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EVALUATING REGULATORY PATHWAYS IN 3D-PRINTED BONE COMPONENT DESIGN AND MANUFACTURING

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Abstract; Bone defects can develop from different origins like infection, tumor, trauma, surgery, congenital etiology, and so on. Human bones can regenerate and repair themselves, although this ability is limited,regulatory pathway in 3D Printing,Bone component design, manufacturing various types of 3D Printed Bone.

INTRODUCTION

Bone defects can develop from different origins like infection, tumor, trauma, surgery, congenital etiology, and so on. Human bones can regenerate and repair themselves, although this ability is limited. When bone damage surpasses its acceptable capacity, it loses its capacity to heal itself and needs to be repaired artificially. Critically small bone defects (CSBDs) are the smallest intraosseous wounds that do not heal on their own. CSBDs can result from diseases or traumas and have a lifetime regeneration rate of less than 10%. Therefore, in order to fix greater defects and CSBDs, external interventions are required. Bone grafting, bone transfer, and bone tissue engineering are the primary therapies used to repair and regenerate CSBDs.

Bone grafting is a surgical procedure that uses transplanted bone tissues and implants to repair and rebuild diseased or damaged bones. Grafting techniques were first applied by Khurits about 2000 BC, when they successfully repaired a tiny skull defect with a piece of animal bone. Millennia later found that the bones showing regrowth surrounding the graft, proving the efficacy of the technique [5]. Bone grafting is feasible because bone tissue can completely regenerate if provided with the necessary space to grow. Bone grafts might be from the same person or from different individuals of the same species.

Types of bone grafts

Autografts The procedure known as "autologous bone grafting" involves taking osseous materials from one anatomic place and transplanting it to another within the same Patient. The iliac crest, mandibular symphysis (chin region), and anterior mandibular ramus (coronoid process) are examples of non-essential bones from which bone can be extracted. The graft has osteogenic properties (marrow- derived osteoblastic cells and preosteoblastic precursor cells), osteoinductive properties (noncollagenous bone matrix proteins, such as growth factors), and osteoconductive properties (bone mineral and collagen).

Allografts Since allograft biobanked bone is also sourced from humans, it is a good substitute for autogenous bone. Allograft bone is usually obtained from a bone bank and is extracted from cadavers who have given their bone so that it can be utilized for living individuals who require it. The main purpose of allografts is to bear mechanical loads and prevent failure in locations where structural support is required. Patients undergoing large transplantation have been found to have good functional status in up to 70% of cases. There are three types of bone allografts available, including Fresh or fresh-frozen bone, ii. iii. Forms-freeze dried bone allograft (FDBA), Demineralized freeze-dried bone allograft (DFDBA).

Xenografts Maatz and Bauermeister introduced bovine bone for the first time in 1957. Xenografts are bone grafts that are utilized as a calcified matrix; they come from species other than humans, such bovine. Bovine, porcine, or equine bones are decellularized, deproteinized, demineralized, and freeze-dried to produce xenografts. Xenografts have shown promising effects in dentistry, although there is limited evidence in orthopedics. Low mechanical qualities and the possibility of zoonotic disease transmission are the problems associated with xenografts.

Synthetic bone grafts Synthetic calcium salt-based bone substitutes provide an osteoconductive alternative to both autologous and allogenic grafts. Ceramics like calcium phosphates (including HA and tricalcium phosphate), bioglass, and calcium sulphate are biologically active materials that can be used to make artificial bone. To boost biological activity, these substances can be combined with growth factors, ions like strontium, or bone marrow aspirate. Because they are only osteoconductive, their biological significance in fracture healing is limited. The majority of studies over the last two decades have concentrated on generating synthetic bone grafts due to the precise control of structural composition and porosity, as well as the absence of disease transmission and donor site morbidity.

What is 3D Printing?

