ADDITIVE MANUFACTURING OF PROSTHETIC DEVICES

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Abstract: The additive manufacturing (AM) also widely known as three-dimensional (3D) printing, becomes a manufacturing revolution and has accelerated the advancement in the field of bio fabrication. However, the latest evolution in AM now opens the door of patient-specific healthcare solutions. The challenging task of customizing production of prosthetics, implants, drug delivery devices, medical instruments, not possible without AM. In what follows, we briefly review the application of additive manufacturing techniques used for the production of prosthetics devices.

Keywords- Bioprinting, Biofabrication, Biomaterials, Medical devices.

I. INTRODUCTION

Additive Manufacturing (AM) is the technology that generate 3D objects by adding layer-by-layer of any material like plastic, metal or concrete. AM technologies comprises the use of a computer, 3D modeling software (Computer Aided Design or CAD), machine equipment and layering material. Once a CAD sketch is produced, the AM equipment reads in data from the CAD file and lays downs or adds successive layers of liquid, powder, sheet material or other, in a layer-upon-layer fashion to fabricate a 3D object. The term AM encompasses many technologies including subsets like 3D Printing, Rapid Prototyping (RP), Direct Digital Manufacturing (DDM), layered manufacturing and additive fabrication. AM application is limitless. Early use of AM in the form of Rapid Prototyping focused on preproduction visualization models. More recently, AM is being used to fabricate end-use products in aircraft, dental restorations, medical implants, automobiles, and even fashion products. While the adding of layer-upon-layer approach is simple, there are many applications of AM technology with degrees of sophistication to meet diverse needs including, a means to create highly customized products for consumers and professionals alike and to produce small lots of production parts [1-4].

Most importantly, an extensive variety of biomedical materials would now be able to be prepared using additive manufacturing techniques with increasing accuracy. Also, a number of AM processes and the resulting products have already been approved by regulatory bodies for (routine) clinical use, and a draft version of FDA guidance for additively manufactured devices has already been published. By increasing the potential of AM, the new researching and developing areas open in the healthcare. This review mainly focusing on types of AM techniques and prosthetic devices developed using AM [5-6].

II. PROSTHETIC DEVICES

In medicine, a prosthesis is an artificial device that replaces a missing body part, which may be lost through trauma, disease, or congenital conditions. Prosthetics are intended to restore the normal functions of the missing body part [7]. Prosthesis classified into inside body and outside body prosthesis and further as shown in Fig 1.

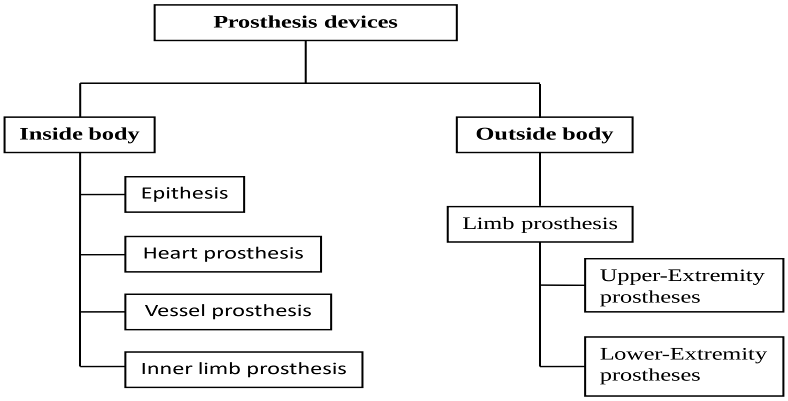


Figure 1. Classification of Prosthesis devices

A. *Heart Prosthesis:*

Mainly there are three types of heart valves prosthesis: the biological, the mechanical and the tissue engineered valves. Mechanical valves further classified into three types– caged-ball, tilting-disk and bileaflet valve shown in Fig. 2 – with many modifications on these designs [8-10].

