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Application of Additive Manufacturing in Metallic Implants

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I. INTRODUCTION

Bones are our body's supporting organs and assist in the actions of tissues. Failure or breakage of them thus needs a robust recovery mechanism and a medical application, implants being one of them. Metal implants are a great boon to the challenges faced in orthopaedics due to bone fractures and other failures. The technologies used in manufacturing them focus on the types of injuries and the absorption qualities of the materials which can support the healing. 3D printing is one of the methods used in manufacturing solid and porous implants.

Eventually, 3D bioprinters will be used to make the structures resembling actual human body parts. Also, CAD (Computer Aided Design) can be used to produce implants layer by layer. So, the materials that we use for these applications need to have certain physical, chemical, and biocompatible mechanical properties, and also, the implants should imitate the bone structure and support the formation of tissues. Material toxicity is also an essential factor that needs to be considered while designing implants since the use of heavy metals or large amounts of some metals can cause damage to the cells and tissues. Finally, the implants are mainly of two broad categories: temporary devices (e.g., bone plates, screws and pins) and permanent implants (e.g., total joint replacements).

II. IMPLANT MATERIALS

Metals, materials, and crucial components in medical sciences allow millions of people to live healthy and everyday lives. The devices implanted in a human body can replace, support, or increase the efficiency of the body parts.

So, the materials used must be compatible with the tissues and not affect cell adhesion. Biocompatibility is an essential but complicated characteristic between the material and the tissue/bone. Their interaction should be positive for tissue integration or bone reconstruction. Appropriate elastic modulus and fatigue strength are necessary to avoid stress shielding, which is otherwise triggered due to the difference between the elastic moduli of the implant and the bone.

Several types include stents, rods, pins, bones, braces, heart valves, hip replacements, implants for the eyes, ears, and skull, and knee replacement implants. The implants can be resorbable or non-biodegradable.

2.1. STAINLESS STEEL

Stainless steel is used in implants to replace tissues and smoothen the healing process. 316L steel is commonly used in surgeries as it has high resistance to corrosion and is compatible with the body fluids. Some materials have inclusion i.e., some amount of Sulphur content, which can increase corrosion, and 316L is devoid of that. Instead, chromium is added to make it corrosion resistant. Similarly, addition of magnetic materials also needs to be avoided as it may lead to change in structure of implants and also interfere in Magnetic Resonance Imaging. To provide stainless steel from an acidic environment, molybdenum is added as a protective layer in the case of surgical implants. One of the most popular metals used for dental crowns, dental surgical equipment, fixing plates, bone screws, and catheters, which is a key component of stainless steel.

2.2. COBALT BASED ALLOYS

Cobalt based alloys are considered to be the safest for implants. Cr_2O_3 passive layer is formed on their surfaces to make them corrosion resistant in chloride environments. These alloys also contain metals with high melting points such as Zr, Ti, Cr, etc. CoNiCrMo alloy is an active material used for implants.

Identifying the possibility that hip implant failure could result in deteriorating neurological symptoms, such as worsening spasticity, in addition to other systemic symptoms is necessary

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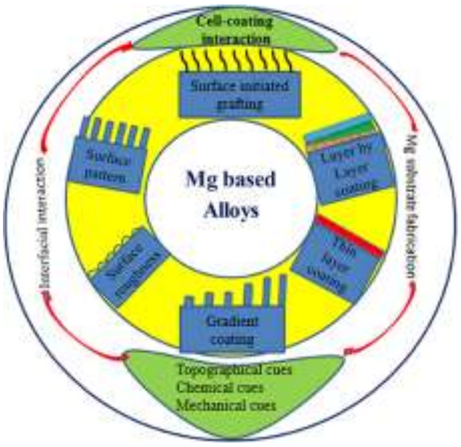
for the diagnosis of cobalt toxicity. All patients with unexplained spasticity should have a thorough surgical history taken, and individuals with cobalt implants should have cobalt toxicity ruled out.

