Sustainable Biocompatible Materials for 3D Printed Fracture Casts: A Comparative FEA Analysis of Mechanical Properties and Environmental Impact

Akash Deshpande[1,*], Gajanan Thokal[1], Ashwini Thokal[2],
Suyash Pawar[3], Kailas Chandratre[4]

[1]Department of Mechanical Engineering, Pillai College of Engineering New Panvel,
Maharashtra 410206, India
[2]Department of Chemical Engineering, Bharati Vidyapeeth College of Engineering Kharghar,
Maharashtra 400614, India
[3]Department of Mechanical Engineering, MVPS KBT College of Engineering Nashik,
Maharashtra 400614, India
[4]Department of Mechanical Engineering, KVN NSPS's LGM Institute of Engineering Education and
Research, Maharashtra 400614, India

ABSTRACT

This research explores the environmental and medical significance of employing diverse biocompatible materials in the development of fracture casts, offering sustainable alternatives to conventional materials. Traditional casts contribute to environmental challenges as non-recyclable medical waste. In contrast, casts made from biomaterials not only address this issue but also ensure non-toxic and safe compatibility with human tissues. The study utilizes 3D printing technology for efficient manufacturing, contributing to both innovation in medical technology and reduced environmental impact. Through a comparative evaluation of three distinct biomaterials, the research provides insights into their mechanical properties. The virtual design and analysis employed showcase a systematic approach, enhancing the credibility of the study. By looking at how traditional casts affect the environment, making sure they are compatible with human tissues, encouraging innovation in manufacturing, and doing a full analysis of the materials, this research has the potential to lead to more sustainable and patient-friendly ways to treat fractures.

Keywords: 3D Printing; Biomaterials (Polyamide-12, Acrylonitrilebutadiene styrene M30i, Polylactic acid); Finite Element Method (FEA); Fracture casts

1. Introduction

Biomaterials play a crucial role in medical applications as they are organic or manufactured substances integrated into clinical procedures to repair, replace, or enhance tissues and organs over time [1]. In the context of 3D printing, biomaterials can be categorized into five groups based on their chemical composition, including metals, polymers, ceramics, composites, and hydrogels, each offering unique benefits and applications. The choice of biomaterial in 3D printing depends on the intended use of the final product [1]. 3D printing, also known as additive manufacturing, is a relatively recent technique for fabricating biomaterials. Various types of biomaterials can be utilized in 3D printing, and the most commonly employed 3D printing methods include FDM, SLA, SLS, and bio printing. For instance, PA12 can be effectively printed using three Stratasys machines: J380, J450, and J900. In this study, we focus on comparing different biocompatible materials, particularly for fracture cases. Given the complexity of the human body, combining materials within human tissues can lead to short or long-term toxicity. Biocompatible materials are vital in medical equipment as they are easy to manufacture, comfortable for patients, and generally non-toxic to living tissues. Despite significant advancements in 3D printing technology for casting techniques, there are limited documented methods for designing and producing biocompatible 3D-printed casts. A previous investigation explored the use of PA2200, a sub-material of PA12, in creating biocompatible casts [2]. This study analyzes PA12, ABS M30i, and PLA, evaluating their characteristics for the same cast to determine the most suitable material for different conditions. The comparison will identify a specific biocompatible material as an alternative to current options, enabling rapid and efficient manufacturing using intelligent modeling techniques for orthopedic casts through 3D printing technology. In the pursuit of assessing the safety and structural integrity of the proposed 3D-printed fracture casts, finite element analysis (FEA) was employed. The results of the current model were meticulously compared with findings presented in a cited publication [3]. Our FEA outcomes revealed an equivalent (von mises) stress of 10.599 MPa and a total deformation of 0.38774 mm. Notably, these values closely align with the equivalent (von mises) stress of 10.18 MPa and a total deformation of 0.15204 mm reported in the cited paper [3], affirming the safety of the cast. Subsequently, the chosen materials PA12, ABS M30i, and PLA underwent rigorous FEA scrutiny when applied to the current cast model. Even though there were differences in mechanical properties such as Young's modulus and density, stress contours for each material were always less than 10% or about the same as those found in the study cited [3]. It is crucial to note that, despite comparable stress contours, noticeable differences in total deformation emerged due to distinct modeling approaches.