3D printing, also known as additive manufacturing (AM), is a process that creates three- dimensional objects of any shape using a digital model or other electronic data sources. This technology works by laying down successive layers of material under computer control. Charles Hull introduced the first commercial 3D printing technology, called "stereolithography," in 1988. Since then, various 3D printing processes have been developed for a wide range of materials and applications. Today, 3D printing is used.

History of 3D Printing

In the early 1980s, Charles Hull, an engineering physics graduate, invented a technology he called "stereolithography" while working on creating plastic objects from photopolymers at Ultra Violet Products in California. This technology, now known as 3D printing, uses an .stl file format to interpret data from a CAD file, enabling electronic communication of instructions to the 3D printer [17]. A few years later, in the early 1990s, Sachs et al. at MIT (Cambridge, MA) developed another 3D printing technology called 3DP. This powder-based freeform fabrication method utilizes a regular inkjet print-head to print binders onto loose powders in a powder bed [18]. The groundwork for the introduction of 3D printing in the medical field was laid by a team of doctors from Harvard Medical School. They manually performed a fully functional urinary bladder replacement by creating a synthetic scaffold made of collagen and polymer, which was then seeded with the patient's cells and allowed to grow until the finished organ was formed [20]. In 2016, a significant milestone was achieved when the Food and Drug Administration (FDA) approved Spritam oral Pills (levetiracetam), the first 3D-printed medication. These tablets were produced by Aprecia Pharmaceuticals using an inkjet printing technology.

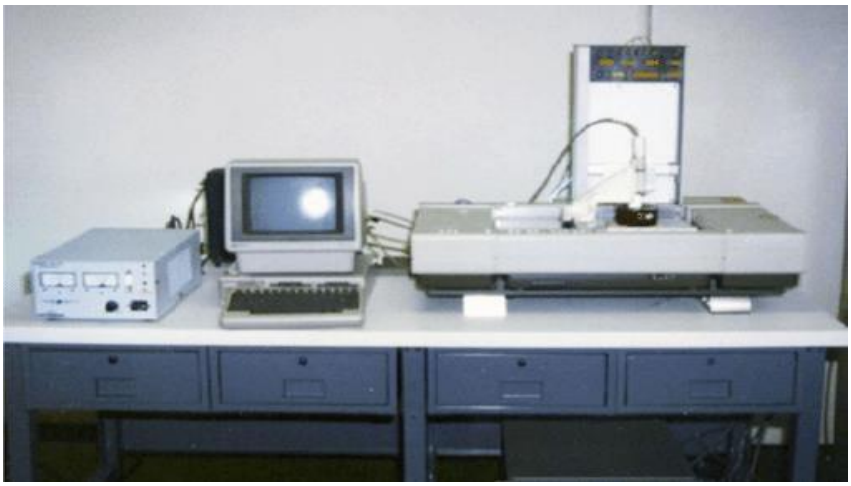

Figure 1.1: The Stereolithography Apparatus by Charles W. Hull

3D Printing Process in Healthcare

To fabricate patient-specific customized 3D printed bone support implants, accurate medical imaging data must be obtained to represent the individual patient's anatomy. For this purpose, computed tomography (CT) and magnetic resonance imaging (MRI) are utilized to provide high-resolution 3D image data. The process of converting medical images into a 3D object involves three main steps: i) Image acquisition, ii) Image post- processing, and iii) 3D printing.

Image acquisition

Image acquisition is the initial and crucial step in generating 3D objects, as the quality of the final object depends on the quality of the data. Today, clinical image acquisition can be performed at ultra-high spatial resolutions (400–600 microns) with excellent contrast quality. Both multi detector computed tomography (MDCT) and magnetic resonance imaging (MRI) are commonly used imaging modalities. Due to the high contrast provided by CT scans, it is the preferred imaging modality in orthopedics when bones are the region of interest for an imaging.The fabrication of customized implants begins with digital imaging and CT scanning to create a 3D image of the patient's defect site in the Digital Imaging and Communications in Medicine (DICOM) format, which is a standard data format for storing, exchanging, and transmitting medical images. This collected image data is then converted into a format that the 3D printer software can utilize to template the object.