2.3. MAGNESIUM ALLOYS

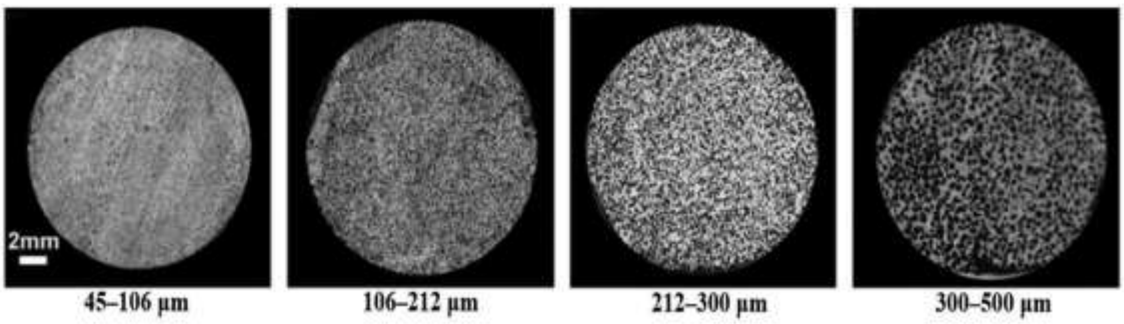
Mg alloys are seen to be a promising alternative to permanent implants since they biodegrade in a physiological setting. Applications for magnesium alloys include tissue engineering, orthopaedics, and cardiovascular systems. Their mechanical properties are enhanced by making their alloy with Aluminium and other rare earth elements. But this also increases their toxicity, being disadvantageous. Despite their great biocompatibility, one of the main obstacles to employing magnesium alloys in clinical applications is their high rate of corrosion. The corrosion rate of magnesium alloys is controlled by the purification of impurities such as Iron, Copper, and Nickel.



https://www.researchgate.net/publication/342069982/figure/fig3/AS:904156718047232@1592579168115/Schematic-illustration-of-interfacial-engineering-of-untreated-Mg-alloys.png
2.1. Schematic illustration of interfacial engineering of untreated Mg alloys

2.4. TITANIUM

Titanium is stronger and lighter in weight in comparison to stainless steel. It is used as an implant material due to its low density, biocompatibility, resistance to corrosion, and low modulus of elasticity. It is strengthened either by alloying or deforming. α + β Ti–6Al–4V and metastable β alloys are considered mainly for implants. The transition from α phase to β phase occurs at ~885 ◦C. The low fatigue strength issue in the case of Ti alloys is solved by dispersion due to the addition of Y_2O_3, SiO_2, and ZrO_2. Ti alloys form strong bonds with the bone and thus integrate easily with bone tissue. Currently, screws and staples used in spinal surgery, ventricular devices, implantable medication pumps, dental implants, and craniofacial implants are made of pure titanium alloys.



https://www.researchgate.net/publication/330031812/figure/fig1/AS:710062943260672@1546303606894/Ti-scaffolds-with-70-porosity-and-different-ranges-of-pore-sizes-41.png
2.2. Ti scaffolds with 70% porosity and different ranges of pore sizes

GE_Additive-Added_Value_for_Spinal_Implants_through_AM.pdf
2.3. Additive manufactured spinal implants

2.5. NICKEL BASED ALLOYS

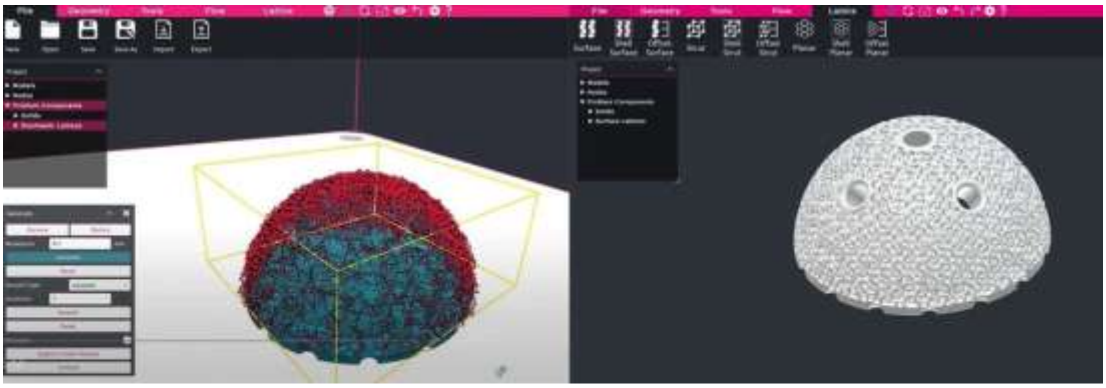
Nickel is also used in an alloy form for implants. It is alloyed with titanium to make nitinol, which is used in dental braces and dental drills. For orthopaedic implants, it is added to stainless steel to increase corrosion resistance. Nickel-titanium alloys(Nitinol) are also used in making devices such as pinal fixation, compression screws, plates, and limb-lengthening devices as well as for cardiac implant devices.