This study shows how important biocompatible materials are in orthopedic applications. It also shows detailed FEA results that shed light on the safety, feasibility, and material-specific considerations for 3D-printed fracture casts.

2. Materials and Methods
2.1 Biomaterials

The biomaterials market has experienced remarkable growth in recent years, propelled by advancements in 3D printing methods. This synergy has revolutionized medical and healthcare industries by enabling the fabrication of intricate structures with tailored properties. The use of biomaterials in 3D printing has significantly enhanced the development of customized implants, prosthetics, and tissue engineering scaffolds. The marriage of biomaterials and 3D printing technologies has not only accelerated the production of patient-specific medical solutions but has also opened new frontiers in regenerative medicine. This

dynamic intersection continues to drive innovation, offering promising avenues for the future of personalized healthcare and bio-fabrication. A biomaterial is a composite material used to replace or interact with living systems, particularly in close proximity to living tissues. Reports suggest that the global market for biomaterials is expected to reach a staggering US$130 billion per year by 2020, with a compound annual growth rate of 16 percent [4].These biomaterials exhibit diverse atomic arrangements, leading to a wide range of structural, physical, chemical, and mechanical characteristics, which in turn enables a vast array of applications within the human body [5]. The classification of these biomaterials is shown in Table 1.

Table 1. Classification of biomaterials including benefits, drawbacks, examples and uses [1, 4, 6, 7].

Types	Advantages	Disadvantages	Examples	Applications
Metal and Metal Alloys	● Extremely durable ● Ductile ● Easy to Fabricate	● Excessive elastic modulus ● Corrosive	● Gold ● Steel ● Chromium	Joint replacements, dental root implants and screws.
Polymers	● Resilient ● Biodegradable ● Biocompatible	● Not strong enough ● Deforms with time ● Leachable in body fluids	● PMMA ● PLAN ● Polycarbonates	Blood vessels, Hip sockets
Ceramics	● Highly Biocompatible ● High material strength	● Brittle ● Not-strong enough ● Difficult to mould	● calcium phosphate salts (HA) ● Glass ● oxides of aluminium and titanium	Dental & Orthopedic implants
Composites	● Strong Tailor-made ● Corrosive resistant	● Difficult to produce ● Laborious manufacturing methods	● Dental filling composites ● Rubber catheters and gloves	Dental Resin, Bone Cement
Hydrogels	● Better skin feel may improve patient compliance ● Easily removed from skin or clothing	● Expensive ● Conventional hydrogels tend to be fragile	● Agarose ● Carrageenan ● Gelatin ● PVA ● Xanthan	Producing contact lenses Hygiene products Wound dressings.

2.2 3D Printing in bio-materials

The application of 3D printing to biomaterials offers benefits throughout the entire production value chain. It decreases the amount of time required to transform a Computer-Aided Design (CAD) into a fundamental component, which accelerates the production of medical devices. Moreover, printing biomaterials with a 3D printer is both energy-efficient and environmentally beneficial. In addition, 3D printing can be used to create custom-made, precisely-engineered components on demand. Growing 3D printing technologies allow for the fabrication of intricate geometric models in orthopedic casts, all while reducing manufacturing time and expense. Although 3D printing provides greater precision and accuracy, it requires more time to manufacture than other techniques [1, 8].

Recent research in the fields of biomaterials and 3D printing has showcased significant advancements and diverse applications. The focus is on intelligent and smart biomaterials designed for sustainable 3D printing applications, highlighting the integration of intelligence into biomaterials for enhanced functionality [9]. Another study delves into the additive manufacturing of sustainable biomaterials specifically tailored for biomedical applications, emphasizing the importance of sustainability in the development of biomaterials for medical use, providing insights into the journey of biomaterial discovery and collaboration in tissue engineering and 3D printing [10]. Together, these studies contribute to the growing knowledge base in the development and application of biomaterials in the realm of 3D printing and biomedical engineering [11].

The following are some of the most commonly used 3D printers for producing biocompatible products.