(a) (b) (c)

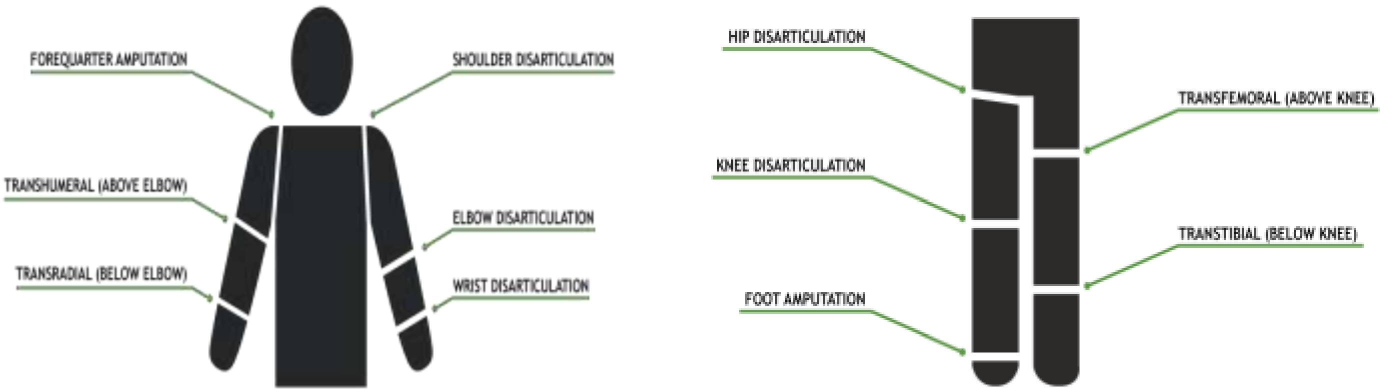
Figure 2. (a) Caged ball valve, (b) tilting-disc valve and (c) Bileaflet valve

B. *Limb prosthesis:*

Limb prosthesis include both upper and lower extremity prosthesis.

Upper-extremity prosthesis are used at varying levels of amputation as shown in fig 3 (a).: elbow disarticulation, wrist disarticulation, forequarter, transhumeral prosthesis, shoulder disarticulation, transradial prosthesis, partial hand, full hand, full finger, partial finger. To replace the arm missing below the elbow, a transradial prosthesis is used as an artificial limb [11-12].

Lower-extremity prosthesis give substitutions at different levels of amputation as shown in fig 3 (b). These include transfemoral prosthesis, hip disarticulation, knee disarticulation, Syme's amputation, transtibial prosthesis, partial foot, foot and toe. The lower extremity prosthetic devices are subcategories into two part; one is trans-femoral and another one is trans-tibial. Trans-femoral and trans-tibial are congenital anomaly resulting in a femoral deficiency and a tibial deficiency respectively [13-15].



(a) (b)

Figure 3. (a) Levels of amputation for upper limb and (b) Levels of amputation for lower limb.

III. ADDITIVE MANUFACTURING TECHNIQUES:

A. Vat polymerization:

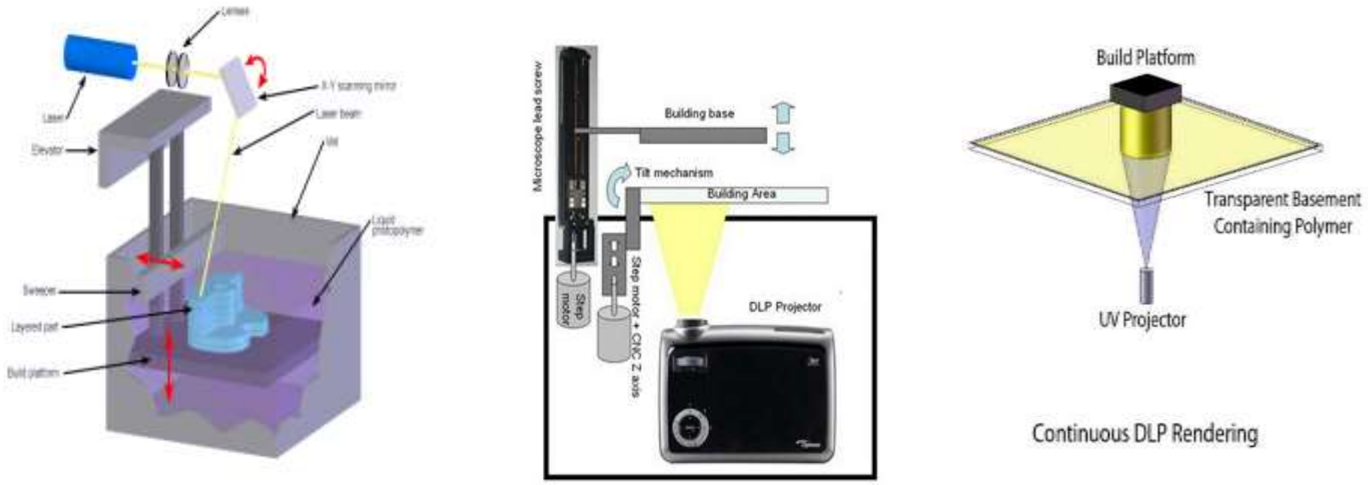
1. **Stereolithography (SLA):** Stereolithography (SLA) is an additive manufacturing - commonly referred to as 3D printing technology that converts liquid materials into solid parts, layer by layer, by selectively curing them using a light source in a process called photopolymerization. SLA is widely used to create models, prototypes, patterns, and production parts for a range of industries from engineering and product design to manufacturing, dentistry, jewelry, model making, and education [16].