F75 and F799 are the categories for cobalt-based alloys used in casting and forging bars, whereas F90 and F562 are the categories for alloys with a higher nickel concentration.

III. ADDITIVE MANUFACTURING

Additive manufacturing is a process in which different physical parts are manufactured layer by layer. In non-technical terms, it is also called 3D printing. 3D printed models of implants can provide better visualisation before surgeries, and thus help in planning them and for better diagnosis. It is typically used in aerospace, automotive, medical and marine industries, as well as in making spare parts for industries.

In general, AM technology uses computer-aided design (CAD) to model 3D objects before fabricating them into structures using a layer-by-layer 3D printing technique. A variety of software programmes are available for developing, changing, and optimising the designed structures during the modelling process, which boosts productivity and raises the calibre of the finished goods. The files must be saved in standard triangulation language (STL) format once the objects have been designed using a CAD software programme in order to be printed afterwards. A CAD file type called STL facilitates 3D printing and computer-aided manufacturing (CAM). The generated STL files are used to build the 3D models layer by layer on the chosen printing equipment during the manufacturing step.



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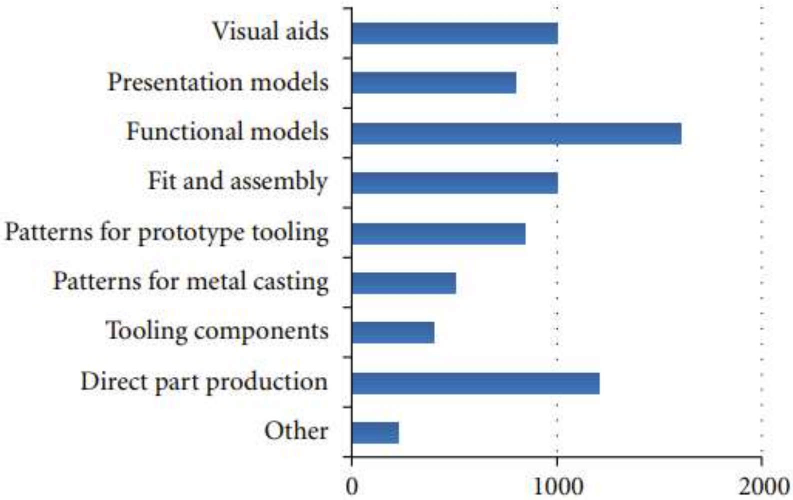
3.1. Designing orthopaedic implant lattice structures with Gen3D Sulis Lattice module software

Prior to performing the CAD modelling, the host's own bone must be scanned as part of the AM of a medical implant. In order to acquire reliable image data from each unique patient, scanning techniques such as X-ray, magnetic resonance imaging (MRI), computed tomography (CT), and others can be used. Using specialised biomaterial software programmes like Mimics and Biobuild, the scanned image data is modified and transformed into 3D CAD models. The abovementioned processes for optimising and 3D printing are carried out once the model has been created.