2.2.1 Fused deposition modeling (FDM)

Fused deposition modeling (FDM) is an additive manufacturing technique that involves the fusion of layers of materials in a specific pattern to build a three-dimensional object, as depicted in Fig. 1(1). The process entails heating the material to a temperature slightly above its glass transition point, after which it is extruded in a precise pattern, either next to or on top of previously extruded layers, ultimately creating the desired model. This method has been documented in various sources [1, 8, 12].

2.2.2 Stereo lithography (SLA)

Stereo lithography is one of the most popular and widely used methods. A high-powered laser is used to harden the liquid resin, which is stored in a reservoir in the desired model form. It is illustrated in Fig. 1(2) [1, 8, 13].

2.2.3 Selective laser sintering (SLS)

SLS is a powder-based 3D printing technique that employs a laser to fuse material layers into a finished product, as illustrated in Fig. 1(3). The build platform descends when the laser draws a cross-section of the CAD design(s) onto a material layer, and another layer is fused on top. The construction platform will continue to descend until all of the layers have been completed and the component is complete [1, 8, 14].

Image 1: Diagrams are illustrating 3D printers. (1.1) Fused deposition modelling (FDM). (1.2) Stereo lithography (SLA). (1.3) SelectiveLaser Sintering Process (Courtesy: Materialgeeza, SLS, Wikipedia) [12] IV. PRINTING PROCEDURE FOR FDM 3D PRINTER

Fig. 1. Fused deposition modeling (FDM).

2.3 Casts in the traditional fracture

Distal radius fractures are common bone injuries that can occur in individuals of all age groups, with higher incidence among children and the elderly [15]. Such fractures can be caused by mechanical impact or underlying bone disorders. Traditional orthopedic casts or outhouses are often employed to immobilize and support the affected upper extremity [3]. These can include plaster casts, splints, and casts made from molded synthetic materials. However, these casts have certain drawbacks, such as their heavy construction and limited ventilation, which can lead to various skin issues and potentially affect bone and joint health [15].

2.4 Biocompatible materials

Biocompatibility is the most widely used word to define the biological needs or biomaterials used in a medical device. The absence of unfavorable tissue responses caused by a substance is known as biocompatibility [16]. The suitability of the orthopedic specialty modeling biomaterial in terms of its features and qualities must be the primary consideration when choosing biomaterials for device design and production. Chemical, toxicological, physical, electrical, morphological, and mechanical characteristics are some of these. Because the human body is such a complicated system, materials can cause toxicity in the short term, in the long term or when mixed with other compounds. Biocompatible materials are therefore essential for all types of medical equipment. In this study, we compare the three different biocompatible materials for manufacturing the casts used in fractures. Some of the examples of biocompatible materials are illustrated in Table 2.
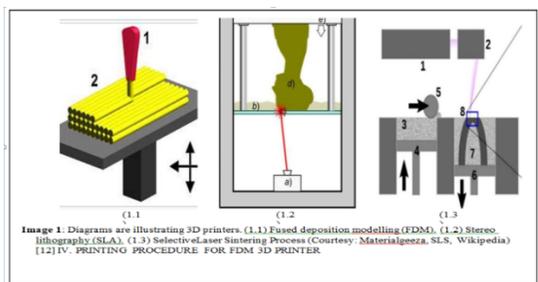
Table 2. Common examples of Biocompatible materials [16, 23].

Materials Type	Compressive strength (MPa)	Tensile strength (MPa)	Young's Modulus (GPa)	Elongation (%)	Applications
Bioglass	40-60	120-150	35	0-1	Bone defect fillers
Stainless Steel	500-1000	460-1700	180-205	10-40	Implants, plates, mini–plates, screws
Titanium Alloy	900	900-1000	110-127	10-15	Implants, plates, screws, Midfacial Fracture Treatment.
PLA	18-93	36-55	3.5	6	Fracture fixation, interference screws
PMMA	5.23	5.39	122.90	5.35	Transportation, architecture, electronics, and health.
PA-12	1600	53	1700	9	Sterilized films and bags for use in the /medical industries, packing material in the food business.
ABS M30i	90	36	2400	4	Engineers in the fields of medicine, and food packaging, instruments, and fittings.