Image post-processing

In the second step, various post-processing tools are employed to process the DICOM images. These software tools collect images to create 2D images through multiplanar reformation, generating coronal and sagittal views for better clinical interpretation. Common tools for 3D post-processing include cutting and visualization tools. The bone is isolated from other tissues and structures such as muscle, fat, skin, and the CT scanner's metal table. Pseudo-colour imaging is applied to the DICOM image pixel data, and the segmented images are used to reconstruct a 3D model. Some of the most popular software packages

for bio- medical 3D-modelling are ProEngineer, Autofab, Anatomics, etc. These segmented contours are then transformed by Computer-Aided Design (CAD) software, and the CAD data is stored in the Stereolithography (STL) format, a standard 3D file format. Engineers can then modify the acquired STL file to fabricate customized 3D-printed bone implants using 3D printers. The modified STL file is subsequently sent to the 3D printer for fabrication.The post-processing stage is crucial for ensuring accurate and precise representation of the patient's anatomy, enabling the creation of customized implants that precisely fit the defect or fracture site.

3D printing

In the final stage, STL files are analyzed by Computer-Aided Design (CAD) software to produce a 3D model. Three-dimensional printing is a process th utilizes 3D CAD data to create physical 3D models . The 3D printing technologies employed in medicine can be classified according to the manufacturing technique, primarily including stereolithography (SLA), fused deposition modeling (FDM), selective laser sintering (SLS), or electron beam melting (EBM). SLA requires photopolymer materials that can be cured by ultraviolet (UV) laser, while SLS relies on tiny particles of thermoplastic, metal, ceramic, or glass powders that are fused together by a laser. The solid-based FDM process works by extruding small beads of molten thermoplastic materials from a nozzle, which subsequently cool and harden to form layers. The powder-based EBM technology involves the use of an electron beam to selectively fuse small particles of metal on the surface of a powder bed. The printing process itself can take anywhere from a few hours to several days, and the costs for these types of printers vary substantially, ranging from less than $1,000 to more than $100,000.