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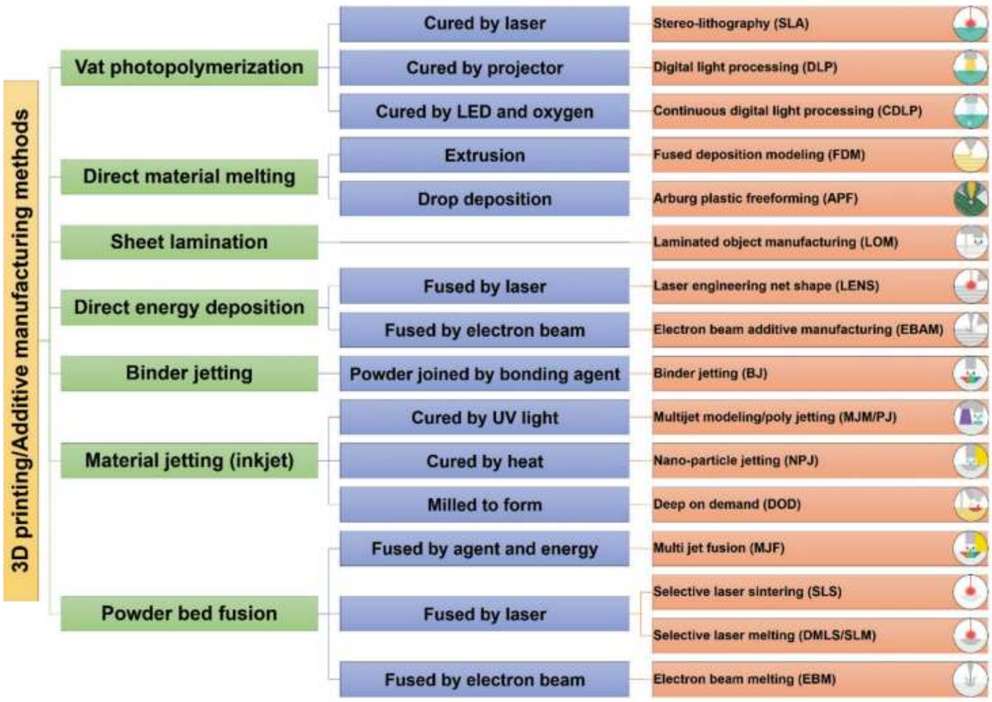
3.2. Different usage for additive manufacturing printing processes



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3.3. An overview of the most important additive manufacturing technologies

Given the relatively few stages in the entire AM process, productivity is considerably increased. It is chosen to be a better method over others due to its ability to form customised and complex structures. AM also potentially contributes in making artificial tissues and organs. AM has applications in inert implants, tools for medical devices, splints, prosthesis, etc.

3.1. BIOMEDICAL APPLICATION

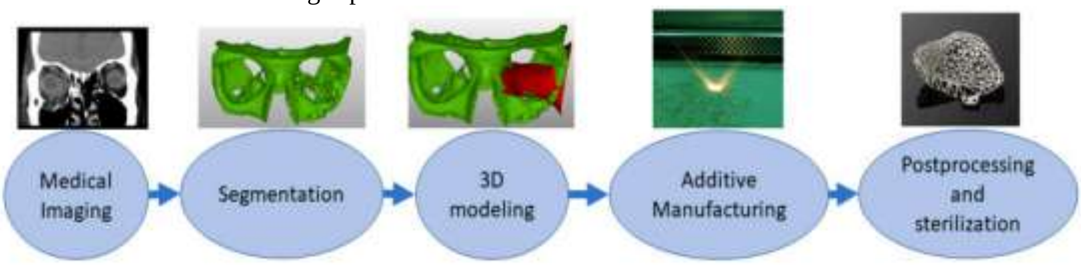
The creation of new clinical technologies has been made possible by developments in metal AM, which has changed the biomedical industry (e.g., guides for surgical procedures, tissue engineering scaffolds, and load-bearing implants). The vast majority of metal AM processes rely on the layer-by-layer continuous fusion of metallic feedstock (powder, sheets or wires) utilising a high energy source (electron beam, laser, or plasma) to create structures from a user-defined CAD model. AM enables the creation of structures with complicated geometries that are not possible using traditional subtractive techniques because of its inherent layer-by-layer operation.