SLA belongs to a family of additive manufacturing technologies known as vat photopolymerization. These machines are all built around the same principle, using a light source—UV laser or projector—to cure liquid resin into hardened plastic shown in figure 4 (a). The main physical differentiation lies in the arrangement of the core components, such as the light source, the build platform, and the resin tank [17].

2. **Digital Light Processing (DLP):** DLP (Digital Light Processing) is a similar process to stereolithography in that it is a 3D printing process that works with photopolymers. The major difference is the light source. DLP uses a more conventional light source, such as an arc lamp with a liquid crystal display panel, which is applied to the entire surface of the vat of photopolymer resin in a single pass, generally making it faster than SL as shown in figure 4 (b). Also like SL, DLP produces highly accurate parts with excellent resolution, but its similarities also include the same requirements for support structures and post-curing. However, one advantage of DLP over SL is that only a shallow vat of resin is required to facilitate the process, which generally results in less waste and lower running costs [18].

In this process, once the 3D model is sent to the printer, a vat of liquid polymer is exposed to light from a DLP projector under safelight conditions. The DLP projector displays the image of the 3D model onto the liquid polymer. The exposed liquid polymer hardens and the build plate moves down and the liquid polymer is once more exposed to light. The process is repeated until the 3D model is complete and the vat is drained of liquid, revealing the solidified model. DLP 3D printing is faster and can print objects with a higher resolution [18].

3. **Continuous digital light processing (CDLP):** CDLP systems render parts by projecting an image through a clear basement plate into a tray containing the resin, curing at the bottom surface rather than the top surface. The parts attach to a build platform which moves upward, away from the basement plate, after each layer is projected [19]. The setup of CDLP as shown in figure 4 (c).



(a) (b) (c)

Figure 4. (a) Stereo lithography apparatus (b) digital light processing (DLP) and (c) Continuous digital light processing (CDLP).

B. Material extrusion:

1. **Fused deposition modeling:** The thermoplastics are liquefied and deposited by an extrusion head, which follows a tool-path defined by the CAD file. The materials are deposited in layers. A plastic filament or metal wire is unwound from a coil and supplies material to an extrusion nozzle which can turn the flow on and off. The nozzle is heated to melt the material and can be moved in both horizontal and vertical directions by a numerically controlled mechanism, directly controlled by a computer-aided manufacturing (CAM) software package. The model or part is produced by extruding small beads of thermoplastic material to form layers as the material hardens immediately after extrusion from the nozzle. Stepper motors or servo motor are typically employed to move the extrusion head [20].

The great advantage of FDM (Fused deposition modeling) is the durable materials it uses, the stability of their mechanical properties over time, and the quality of the parts. The production-grade thermoplastic materials used in FDM are suitable for detailed functional prototypes, durable manufacturing tools and low-volume manufacturing parts. Ideally FDM used for Low-volume production of complex end-use parts; prototypes for form, fit and function testing; prototypes directly constructed in production materials; pharmaceutical and biotechnology industries; food and drug packaging and the medical devices industry [21].