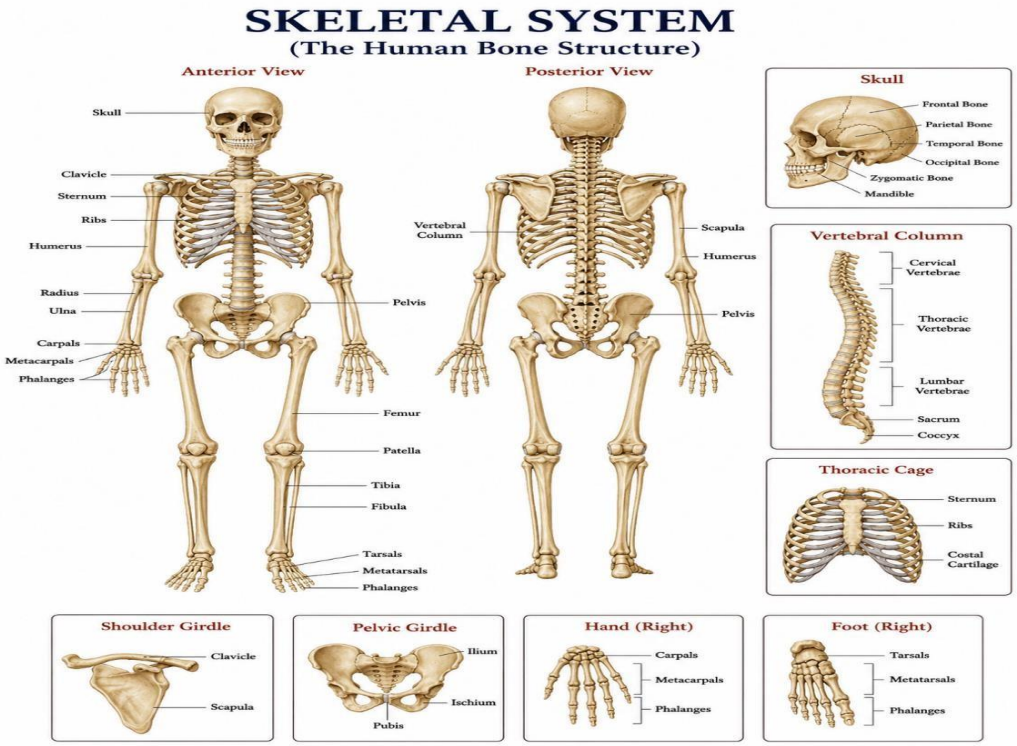

Figure 1.2: Skeletal system of bone

Need or Rationale of The Work

i. 3D printing offers the potential to revolutionize the production of bone components by enabling the customization of implants to match individual patient anatomy.

ii. Research in this area will provide insights into the barriers and opportunities associated with adopting 3D printing for bone component fabrication.

iii. This technology can produce intricate and complex geometries that are challenging or impossible to achieve with traditional manufacturing methods.

iv. Research in this area can help identify cost-effective approaches to designing and manufacturing these components while maintaining high-quality standards.

RESEARCH METHODOLOGY

This chapter presents the details about the methodology including the details of material selection process, selection of printing technology, developing 3D CAD model by and regulatory aspects of 3D printed implants. Furthermore, the details of testing and validation of 3D printed implant.

Selection of Materials

The selection of appropriate materials is a crucial step in the fabrication of 3D printed bone implants. This process involves evaluating various available materials and their properties to ensure they meet the specific requirements for bone implants. The chosen materials must also be compliant with regulatory standards to ensure patient safety and effectiveness. This section details the criteria and processes used for selecting the optimal materials for 3D printing bone components, including an overview of potential materials, their properties, and regulatory considerations.

Criteria for selection of material

The selected material should have the following criteria to ensure the functionality, safety, and regulatory compliance of the final product.

Biocompatibility:

The material must not produce any toxic responses in the body. It should either be inert (not react with body tissues) or bioactive (support bone growth and integration).

Mechanical and elastic properties:

The material should possess sufficient mechanical strength to withstand physiological loads without deforming or breaking. Additionally, its modulus of elasticity should be similar to that of natural bone to avoid stress shielding.

Osteoconductivity and Osteoinductivity:

The material should support the attachment and growth of new bone cells on its surface. As we as the material should promote the differentiation of progenitor cells into osteoblasts, enhancing bone regeneration.

Available materials for 3D printing of bone implants

The production of consistent, high-quality customized 3D printed bone implants necessitates the use of high-quality materials that meet stringent specifications.

Ceramics

Nowadays, 3D printing technology allows for the production of ceramic objects without large pores or cracks by optimizing the parameters and setup, resulting in good mechanical properties.

Zirconium oxide:

Zirconium oxide is a polymorphic material that exists in three allotropic forms: monoclinic, cubic, and tetragonal. Zirconium ceramics, which are crystalline zirconium oxides, exhibit remarkable properties such as high chemical stability, impressive mechanical strength, and excellent biocompatibility. These characteristics make zirconium ceramics suitable for various biomedical applications, including dental restorations, hip joints, body implants, and bone fixings. However, in current biomedical applications, yttria-stabilized tetragonal polycrystalline zirconium oxide (Y-TZP) is the preferred form of zirconia ceramics.

Tricalcium phosphate:

Tricalcium phosphate (Ca3(PO4)2) is a bioactive compound frequently used as a component in bone replacement implants because of its potential to stimulate osteoblastic development in progenitor cells. The remarkable success of tricalcium phosphate as a biomaterial for bone regeneration is because of its biocompatibility, bioactivity, osteoconductivity, and biodegradability.

Hydroxyapatite (HA):

Bone can be considered a natural nanocomposite consisting of collagen fiber networks impregnated with calcium phosphates, primarily hydroxyapatite (HA) nanocrystals.