3.2. ADVANTAGES OF ADDITIVE MANUFACTURING IN IMPLANTS

The field of medicine can use additive manufacturing printing technology in a wide variety of ways. The ability to quickly create prototypes, perform very high-quality bone transplants, and create models of patients' damaged bone for study is revolutionising medical practice. In order to better prepare for surgery and plan it, doctors can use additive manufacturing printing techniques to scan and create physical models of patients' damaged bones. Bone transplants can now be performed by printing them, and additive manufacturing techniques allow for the creation of transplants that are nearly identical to the original. Depending on the bone that needs to be replaced, doctors have the choice of creating a precise metal transplant that is equal to the original or a porous-controlled substance that will facilitate osteoconductivity. Density, pore size and shape, and pore interconnectivity are essential criteria that will control tissue ingrowth and the mechanical characteristics of the implant bone. These implants are three to five times more mechanically robust than those made using conventional methods, and there is less chance that micro debris that breaks during the treatment will induce inflammation.

IV. IMPLANTS

An implant is a medical device designed to replace a missing biological component, maintain a damaged biological structure, or enhance an already existing biological structure. Medical implants are manufactured objects, as opposed to transplants, which involve the implantation of biomedical tissue. The surface of implants that come into touch with the body may be made of a biomedical material like titanium, silicone, or apatite, depending on what is most functional. Certain implants, like cochlear implants and artificial pacemakers, contain electronics. Certain implants are bioactive, such as stents that distribute drugs subcutaneously or implantable pills that do the same.



4.1. Typical process flow for implants
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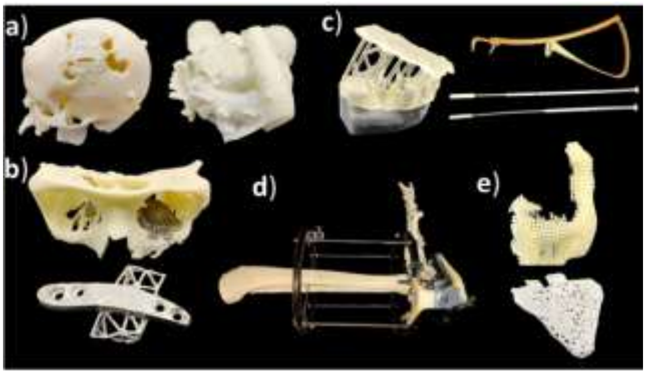
Mechanical strength, porosity and biodegradability are the most important factors to be considered while making implant devices. High strength implants support better physical activity. It also prevents stress shielding if made of proper elastic modulus. High porosity makes devices more biocompatible, which is necessary for bone generation. The structure also needs to be open cellular, necessary for cell migration.



4.2. (a) Medical models; (b) implants; (c) tools, instruments and parts for medical devices; (d) medical aids, supportive guides, splints and prostheses; (e) biomanufacturing
https://www.mdpi.com/materials/materials-14-00191/article_deploy/html/images/materials-14-00191-g001-550.jpg

4.1. MECHANICAL PROPERTIES OF IMPLANT MATERIALS

The kind of material chosen for a given application is determined by its mechanical characteristics. Hardness, tensile strength, elasticity, and elongation are a few of the characteristics that are necessary to be considered. The majority of mechanical properties depend on the type of alloy (i.e., alloy chemistry) and the processing (i.e., microstructure). One exception is the elastic (Young's or shear) modulus, which is more influenced by the kind of alloy than its microstructure.

While alloying chromium predominantly contributes to the exceptional corrosion resistance of Co-Cr-based alloys, their superior mechanical qualities compared to stainless steels are a result of the crystalline nature of the basic element cobalt.

Material	**Young's Modulus E (GPa)**	**Yield Strength, s_y (MPa)**	**Tensile Strength, s_{UTS} (MPa)**	**Fatigue Limit, s_{end} (MPa)**
Stainless steel	190	221-1213	586-1351	241-820
Co-Cr alloys	210-253	448-1606	655-1896	207-950
Titanium (Ti)	110	485	760	300
Ti-6A1-4V	116	896-1034	965-1103	620

Mechanical properties of metallic biomaterials

4.2. ORTHOPAEDIC IMPLANTS

Human tissues are mainly made up of proteins(consisting of polymers) and bone material(consisting of ceramics) , and have very low traces of metals. The use of metals and their alloys as structural biomaterials in surgical treatment, particularly in orthopaedic surgery, has been dominant, with more recent applications in non-osseous tissues like blood vessels. These might be either temporary implant devices or permanent joint replacements. Because of their great structural integrity, corrosion resistance, and biocompatibility, metallic materials such as cobalt-chromium alloys, stainless steel. titanium alloys, and tantalum are widely applied in permanent orthopaedic implants.

