Additive Manufacturing of Carbon Fiber Reinforced Composites for Medical Application: Issues and Challenges

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Abstract—The loss of a limb from an accident, war or disease is more common than one might imagine. Global market for prosthetics and related orthotics (body part braces) together is $2.8 billion. Demand for foot prosthetics has created a market for carbon fiber. Carbon fiber provides more energy storage and return (known as dynamic response) than any other material. Continuous carbon fiber/PEEK is used as an alternative to metals in the fabrication of implantable load-bearing components for orthopedic applications. Fused deposition modeling (FDM) is a rapidly growing three-dimensional (3D) technology. The advances in 3D printing technologies give unconstrained design choice. 3D printing is widely used by Industry leaders in biomedical field now days. The boom in biomedical 3D printing research is wholly supported by its successful commercial use and promises rapid progress and translation to public use. Polyether-ether-ketone (PEEK) is a biocompatible high-performance polymer, which is appropriate to be used as an orthopedic/dental implant material. The mechanical properties and biocompatibility of FDM-printed PEEK and its composites are not well clear. Therefore, the FDM-printed CFR-PEEK composite with suitable mechanical strengths has potential as a biomaterial for bone grafting and tissue engineering applications. Objective of this paper is to suggest the optimal implant. The optimal implant is, strong but somewhat flexible, with a modulus of elasticity as close as possible to that of the bone. New polymeric and composite materials are need to be developed to fulfill this requirement.

Keywords— Carbon fiber, PEEK, biocompatible, Optimal implant, Modulus of elasticity component

I. INTRODUCTION

Three-dimensional (3D) printing is a manufacturing method in which objects are prepared by fusing or depositing materials. A large variety material are available such as plastic, metal, ceramics, powders, liquids, or even living cell in layers to manufacture a 3D object. This process is also known as additive manufacturing (AM), rapid prototyping (RP), or solid free-form technology (SFF). Several 3D printers are alike to traditional inkjet printers. Although the end product produced is a 3D object in 3D printing. It is expected that 3D printing to transform medicine and other fields [1].

With the several 3D printing processes available, which employ altering printer technologies, speeds, and resolutions, and several materials. These technologies are able to build an object of approximately any shape as defined in a computer-aided design (CAD) file. The 3D printer first follows the instructions in the CAD file to build the foundation for the object, moving the print head along the x-y direction. To make a 3d object, moving the print head vertically in the z-direction continuously layer by layer [1].

II. ADDITIVE MANUFACTURING TECHNIQUES IN MEDICAL FIELD

Additive Manufacturing (AM) provides wide-ranging customization as per the requirement of individual patient data and particular Medical applications. With the help of customized software individual patient models are prepared in three-dimensional (3D) sections. These consist of implants, soft tissue, foreign bodies, vascular structures, etc [2, 3]. 3D printing has found its application in various medical applications as new orthopedic products, Fabrication of customized maxillo-facial prosthesis; dentistry etc [2, 4]. Apart from this Additive manufacturing also provides an acceptable result for skeleton models [2, 5].

Apart from various well establish Medical Rapid Prototyping techniques like fused deposition modeling (FDM), stereo lithography (SLA) and Inkjet 3D printing, Recently advanced techniques like Direct Metal Laser Sintering (DMLS), Selective Laser Sintering (SLS), Selective Laser Melting (SLM), and Electron Beam Melting (EBM) are being used to manufacture implant with satisfactory dense in metallic form. In a few hours, the DMLS machine can produce 3D parts with high complexity and accuracy [6]. Some other technologies are digital light processing (DLP), multijet moulding (MIM), laminated object manufacturing (LOM), direct ink writing (DIW) and inkjet printing. These technologies can be normally categorized into four groups namely liquid based (SLA, MJM and RFP), powder based (SLS, EBM, 3DP and LOM), solid sheet based (LOM), and filament based (FDM and FEF) [6].

A. Direct metal laser melting (DMLM)

DMLM is an additive manufacturing process that melts ultrathin layers of metal powder with the use of lasers to build a three-dimensional object. Objects are prepared directly from an .stl file generated from CAD (computer-aided design) data. The lasers selectively melt thin layers of tiny particles results in objects having fine, dense and homogeneous characteristics. The fabrication of functionally graded metallic implants is possible with the Laser-forming methods,
like DLMS, allow with a gradient of porosity perpendicular to the long axis, which is helpful for bone in-growth.

B. Selective Laser Melting (SLM) & Selective Laser Sintering (SLS)
SLM and SLS are two AM processes differentiated by the degree to which materials are melted. SLM involves the full melting of material, whereas SLS involves sintering (partially melting) material. Here “selective” refers to the precise melting of ultra-thin layers of build material. Since selective laser melting (SLM) requires complete melting at very high temperatures, object distortions and stresses are more of an issue. However, full melting minimizes porosity. SLM presents a new possibility to manufacture individual biodegradable implants made of b-TCP/PDLLA. The advantage of combining these materials are the reduction of the acidic environment and the enhancement of the mechanical properties compared with parts made of only one material [8]

C. Electron Beam Melting
Electron beam melting (EBM) is one of the latest AM techniques using a computer-controlled electron gun to create fully dense 3D objects directly from metal powder. EBM found several applications in aerospace, automotive, and medical/orthopaedic implant industries. The basic principle of this technology is the generation of structures by the selective melting of discrete powder layers by an electron beam under vacuum conditions. Electron beam melting is similar to laser melting, but working with an electron beam instead of a laser.