Polymer

3D printing technologies are extensively utilized for the production of polymer components, ranging from prototypes to functional structures with complex geometries. Polymers are known for their biocompatibility, biodegradability, and broad applications in bone, dental fixation, and tissue engineering . However, a single polymer material often exhibits certain deficiencies, such as low surface osteogenic properties or high brittleness, which can be mitigated by compounding with other materials to prepare bone implants.

Poly (lactic acid) (PLA):

Poly (lactic acid) (PLA) is the most widely used material in fused deposition modeling (FDM) 3D printing, and it has gained recognition as a promising material due to its eco-friendly nature, biocompatibility, and processability. PLA is a semi-crystalline polymer produced through polymerization or polycondensation.

Acrylonitrile butadiene styrene (ABS):

Acrylonitrile butadiene styrene (ABS) is a thermoplastic polymer that finds applications in various fields due to its excellent mechanical properties, chemical resistance, and cost-effectiveness.

Polyether ether ketone (PEEK):

Polyether ether ketone (PEEK) is a high-performance organic thermoplastic polymer that is colorless and well-suited for creating accurate, high-quality parts through 3D printing. PEEK is a biocompatible material that easily interacts with the human body, making it an excellent choice for medical applications such as prosthesis replacements, stents, and other medical implants.

Metals and metal alloys

Metallic materials possess excellent physical properties, enabling their use in complex manufacturing processes, ranging from printing human organs to aerospace parts.

Stainless steel and Its Alloys:

Stainless steel has long been the most popular choice among metallic implants, thanks to its affordability and ease of fabrication. This versatile group of iron-based alloys contains a significant amount of chromium (11–30 wt %) and varying levels of nickel.

Titanium and Its Alloys:

Titanium has a proven track record of successful use as an implant material, mainly due to its excellent biocompatibility, which is attributed to the formation of a stable oxide layer on its surface.

Why PEEK is best?

The selection of an ideal material for 3D printed bone implants is critical to ensuring the success and longevity of the implants. Among the various materials available, Polyether Ether Ketone (PEEK) stands out as one of the most promising options. PEEK is a high-performance thermoplastic polymer known for its exceptional mechanical properties, biocompatibility, and chemical resistance. Its unique combination of characteristics makes it highly suitable for use in medical implants, particularly in orthopedic applications.

Properties of PEEK material

Biocompatibility

Polyether ether ketone (PEEK) has been extensively studied both in vivo and in vitro to assess its biocompatibility. Numerous studies have reported favorable biological responses, indicating that PEEK is well-tolerated by tissues and cells.

Mechanical Properties

PEEK is a chemically inert compound that is insoluble in most conventional solvents at room temperature, with the exception of 98% sulfuric acid. Its water solubility at room temperature is 0.5 w/w%. PEEK's modulus of elasticity ranges from 3 to 4 GPa, which is close to, but not identical to, that of human cortical bone (7–30 GPa). The melting temperature of PEEK is 334°C, with a crystallization peak at 343°C and a glass transition temperature of 145°C.

Osteoconductivity and Osteoinductivity

PEEK-based implants with smooth and hydrophobic surfaces are bioinert, which means they have a limited ability to bond with bone tissues. To address this issue, researchers have focused on enhancing the bioactivity of PEEK through two main strategies: surface modification and the incorporation of bioactive particles into PEEK substrates.

Manufacturability

One of the advantages of PEEK is its compatibility with various 3D printing technologies. All types of 3D printers, regardless of their working principles, can accept input from CAD software, MRI/CT scans, and reverse engineering tools.

Regulatory Compliance

Polyether ether ketone (PEEK) has gained attention as a promising material for orthopedic implants due to its favorable biocompatibility, chemical resistance, and mechanical properties. However, as of 2022, to the best of our knowledge, no PEEK orthopedic implant manufactured using additive manufacturing (AM) has been approved for market entry.