4.3. METALS USED IN KNEE REPLACEMENT

Potential uses for carbon-tantalum cellular materials include the creation of hips and knees as well as void filling in bone scaffolds. A novel ceramic knee implant uses the zirconium alloy Zr-2.5Nb. The Zr-2.5Nb alloy has a 100 GPa modulus, which is comparatively low. In place of the metal tray and plastic insert used in other knee replacements, the zirconium alloy is coupled with an all-plastic tibial component. This new knee may

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endure 20 to 25 years, according to some experts. Cobalt alloys were subsequently adopted in additional complete joint replacements at load-bearing sites, including knee and ankle joints, due to the enormous success of its application in total hip replacements. Although there is no agreement on which material is better appropriate, cobalt-chromium alloys are sufficiently robust and are one of the two metals most frequently used in knee implants, alongside titanium. 3D printed Tantalum is also a good material for total knee replacement.

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4.3. Artificial incongruent knee joints

4.4. ORTHODONTIC WIRE

In situations when treatment will take a lengthy time, orthodontic brackets and wires are frequently used. To reduce the discomfort, scientists are looking into different kinds of arch wires. Currently, a variety of materials are employed, including nickel titanium, beta titanium, copper, and stainless steel. Orthodontic arch wires come in a variety of designs, including square, round, rectangular, and bevelled surfaces. The friction between the arch wire and the bracket was continuously reduced via progression. Due to its improved flexibility, heat-activated multi-modulus wire reduces angular friction.

Dentists are primarily interested in nickel titanium (NiTi) wires with increased resilience and variable heat activation variation, as excessive stress on the NiTi wire results in permanent distortion.On NiTi wires, surface coatings are used to lower the friction at the wire surface. With twice the flexibility and half the force of stainless steel, beta titanium wire seems to be the transitional wire between NiTi wires and that material. In comparison to other nickel titanium wires, copper NiTi is said to be more resistant to permanent distortion. Archwires are made from a variety of materials that fall under the following categories, including noble metal alloys, copper nickel titanium alloys and arch wires made up of stainless steel, cobalt-chromium, nickel titanium, beta titanium.

V. MAKING IMPLANTS WITH ADDITIVE MANUFACTURING

5.1. FRICTION STIR ADDITIVE MANUFACTURING (FS-AM)

The solid-state additive manufacturing method known as FS-AM was created to address issues with internal cavities, inclusions, shrinkage, internal porosity, microstructural inhomogeneity, and low mechanical qualities as a result of its operating below the melting temperature. A variety of techniques, including FS-AM, are used to deposit materials layer by layer while rotating tools create high temperatures and considerable plastic deformation. Surface cladding, friction surfacing, modifying functionally graded composition, and offering cutting-edge materials made of wire/powder are all involved in this.

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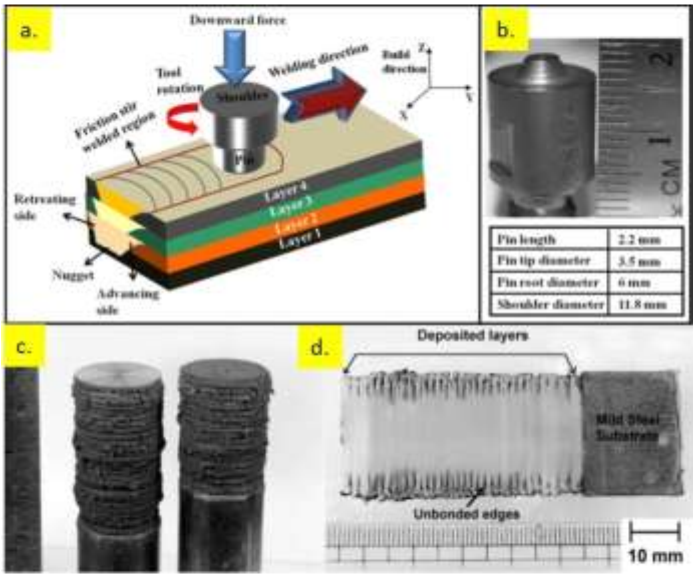

https://www.researchgate.net/profile/Sanjay-Kumar-140/publication/333842171/figure/fig13/AS:772040948715521@1561080314508/a-Schematic-illustration-of-the-friction-stir-additive-manufacturing-FSAM-process.png