III FOUR MAJOR APPLICATIONS REVOLUTIONISING THE MEDICAL INDUSTRY

A. Bioprinting tissues and organoid
Bioprinters use a computer-guided pipette to layer living cells, referred to as bio-ink, layer by layer to create synthetic living tissue in a laboratory. That can be used for medical research as they exact replica of an organs on a miniature scale. It can be one of the cheaper options to human organ transplants.

B. Surgery preparation assisted by the use of 3D printed models
One more role of 3D printing is creating patient-specific organ replicas in the medical field. These replicas can be used by surgeons to practice on before performing complex operations. It can speed up procedures as well minimize strain for patients. It can also play a significant role in clinical treatment and in medical education. There is no obligation for biocompatibility of materials in such cases.

C. 3D printing of surgical instruments
3D printers also used to manufacture disinfected surgical instruments which can be used to operate on tiny areas without causing preventable extra damage to the patient. That will also minimize recovery time of patient.

D. Custom-made prosthetics using 3D printing
3D printing can be used to produce prosthetic limbs that are as per the need of the wearer. That means proper customized product can be produced with minimum time. It is common for amputees to stay weeks or months to receive prosthetics through the customary route; however, 3D printing appreciably speeds up the process, as well as creating much cheaper products that offer patients the same or some times better functionality as usually manufactured prosthetics. The low cost of these products makes them particularly applicable for use with children, who quickly outgrow their prosthetic limbs.

Permanent non-bioactive implants
Permanent medical implants commonly used in dentistry and orthopaedics require non-degradable biomaterial and offer good biocompatibility after surgical operation. Compared with fabricating implants by means of traditional machining technology, 3D printing can achieve personalized real-time manufacturing of any complex implant with high dimensional accuracy and short production cycles. During traditional bone treatments, stress-shielding phenomena can easily occur because traditional metallic implants present greater stiffness than bone, which will eventually compromise bone integrity. [6, 7]

IV BENEFITS OF 3D PRINTERS IN HEALTHCARE

A. Customizable
Bearing in mind human anatomy is as diverse as every human being on the planet, the point that 3D printer being able to customize your output is a key feather to understanding anatomy on an unforeseen level. This is true for prosthetics based on the characteristics of the patient, production of different types of tissues, for recreating difficult bone disorders as per individual needs, and even equipment and medicine. Each patient can get the customized solution they need, thus revolutionizing the healthcare industry. 3D printing can produce made-to-order jigs and fixtures for use in operating rooms. Custom-made implants, fixtures, and surgical tools can have a positive impact in terms of the time required for surgery, patient recovery time, and which is followed by success of the surgery or implant.

B. Cost Effective
Large scale productions are preferred over batch or small productions as it is fairly cheap. 3D printers offer opportunity for reasonably priced smaller production runs and prototyping. Even it offers to repeat smaller procedures to be tested and developed as per the end consumer’s requirement with multiple iterations without affecting end cost. All the outputs
will be economical, as the cost of human resources is absolutely eliminated. This is especially true for small-sized standard implants or prosthetics, such as those used for, spinal, dental, or craniofacial disorders and products that are highly complex or require frequent modifications like in children & young person.

C Efficient
As the conventional process of making a prosthetic or an implant or even developing a prototype involves long hours and delivery time. That will make the patient to wait for years. 3D printing offers the advantage of completely automated process with the accurate available readings. That will result the speedy and trustworthy output. The process more smooth and well-organized as one can produce numerous scaled replicas too with high productivity. “Fast” in 3D printing means that a product can be made within several hours. That makes 3D printing technology much faster than established methods of making items such as prosthetics and implants. The conventional methods necessitate different mechanical processes like milling, forging etc along with a long delivery time. In addition to speed, 3D printing also offers other qualities, like the resolution, accuracy, reliability, and repeatability.

D Democratization and Collaboration
As the process become easier and cost-effective with continuous progress, more researchers and professionals add with time to develop designs and innovate, which further results in simpler solutions in order to make an idea into reality.

The nature of 3D printing data files also offers an unprecedented opportunity for sharing among researchers. Researchers can access downloadable .stl files that are available in open-source databases. The National Institutes of Health established the 3D Print Exchange (3dprint.nih.gov) in 2014 to promote open-source sharing of 3D print files for medical and anatomical models.