Availability and Cost

PEEK (polyetheretherketone) is increasingly becoming a material of choice for medical implants due to its unique combination of properties. PEEK is readily available from various manufacturers and suppliers worldwide, ensuring a consistent supply for medical and industrial applications.

Selection of Printing Method

The selection of an appropriate 3D printing method is a critical step in the fabrication of bone implants, particularly when using high-performance materials such as polyetheretherketone (PEEK). The printing method chosen must not only be compatible with the physical and chemical properties of PEEK but also meet the stringent requirements for producing medical-grade implants. PEEK's high melting point, excellent mechanical properties, and biocompatibility make it an ideal candidate for bone implants; however, these same parameters also pose significant challenges for 3D printing technologies.

Criteria for selection of printing method

When selecting a 3D printing method for fabricating PEEK bone implants, several critical criteria must be considered to ensure the method is suitable for the material's properties and the intended medical application.

Temperature Capability

The printing method must be capable of operating at the high temperatures required to process PEEK, which has a melting point around 343°C. This includes having high-temperature extruders (380-440°C) and heated build chambers.

Bed Temperature

The method must support a bed temperature range of 130 to 150°C, which is essential for preventing warping and ensuring proper adhesion of PEEK layers during the printing process.

Precision and Accuracy

High precision and accuracy are essential to create detailed and complex implant geometries that fit the patient's anatomy precisely.

Speed and Efficiency

The method should offer a balance between printing speed and quality. Faster production times are advantageous for reducing lead times and costs, but not at the expense of the implant's structural integrity and performance.

Cost-Effectiveness

The overall cost of the printing method, including equipment, materials, and operational expenses, should be economically viable. While PEEK itself is a costly material, the printing process should not increase the total manufacturing costs.

Availability of FDM Printer

Fused Deposition Modeling (FDM) printers are among the most widely available and accessible 3D printing technologies globally. Due to their relatively low cost, ease of use, and ability of handling various thermoplastic materials, FDM printers are commonly found in academic institutions, research facilities, and commercial markets.

Figure 5.1: Aion NX 3D printer available at Suryodaya College of Engineering & Technology, Nagpur

Designing the 3D Model of Bone Implant

The design of customized bone implants is crucial for ensuring optimal fit, function, and patient outcomes in orthopedic surgeries. Traditional implant manufacturing methods often rely on standardized designs, which may not adequately address the anatomical variations among patients.

Dimensions for customized radius bone plate

Distal radius fractures (DRF) and radial head/neck fractures are among the most prevalent types of fractures in the upper extremity. Radial head fractures account for approximately one-third of all elbow fractures. Previous research indicates that the average length of the radius bone is approximately 210.01 ± 10.92 mm for females and 228.60 ± 11.22 mm for males [81]. The mean anteroposterior radial head diameter is reported to be 22.34 ± 2.30 mm, while the mean transverse diameter is 21.45 ± 2.36 mm. Notably, the anteroposterior diameter is typically 4% greater than the transverse diameter, with a difference of 0.89 ± 0.06 mm. These dimensions are crucial in designing and evaluating the effectiveness of radial bone plate.

Table 5.1: Dimensions of customized distal radius bone plate

Shape of Plate	Half Curved
Length	72 mm
Thickness	3.5 mm
Diameter	19 mm
Depth of plate	6 mm
Screw Hole Diameter	5.5 mm
Distance between two screw holes	5 mm

Raw design of the bone plate

After determining the essential dimensions of the customized distal radius bone plate, I proceeded to create an initial raw design. This preliminary sketch serves as a blueprint, guiding the detailed 3D modeling process. The raw design outlines the basic structure and key features of the bone plate, ensuring it aligns with the anatomical specifications derived from the literature review. The following raw design sketch illustrates the basic shape, size, and positioning of screw holes, providing a foundation for the development of a detailed and patient-specific 3D model.