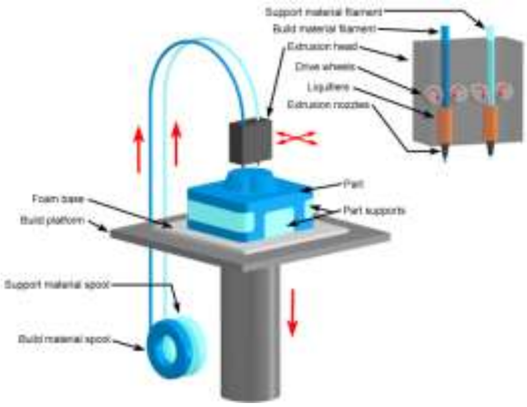
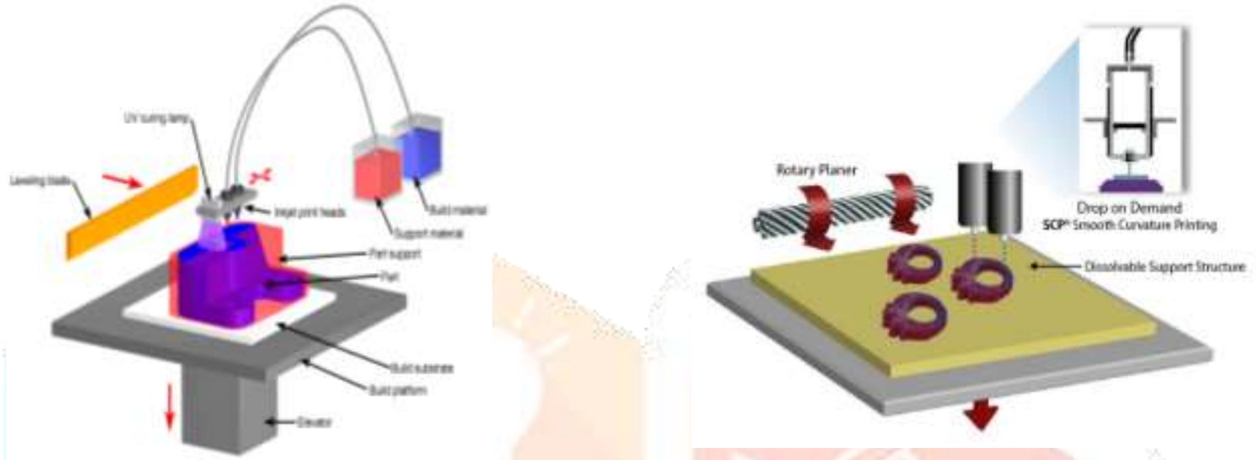


Figure 5. Fused deposition modeling

C. Material jetting:

In material jetting, a printhead (similar to the printheads used for standard inkjet printing) dispenses droplets of a photosensitive material that solidifies under ultraviolet (UV) light, building a part layer-by-layer. The materials used in MJ are thermoset photopolymers (acrylics) that come in a liquid form. Material jetting can produce smooth parts with surfaces comparable to injection molding and very high dimensional accuracy. Parts created with Material Jetting have homogeneous mechanical and thermal properties. The multi-material capabilities of MJ enables the creation of accurate visual and haptic prototypes. Material jetted parts are mainly suitable for non-functional prototypes, as they have poor mechanical properties (low elongation at break). MJ materials are photosensitive and their mechanical properties degrade over time. The high cost of the technology may make Material Jetting financially not viable for some applications. A variation of the MJ process uses Drop-On-Demand (DOD) printheads to dispense viscous liquids and create wax-like parts. DOD is used almost exclusively for manufacturing investment casting patterns [22-23].