2.4.1 Polyamide-12 (PA12)

PA 12 (also known as Nylon 12) is a versatile general-purpose plastic with a wide range of additive uses. It is recognized for its harshness, tensile strength, and impact strength. These are all terms that may be used to describe a material's toughness, tensile strength, impact strength, and ability to bend without breaking [17]. PA12 has the lowest water absorption of any commercially available PA, with eleven carbon atoms among carbon-amide groups, and gives the best stability in thermal and mechanical qualities (see Table 3). PA12 has the advantages of causing little tissue reactivity, being lightweight, having long-lasting tensile strength and high elasticity, being moisture absorbent, and having temperature-varying electrical characteristics. It is used in the automotive and electrical industries, mechanical engineering, precision molding, and sporting and recreational items. It is also used in food packaging, sterilized films, and bags for pharmaceutical and medical purposes.

Table 3. Properties Table of PA12 [18].

Material Name	Chemical properties	Electrical properties	Thermal Properties			
	Water Absorption (%)	Resistivity (Ω mm²/m)	Melting temperature (°C)	Specific Heat (J/(kg K))	Thermal Conductivity (W/(m K))	Thermal Expansion (×10⁻⁶/K)
PA12 MAX	1.6	2.5×10^{19}	190	1.2	0.24	100
PA12 MIN	1.45	1×10^{17}	190	1.17	0.42	80

2.4.2 Poly-lactic Acid (PLA)

Poly-lactic acid is the smallest organic molecule that can be optically active with either the L (+) or D (-) stereoisomer. It is made by animals, plants, and microbes. It is extensively utilized in medical applications due to its biocompatibility and bio dissolvability in the human body, where the ester backbone is hydrolyzed to produce non-harmful and non-toxic chemicals [19]. PLA has several advantages, including being more environmentally friendly, having a shinier and smoother look with a glossy finish, and being more cost-effective (see Table4). During the printing process, it emits a pleasant aroma. In the manufacture of the finished product, no hazardous fumes are released. Even on a chilly surface, printing is simple. PLA is used in tissue engineering, drug carriers, skin and tendon regeneration, dentistry, and orthopedics.

Table 4. Properties Table of PLA [18].

	Heat deflection temp (°C)	Specific gravity	Melting temperature (°C)	Specific Heat (J/(kg K))	Thermal Conductivity (W/(mK))	Glass transition temperature
PLA	55	1.27	165	2.06	0.195	45-60

2.4.3 Acrylonitrile butadiene styrene M30i (ABS M30i)

ABS-M30i is biocompatible in its raw condition and complies with ISO 10993, much as ABS-M30i is in strength, durability, and fine feature detail [20, 21] (see Table 5). The material is suitable for end-use components and form, fit, and function testing due to these material characteristics. ABS M30i has also passed ISO 18562 gas and airway component testing for respiratory and ventilation medical equipment [22]. Medical use, food handling, pharmaceutical packaging, surgical planning, and modeling tools are some of the applications of the ABS M30i [21].

Table 5. Properties Table of ABS M30i [22].

Material Name	Other properties	Electrical properties	Thermal Properties			
	Specific Gravity (ASTM D792)	Volume Resistivity (Ohm-cm)	Melting temperature (°C)	Glass Transition (Tg)	Heat Deflection (HDT) @ 66 psi, 0.125" unannealed	Thermal Expansion (mm/mm/°C)
ABS M30i	1.04	1.5×10^{14} to 6.0×10^{13}	Not applicable	108°C (226°F)	96°C (204°F)	8.46×10^{-05} to 8.82×10^{-05}

3. Analysis
3.1 Finite element method

In engineering and physics, Finite Element Analysis (FEA) is a sophisticated numerical technique used to simulate and analyze complex physical phenomena. Beginning with the discretization of complex structures into triangles, quadrilaterals, tetrahedra, or hexahedra, the process makes the analysis more manageable. A mesh is generated after discretization by connecting nodes to represent the entire structure. A set of equations derived from the principles of mechanics or physics describe the behavior of each element. This assembly of element equations represents the entire structure as a global system of equations. This global system is subjected to boundary conditions, simulating constraints or external forces and reflecting actual conditions. Numerical techniques, such as the direct stiffness method, solve the system and provide insight into the response of the structure. Post-processing involves extracting pertinent information from numerical results, such as stress distribution and deformation. Validation using experimental data or analytical solutions guarantees precision. FEA is iterative, permitting refinement based on results obtained. FEA is a versatile and powerful tool for simulating and comprehending complex physical behaviors across diverse engineering disciplines.