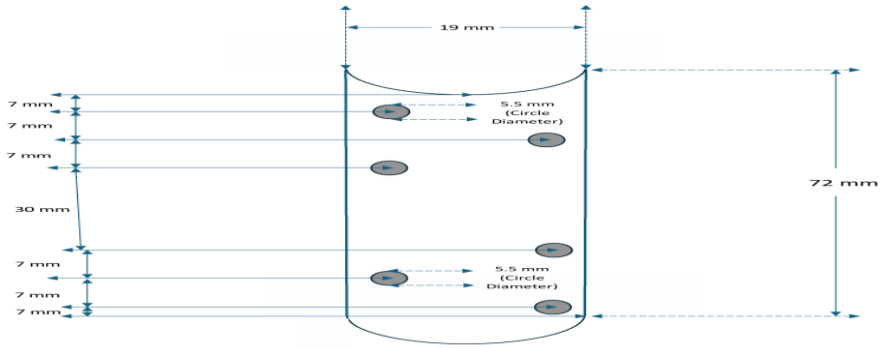

Figure 5.2: Raw design and dimensions of the radius bone plate (Upper view)

3D Model of bone plate

To convert the initial design sketches into a detailed 3D model, a powerful computer-aided design (CAD) software tool was employed. The software chosen was CREO (formerly known as Pro/ENGINEER), a product design software developed by PTC for 3D modeling. CREO is a comprehensive, integrated family of product design software widely used by thousands of leading manufacturers worldwide.

(A) (B) (C)

Figure 5.4: 3D model of distal radius bone plate (A) Right side view (B) Left side view

(C) Front view

Regulatory Aspect of 3D Printed Bone Implants

Regulatory compliance is a critical aspect of developing 3D printed bone implants for clinical use. As an emerging technology, additive manufacturing for medical devices faces unique challenges and considerations from a regulatory point of view. To navigate these challenges, a comprehensive understanding of the relevant regulatory frameworks, guidelines, and industry standards is essential.

RESULTS AND DISCUSSION

This chapter presents the experimental results and corresponding discussion. It includes detailed specifications of the FDM printer and the raw material (filament) used, along with photographs of the finished products. A comparative analysis between human bone, titanium, and PEEK is provided and discussed. Various 3D printing methods are also compared and discussed. Furthermore, the existing regulatory frameworks for 3D printed implants (Medical Device) in various countries are studied and discussed. The results are discussed in view of the reported literature and the overall findings from the obtained results are summarized.

3D Printing of Radius Bone Plate

The INTAMSYS FUNMAT HT 3D printer was utilized for the fabrication of radius bone plate in this study. This industrial-grade fused deposition modeling (FDM) 3D printer is specifically designed to handle high-performance materials like PEEK, making it suitable for printing biocompatible and medical-grade polymers. Table 6.1 summarizes the key specifications of the INTAMSYS FUNMAT HT 3D printer.

Table 1: Specifications of the FDM printer used in the present work

Sr. No	Specification	Value
1	Printing Technology	Fused Deposition Modeling (FDM)
2	Build volume	260mm x 260mm x 260mm
3	Supported materials	PEEK, ABS, PLA, Nylon, etc
4	Filament diameter	1.75mm
5	Power consumption	1200W, 110V, 10A
6	Nozzle Temperature	Up to 450°C
7	Build plate temperature	160°C (320°F)
8	Chamber Temp	90°C (194°F)
9	Print Speed	30-300mm/s
10	Supported file format	STL, OBJ
11	Connectivity	Ethernet, SD Card

The INTAMSYS FUNMAT HT offers a wide range of features that ensure precision and reliability in 3D printing. It is equipped with a high-temperature nozzle capable of reaching up to 450°C, a heated build chamber that maintains a consistent temperature of up to 90°C, and a heated build plate that can

reach up to 160°C. These capabilities are essential for printing with PEEK, which requires high processing temperatures to ensure proper layer adhesion and overall print quality. Additionally, the printer supports a build volume of 260 x 260 x 260 mm, providing a good space for producing large or multiple parts in a single print run. Figures 6.1 and 6.2 provide visual representations of the INTAMSYS FUNMAT HT 3D printer used in this study.