(a) (c)

Figure 6. (a) Material jetting and (b) Drop on demand

D. Powder bed fusion:

1. Multi jet fusion: Though this technology is powder-based, does not using any types of laser. The powder bed is heated uniformly at the outset. A fusing agent is jetted where particles need to be selectively molten, and a detailing agent is jetted around the contours to improve part resolution. While lamps pass over the surface of the powder bed, the jetted material captures the heat and helps distribute it evenly. Multi Jet Fusion uses a fine-grained PA 12 material that allows for ultra-thin layers of 80 microns. This leads to parts with high density and low porosity, compared to PA 12 parts produced with Laser Sintering. It also leads to an exceptionally smooth surface straight out of the printer, and functional parts need minimal post-production finishing. That means short lead times, ideal for functional prototypes and small series of end-parts. Multi Jet Fusion is use for low-volume production of complex end-use parts; prototypes for form, fit and function testing; prototypes with mechanical properties to rival those of injection-molded parts and series of small components as a cost-effective alternative to injection molding [24-25].

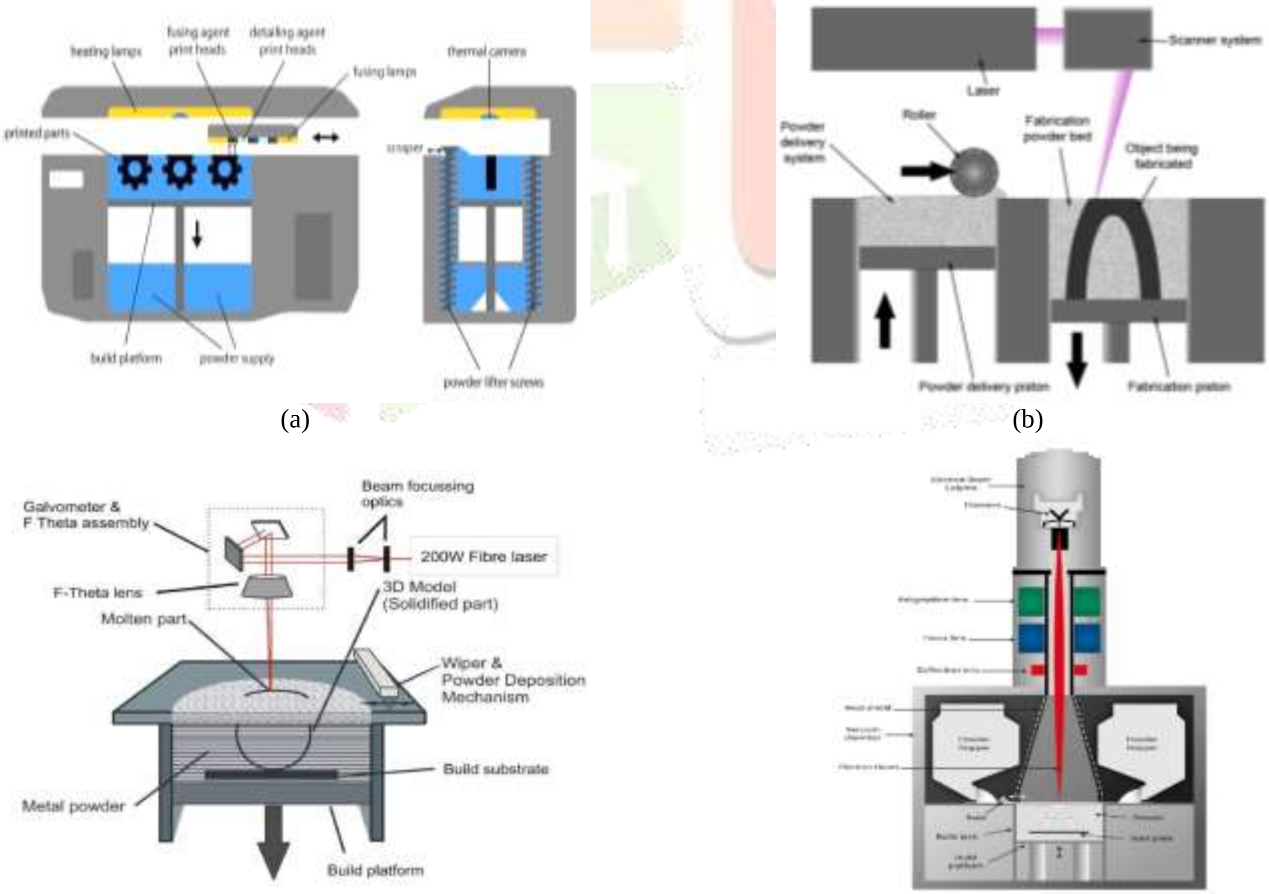
2. Selective laser sintering: SLS involves the use of a high power laser to fuse small particles of plastic, metal, ceramic, or glass powders into a mass that has a desired three-dimensional shape. The laser selectively fuses powdered material by scanning cross-sections generated from a 3-D digital description of the part (for example from a CAD file or scan data) on the surface of a powder bed. After each cross-section is scanned, the powder bed is lowered by one layer thickness, a new layer of material is applied on top, and the process is repeated until the part is completed [26-27].

