) [37-38], Fused Deposition Modelling [39-40], Stereo-lithography [41], Ink – Jet Printing and Bio-printing [32-33]

Table 1: US FDA Approved 3D printed biomedical material [34]

Material	Application
CP-Ti	Screw and abutment
Ti-6Al-4V	Artificial valve, Stent, Bone fixation
Ti-6Al-7Nb	Crowns, Knee joint, Hip joint
Ti-5Al-2.5Fe	Spinal implant
Ti-15 Zr-4Nb-2Ta-0.2Pd	Crown, Bridges, Dentures, Implants
Ti-29Nb-13Ta-4.6Zr	Crown, Bridges, Dentures, Implants
83%–87%Ti-13%–17%Zr (Roxolid)	Crown, Bridges, Dentures
316L	Knee joint, Hip joint, Surgical tools, Screw
Co-Cr-Mo, Co-Ni-Cr-Mo	Artificial valve, Plates, Bolts, Crowns, Knee joint, Hip joint,
NiTi	Catheters, stents,
PMMA, PE, PEEK	Dental bridges, articular cartilage, Hip joint femoral surface, Knee, Joint bearing surface, Scaffolds
SiO ₂ /CaO/Na ₂ O/P ₂ O ₅	Bones, Dental implants, orthopedic implants
Zirconia	Porous implants, Dental implants
Al ₂ O ₃	Dental implants
Ca ₅ (PO ₄) ₃ (OH)	Implant coating material

It may be observed from the table above that materials Ti-6Al-4V, Co-Cr-Mo, Co-Ni-Cr-Mo are suitable for applications related to heart.

4. Challenges in integration of AM techniques with fabrication of VADs & TAHs

Freedom of design, mass customization, multi-material fabrication and the ability to produce even complex geometries are the possibilities that AM techniques had helped the researchers and all the stake holders. While Yu et al. [32] opines that 3D bioprinting will eventually become one of the most efficient, reliable, and convenient methods to biofabricate tissue constructs in the near future when combined/integrated with the stem cell technologies and advanced materials engineering approaches featuring stimuli-responsiveness. Maria et. al. [43] opines that maturation of 3D bioprinted tissue or organ depends on nutrients delivery, gas exchanges, and waste removal with the most critical challenge in bioprinting being vascularization of created thick tissue. AM

techniques reported in [16] for making dense electronic board assemblies, if coated with biocompatible materials reported in [34, 42-43] and integrating with electrical motors created with AM techniques reported in [17-22] to pump the blood could, potentially address the challenge of vascularization of 3D printed organs. Hence use of several AM techniques to 'part produce' individual components and integrating them would probably complement electromechanical circulatory systems with bioengineered tissues and eventually become long-sought 'holy grail' in the form of, probably next-generation 'integrated-VADs' and 'integrated-TAHs'.

Acknowledgments

The authors gratefully acknowledge the funding for this work by Jawaharlal Nehru Technological University Hyderabad under TEQIP – III scheme and also thank Geethanjali College of Engineering and Technology Hyderabad and CVR College of Engineering, Hyderabad for their support.

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