The design process of the cast involved creating a 3D model of the outer cover with proper ventilation holes using CAD software, specifically Solid Works by Dassault Systèmes in 2016. The dimensions of the cast were calculated based on the average size of a human wrist and the length of the arm. The top end of the cast was designed using an ellipse, and another ellipse was sketched at the arm's length. These two ellipses were connected using the spline tool, and the sketch was then converted into a 3D model using the Loft Feature. To ensure proper ventilation, holes were designed in a circular pattern, each with a diameter of approximately 1 cm. The thickness of the cast was set at 0.2 cm, and the material chosen for the cast was PA12. The weight of the cast achieved using this material was 162.76 grams [2]. During production, the cast can be split in half and joined together using Velcro straps [3, 15]. These straps can be adjusted to tighten or loosen the cast, depending on the thickness of the patient's arm. For FEA, the Solid Works CAD model was converted into IGS and Step file formats and imported into Workbench 2020 by ANSYS in India. The purpose of this research is to compare various materials, so the density and Young's modulus of each material were altered based on their respective mechanical characteristics. These materials were then applied to the cast, and the upper and lower ends were secured, as Velcro straps can secure the opening edges when the cast is applied to a patient (see Fig. 2).
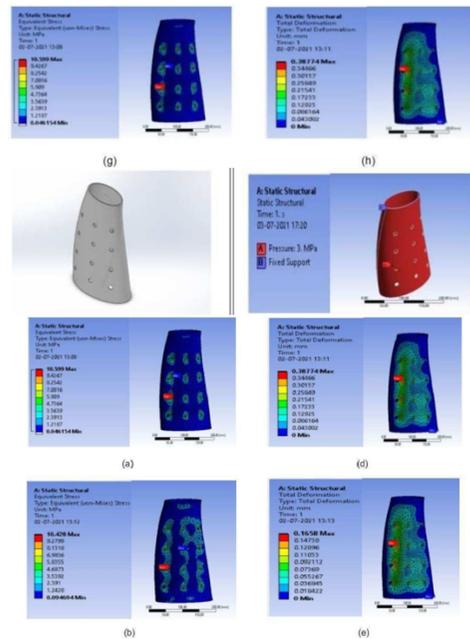

Fig. 2. Boundary condition of the FEA model with pressure of 3MPa applied on the cast (as shown at point A) and fixed constraints on open ends (as shown at point B).

Consequently, the opening edges were defined as fixed constraints for the analysis. The cast was subjected to a horizontal pressure of 3 MPa [3], and as a result, Total

Deformation and Equivalent Stress were calculated to assess the performance and structural integrity of the cast under this load condition.

Table 6. Comparison of Referred Cast & Current Cast using the same material.

Mechanical Properties	Referred Results	Current Results
Equivalent (von Mises) Stress$_{MAX}$	10.18	10.599
Total Deformation$_{MAX}$	0.15204	0.38774

Table 7. Comparison of the different materials on the current cast.

Mechanical Properties	Material Name			
	HDPE/PP	PA12	PLA	ABS M30i
Total Deformation$_{MAX}$	0.38774	0.38774	0.1658	0.00024676
Equivalent (von Mises) Stress$_{MAX}$	10.599	10.599	10.428	10.395

4. Result and Discussion

The results of the current model were compared with those presented in the cited publication [3] to assess the safety of the cast. The equivalent (von Mises) stress for the current model was found to be 10.599 MPa, with a total deformation of 0.38774 mm.

In comparison, researchers in the cited paper reported an equivalent (von Mises) stress of 10.18 MPa and a total deformation of 0.15204 mm. The close similarity between the two sets of results confirms the safety of the cast in the current study, aligning well with previously established safety parameters. When applying different materials to the cast model, stress contours were generally under 10% or approximately equal to those observed in the cited paper [3]. Despite variations in mechanical characteristics such as Young's modulus and density, the materials HDPE/PP and PA-12 showed almost identical results. PA12 emerged as a preferable choice due to its good resistance to abrasions and UV, coupled with excellent dimensional stability, making it ideal for applications prioritizing safety, durability, or long-term reliability. Next, the materials chosen for this research were applied to the current cast model, and the results were analyzed. Despite variations in the mechanical characteristics of different materials, such as Young's modulus and density, the stress contours obtained were mostly under 10% or approximately equal to those in the cited paper [3]. Although the stress contours were comparable, significant differences were observed in Total Deformation due to the different modeling approaches used. For example, variations in thickness may be noticeable in the cast model.