5.1. (a)Schematic illustration of the friction stir additive manufacturing (FSAM) process. Here, the build direction is perpendicular to the welding direction. (b) Photograph and dimensions of the tool used in the current study. (c)3D rod (length: 50 mm and thickness: 1.5 mm) made of stainless steel. (d) Macrograph of longitudinal section of the friction deposit sample

Plastic deformation (which contributes 45.6% of the total heat) and friction (which contributes 54.4% of the total heat) have an impact on the heat generation. When compared to fusion-based AM techniques, the components produced with the FS-AM process offer low residual stress, refined microstructure, reduced distortion, and a greater construction rate. Harder material (nickel-based alloys) has a construction rate of less than 0.5 kg/hr while metallic material (aluminium alloys) has a building rate of 10 kg/hr. The accuracy of the material increases with the lower building rate. Additionally, by adjusting process variables like forging pressure, rotating speed, diameter, etc., the technique's precision might be increased.

5.2. LASER ADDITIVE MANUFACTURING (LAM)

Currently, the main materials utilised in 3D printing are polymers and specific grades of metal (such titanium, Inconel, aluminium, and stainless steel). Aluminium composites, which make up the majority of aircraft materials, can be used in laser additive printing to create parts with nearly perfect net shapes and great performance. With precise shaping and control over the mechanical properties of the material, LAM can print quickly. Rapid material fusion caused by the laser's high energy density leads to higher mechanical characteristics and a more refined grain structure. The image illustrates how the LAM is further divided into categories based on the partial and complete melting of particles.

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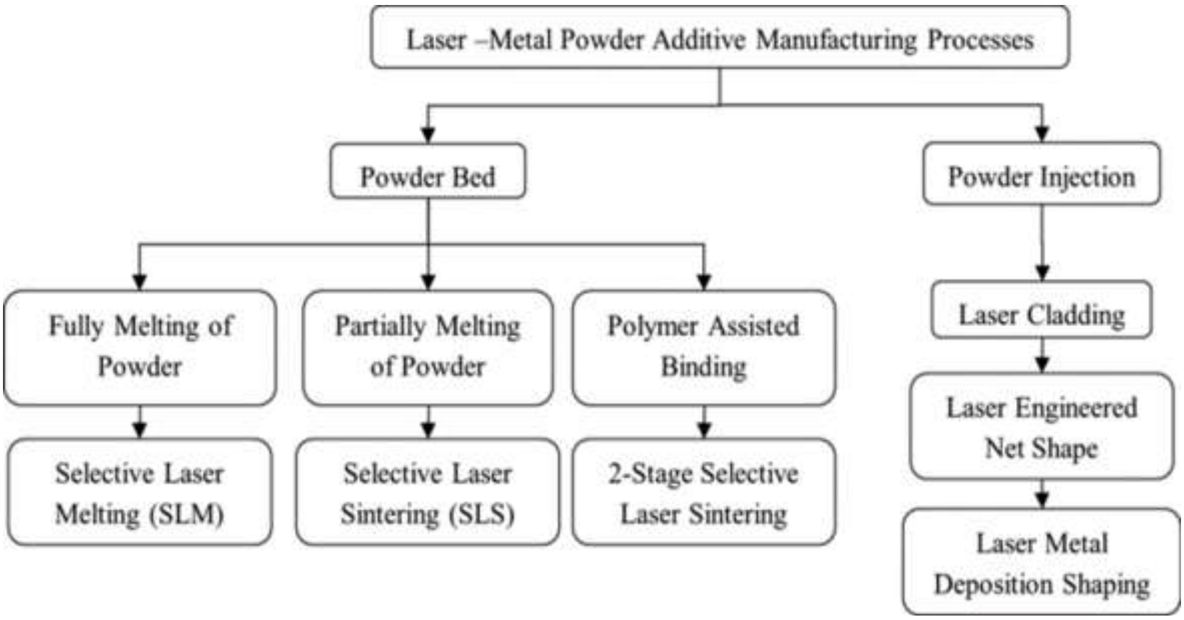
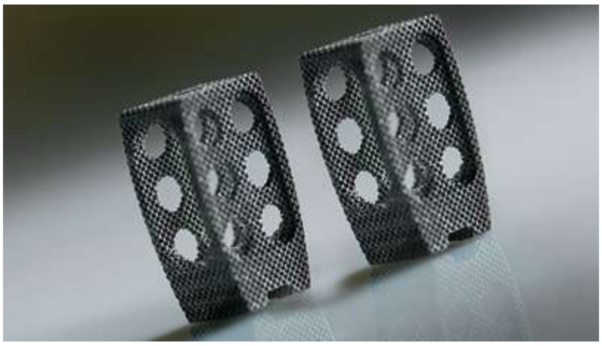