Figure 4.1: Photograph of the INTAMSYS FDM printer

Figure 4.2: Photograph of the INTAMSYS FDM printer

Comparison of Human Bone, Titanium and PEEK

Table 2: Comparison of the properties of natural bone and most common materials used for the fabrication of customized bone implants

Factor	Human Bone	Titanium	PEEK
Biocompatibility [50,84]	Biocompatible	Biocompatible	Biocompatible
Density (g/cm^3) [49]	1.8 g/cm^3	4.43 g/cm^3	1.23 - 1.32 g/cm^3
Tensile strength (MPa) [47,85]	70 - 200 MPa	960 - 970 MPa	90 - 100 MPa
Elastic Modulus (GPa) [86,87]	3 - 30 GPa	110 GPa	4 - 8.3 GPa
Radiolucency [88,89]	Radiopaque	Radiopaque	Radiolucent
Osseointegration [50,90]	Naturally integrates with surrounding tissues	Supports osseointegration	Supports osseointegration
Cost [91]	N/A	₹ 30,000 to ₹ 40,000	₹ 10,000 to ₹ 15,000

ISO and ASTM Standards

In 2009, the American Society of the International Association for Testing and Materials (ASTM), formerly known as the American Society for Testing and Materials, established an international committee on "Additive Manufacturing" technologies, referred to as the F42 committee [39,101]. The F42 committee meets twice a year, typically in Spring and Fall, with around 150 members attending two days of technical meeting.

Table 3: Existing ISO/ASTM active standards for AM relevant to patient-specific implants

Sr. No	Standard Designation Code	Standard
1	ISO/ASTM52900	Standard Terminology for Additive Manufacturing (AM)—General Principles—Terminology
2	ISO/ASTM52901	Standard Guide for Additive Manufacturing—General Principles—Requirements for Purchased AM Parts
3	ISO/ASTM52910	Additive Manufacturing—Design Requirements, Guidelines, and Recommendations
4	ISO/ASTM52915	Standard Specification for Additive Manufacturing File Format (AMF) Version 1.2
5	ISO/ASTM52921	Standard Terminology for Additive Manufacturing—Coordinate Systems and Test Methodologies
6	ASTMF2924	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion
7	ASTMF2971	Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing
8	ASTMF3049	Standard Guide for Characterizing Properties of Metal Powders Used for Additive Manufacturing Processes
9	ASTMF3001	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
10	ASTMF3091	Standard Specification for Powder Bed Fusion of Plastic Materials
11	ASTMF3122	Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes
12	ASTMF3213	Standard for Additive Manufacturing—Finished Part Properties—Standard Specification for Cobalt-28 Chromium-6 Molybdenum via Powder Bed Fusion
13	ASTMF3301	Standard for Additive Manufacturing–Post Processing Methods–Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion1,2
14	ASTMF3302	Standard for Additive Manufacturing—Finished Part Properties—Standard Specification for Titanium Alloys via Powder Bed Fusion
15	ASTMF3303	Standard for Additive Manufacturing—Process Characteristics and Performance: Practice for Metal Powder Bed Fusion Process to Meet Critical Applications

CONCLUSION

In the current work, the promising potential of 3D printing technology for the fabrication of bone implants, specifically using Polyether ether ketone (PEEK) material, was assessed. The regulatory framework was thoroughly investigated to understand the existing essential standards and approval processes for 3D printed bone implants. Based on the obtained results and studies, the following conclusions are drawn. Due to the biocompatibility and excellent mechanical properties (similar to the bone), PEEK-based implants produced through 3D printing technology can become an alternative to traditional titanium and stainless-steel implants.The ability of polyether ether ketone (PEEK) to meet medical requirements can open up new market opportunities, such as customization and manufacturing of precise replicas of bones.

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