It is essential to note that our model is a single body, while the cited papers [3, 15] have divided their casts into multiple sections. Additionally, the application of pressure in both models was similar but not identical during the study. Based on the estimated FEA values, HDPE/PP and PA-12 materials showed almost identical results, although their mechanical properties differ. PA12 appears to be more preferable than HDPE/PP as it exhibits good resistance to abrasions and UV, along with excellent dimensional stability. These properties make it an ideal choice for applications where safety, durability, or long-term reliability is critical.

• 3D printing can achieve the precision and accuracy necessary for creating such clinical models.
• There are now just a handful of 3D printers that can manufacture biocompatible materials.
• The newly developed cast was designed in CAD software with extrusion-cut holes for ventilation to prevent irritation and infections.
•Engineering evaluations using FEA confirmed that the materials used in the research are safe.
• These materials were studied and analyzed as being polymers; they are flexible and have low melting points. Thus, they could be more easily fabricated than conventional ceramics and metals.
•In terms of strength, ABS M30i is the strongest of all the materials. PLA, on the other hand, is not particularly robust, but it is a good material for fracture castings since it is widely accessible.
•These fracture casts, once manufactured, can be used multiple times by disinfecting with chemical solutions after every usage, thereby decreasing medical waste.

All of the materials utilized in the analysis exhibited equivalent (von Mises) stress values that were either equal to or less than the values in the cited study, signifying that these materials can also be used to manufacture the cast. In comparison to other materials, ABS M30i has a very low stress value. PLA stands out among the other materials because its stress value is lower, but it is easily accessible, which is significant. The study compares a 3D-printed cast's safety with a cited publication, finding close alignment in stress and deformation values. Different materials, such as HDPE/PP and PA-12, show nearly identical stress results, with PA-12 preferred for its durability. Noteworthy differences in total deformation arise from varied modeling approaches. The study's single-body model differs from multi-sectioned casts in cited papers. The article emphasizes 3D printing precision, material safety confirmed by FEA, and highlights the suitability of polymers like ABS M30i and PLA for medical applications

5. Conclusions

Biocompatible materials present a promising alternative for the development of fracture casts, offering non-toxic and safe compatibility with human tissues compared to traditional materials. This potential suggests a shift towards more patient-friendly and sustainable orthopedic solutions.

The utilization of 3D printing technology in creating fracture casts enables precise and accurate manufacturing, resulting in casts that are customized to individual patient needs. This personalized approach can lead to improved patient comfort and faster recovery times.

Finite Element Analysis (FEA) is a sophisticated numerical technique extensively used in engineering and physics for simulating and analyzing complex physical phenomena. This comprehensive approach underscores the versatility and power of FEA in understanding and optimizing complex physical behaviors in diverse engineering applications.

The study advocates for personalized fracture casts using biocompatible materials like PA12, ABS M30i, and PLA. 3D printing ensures precise, patient-specific casts, enhancing comfort and recovery. Finite Element Analysis optimizes physical behaviors. ABS M30i offers superior strength and cost-effectiveness.

The virtual design and analysis conducted on the fracture casts using CAD software and 3D printing exemplify the potential of this technology in the medical field, offering efficiency and reduced environmental impact compared to traditional casting methods.

The research highlights the importance of exploring innovative and sustainable solutions for fracture management, considering the environmental consequences associated with conventional casting materials. By adopting biocompatible materials and 3D printing technology, the medical community can contribute to more eco-friendly practices and improved patient outcomes.

In summary, the study concludes that the examined biocompatible materials, PA12, ABS M30i, and PLA, are all viable options for 3D-printed fracture casts, each with its specific advantages. The findings contribute valuable insights for selecting suitable materials based on application requirements, safety considerations, and ease of fabrication through 3D printing technology

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