Classification of laser-metal additive manufacturing process

5.3. SCALING ADDITIVE MANUFACTURING

Compared to traditional manufacturing processes like milling or casting, additive manufacturing (AM) presents a great chance to overcome several economic and technological barriers to the production of orthopaedic implants. The economic case to switch from traditional to additive manufacturing is obviously highly influenced by equipment and powder prices, but the technology is currently at a place where these costs are competitive and can compete with conventional manufacturing techniques. Companies will find it easier to push production to scale in a variety of industries, from spinal implants, joints, and hip cups to craniofacial surgery, where, for instance, increasingly precise and personalised trauma plates and skull implants are being developed.



5.2. Details of spinal cages can now be created with additive manufacturing rather than milled

https://www.sme.org/globalassets/sme.org/technologies/articles/2020/05---may/ge-additive-5.jpg

5.3. A titanium hip cup created with additive manufacturing

https://www.sme.org/globalassets/sme.org/technologies/articles/2020/05---may/ge-additive-4.jpg

5.4. ELECTRON BEAM WELDING (EBM)

The Electron Beam Melting (EBM) technique has the potential to unleash a new wave of additive innovation as a proven leader in cost-effective additive manufacturing (AM) solutions for the production of orthopaedic implants and aerospace applications. This cutting-edge technology enables flexibility in design, superior material qualities, and stacking capacities. High-power electron beams are used in the EBM process to produce the energy required for high melting capacity and high productivity. The vacuum and hot process together guarantee a clean and controlled environment and enable you to make parts with zero residual stress.

https://amfg.ai/wp-content/uploads/2019/08/akec-ebm-product-group-e1565863863331.jpg
5.4. 3D printed implants using EBM technology

VI. CHALLENGES AND FUTURE DIRECTIONS

Despite significant advancements in the use of AM for biomedical applications, some areas still need to be improved upon to realise the full promise of this game-changing manufacturing technique. Topology optimization is becoming more prevalent, but widespread usage of this computational tool is still a ways off. In addition, to increase the ability to print complex structures, metal AM resolution must be improved from microscale to nanoscale. As we start to print smaller features with higher precision, improving geometrical integrity may also lead to a broader use of topology optimization techniques. Yet, there remains an unavoidable trade-off between deposition rate and accuracy that will continue to serve as a design constraint for emerging techniques with improved resolution.

Manufacturing is becoming simpler thanks to advances in generative design, cloud computing, automation, and artificial intelligence (AI) software. For instance, improvements in dental 3D printing software can repair models, and generative design can bridge the gap between traditional and additive production. With the use of cloud software, customers can directly access 3D printing equipment for production on demand. This software can also aggregate and optimise manufacturing capacity among machines. Software for additive manufacturing will soon become more predictive, identifying equipment that may need maintenance or automatically modifying printing parameters to assure steady production from machine to machine without a human operator. With more advanced projection screens and resin-printing techniques, accuracy and the ability to print tiny features or components will continue to improve.

A Pune-based firm called Prayasta 3D Inventions Pvt Ltd, which is developing 3D-printed breast implants, has won a national technology award for 2022 from the Department of Science and Technology (DST).

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