3. Selective laser melting: The process starts by slicing the 3D CAD file data into layers, usually from 20 to 100 micrometers thick, creating a 2D image of each layer; this file format is the industry standard .stl file used on most layer-based 3D printing or stereolithography technologies. This file is then loaded into a file preparation software package that assigns parameters, values and physical supports that allow the file to be interpreted and built by different types of additive manufacturing machines. With selective laser melting, thin layers of atomized fine metal powder are evenly distributed using a coating mechanism onto a substrate plate, usually metal, that is fastened to an indexing table that moves in the vertical (Z) axis. This takes place inside a chamber containing a tightly controlled atmosphere of inert gas, either argon or nitrogen at oxygen levels below 500 parts per million. Once each layer has been distributed, each 2D slice of the part geometry is fused by selectively melting the powder. This is accomplished with a high-power laser beam, usually an ytterbium fiber laser with hundreds of watts. The laser beam is directed in the X and Y directions with two high frequency scanning mirrors. The laser energy is intense enough to permit full melting (welding) of the particles to form solid metal. The process is repeated layer after layer until the part is complete [28-29].

This technology is used to manufacture direct parts for a variety of industries including aerospace, dental, medical and other industries that have small to medium size, highly complex parts and the tooling industry to make direct tooling inserts. Medical devices are complex, high value products. They have to meet customer requirements exactly. These requirements do not only stem from the operator’s personal preferences: legal requirements or norms that differ widely between regions also have to be complied with. This leads to a multitude of varieties and thus small volumes of the variants offered [30-31].

4. <u>Electron beam melting</u>: Electron beam melting (EBM) is an innovative additive manufacturing (AM) process in which metal powder or filament is completely melted by a concentrated beam of electrons. Production in a vacuum chamber ensures that oxidation will not compromise highly reactive materials like titanium. Vacuum production is also required so electrons don’t collide with gas molecules. Not long ago, most EBM projects merely illustrated the considerable possibilities of the AM process. Today, the potential of electron beam melting technology is more fully realized as it is used to print components used in demanding aerospace, automotive, defense, petrochemical and medical applications [32-33].

A tungsten filament in the electron beam gun is superheated to create a cloud of electrons that accelerate to approximately one-half the speed of light. A magnetic field focuses the beam to the desired diameter. A second magnetic field directs the beam of electrons to the desired spot on the print bed. Electron beam melting is a high-energy, high-temperature process. This was illustrated by researchers at NASA’s Marshall Space Flight Center when they measured temperatures as high as 2,000 degrees C in the electron beam melting process. Once a component or prototype has been printed, the build envelope is removed and the build platform and attached object are removed from the loose powder. Powder clinging to the object or remaining in internal cavities is blown or blasted away. Post-processing methods, including hot isostatic pressing (HIP), heat treatment in inert gas or vacuum heat treatment may be employed to release residual stresses and improve mechanical properties. In some instances, machining may be used to deliver parts with required critical tolerances. CNC machining, sandblasting and shot peening, plating and electropolishing are available to refine the slightly bumpy finish of an EBM-produced part as required. Electron beam melting technology builds high-strength parts that take advantage of the inherent properties of the metals processed. EBM virtually eliminates impurities that may otherwise intrude when using traditional methods of fabrication. Electron beam melting includes two technologies -- powder bed fusion (PBF) and fused deposition. The former uses powdered metal to build objects while the latter uses wire filament [32-34].



(a) (b)

(c) (d)

Figure 8. (a) Multi jet fusion (b) Selective lase sintering and (c) Selective laser melting and (d) Electron beam melting

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