V ADDITIVE MANUFACTURING FOR BONE
Bone is a complex tissue that continually undergoes dynamic biological remodeling & has an ability to remodel itself to repair damage. Metal implant, Metals and alloys have a extended history as bone implants. Stainless steels, cobalt (Co) based alloys (CoCrMo), and titanium (Ti) and its alloys are extensively used due to their good biocompatibility, satisfactory mechanical strength and superior corrosion resistance. However, stress shielding is the main concerns due to deference in stiffness, as implant are usually much stiffer than natural bones. Stress shielding is further a major source for bone resorption and ultimate collapse of such implants [9]. The need for cost-effective, inexpensive solutions for prosthetics is particularly important for growing children which results in more costs. Although limb loss affects a range of populations (e.g., veterans, diabetic patients, and children), the intensification of prosthetics for children and young adults is particularly significant. Thus, 3D printed prosthetics may pretense as a feasible solution. Due to their rapid growth, children and youths need multiple prosthetics. When an adult is fitted with a prosthetic, growth patterns are comparatively unchanging and only occasional adjustments are required[11]. AM opens to new opportunities and challenges of designing complex shapes while designing the infill ratio, the internal structure geometry and locally controlling material composition and behavior with FDM (Fused Deposition Modeling) technology[10]. 3D Printability mimics the traditional manual production process in a digital environment,. It uses a scanner to capture the external shape of the limb rather utilizing a plaster cast. Instead of modifying the prosthetic device by adding or subtracting in plaster, it adds or subtracts material with the use of 3D modeling software [11].

VI MATERIALS FOR BONE PARTS
The concept of natural fibers is also being employed and tested including wood particulates and bamboo fibers and may be applicable to low-cost O&P devices. The use of composite materials for manufacturing bio implants is not new; the development of composite materials for orthopaedic applications has been performed for more than three decades. In 1994, carbon fiber/PEEK (C/PEEK) polymer composites were developed as implant materials (Albert et al., 1994) [13]. Carbon fibers have multiple potential advantages in developing high-strength biomaterials with a density close to bone for better stress transfer. It was found that this composite implant exhibited 10–40% lower contact stresses in the distal region as compared to a titanium-alloy implant. The polymer-based composite biomaterials have gained attraction because of their tailor-made properties comparable to those of the host tissues. Therefore, innovations in the fabrication of composite materials are increasing the possibility of improved implant performance [14]. Magnesium (Mg) is a biodegradable implant material that provides an exceptional level of biocompatibility along with needed mechanical properties. In studies conducted involving Mg-based implants have shown that this element is suitable because it exists in human organisms. Mechanical properties of Mg alloys are superior compared to different classes of biodegradable synthetic polymers [15]. Recent developments have improved the properties by adding/doubling specific strength of a polymer feedstock material and by adding additional filler materials such as glass, carbon fiber, etc. to the polymer.

VII PROBLEMS & LIMITATIONS OF CURRENT MATERIALS
The most elementary requirement of a material powder to meet the criteria for AM is that it should have a uniform/spherical geometry along with homogenous particle distribution without any agglomeration. So there is a vital need of method which can generate particles with accurate spherical morphology for various AM technologies. One probable resolution is to examine the next generation systems and focus on single technique where the user obtains material (polymers, ceramics, composites, and metals) with spherical geometry [7]. It is difficult to achieve material in powdered form with required particle size is the main obstacle in AM.
Most of materials which are commercially available are not available in fine powdered form. There is a need to further alter these materials to a suitable particle size by mechanical procedures which results in deformed/irregular shape. Many fabrication techniques which are currently adopted to produce micro particles for AM lack homogeneous distribution, unique size dispersion, spherical morphology and lack of batch to batch reproducibility. Most of the particles that are generated are uneven spherical shape, angular, rounded, and acicular, flakes, spongy, and potato-shaped particles which finally end up in a weak condensed part with extremely low density and inadequate properties. By employing irregular and non-uniform particles, components of AM will tend to reduce the accuracy and 3D part printing features such as surface roughness, minimum feature size, and porosity gets affected. To an extent, this leads to complications in removing the un-sintered powders. Lack of these unique features hinders the idea of prototype and its conversion to an end-product. Due to manufacturing process drawbacks, flow time and packing density can be affected very severely in 3D printing. The increase in flow time and decrease in the packing density occurs due to the irregular particles size and agglomeration. Another main challenge to address in AM is anisotropy. The effective strength in Z-direction (build direction) is always lower than x and y directions due to controlling difficulties in Z-directions. Like most of AM technologies, Inkjet printing technology has also been used to fabricate 3D objects for high precision applications. [7]

IX RESEARCH DIRECTION

Response of each material for the different AM processes may be different, so experimental studies must be done for each material type to optimize process parameters and to define product properties. There were significant differences in bending strength, bending stiffness and hardness of the EBM manufactured samples. The diversity of materials and strength of final products are insufficient and not able to meet expected need. Biomaterials and biocompatible nano additives must be developed for any 3D printers. The used file formats such as STL and AMF (additive manufacturing file format—suggested by ASTM) of AM methods do not contain product manufacturing information. This will results in some errors in process and unable to obtain needed dimensional precision and reproducibility. To gather desired surface quality, post-processing activities are essential. New materials such as polymer, metal, ceramic and composite structures of these materials group are one of the most developing and promising areas of AM technology. Software also being improved for converting patient imaging data more precisely to the AM system and producing orthopaedic, dental implant [16].

REFERENCES