

# Development of Personalized Medical Devices using Advanced Manufacturing Techniques

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**Abstract:** The rapid advancement of advanced manufacturing techniques has opened new opportunities for developing personalized medical devices tailored to individual patient needs. Unlike conventional mass-produced solutions, personalized devices are designed using patient-specific anatomical and physiological data, ensuring higher comfort, enhanced performance, and improved treatment outcomes. This paper presents an integrated approach that combines advanced imaging modalities, computer-aided design (CAD), and cutting-edge manufacturing methods such as additive manufacturing, selective laser melting, and precision CNC machining to create customized medical devices. The process begins with acquiring accurate patient data through medical imaging techniques such as CT or MRI scans, which are then processed to develop three-dimensional models. These models undergo optimization based on mechanical, biocompatibility, and ergonomic considerations before fabrication. Algorithms for geometry adaptation, topology optimization, and material distribution are incorporated to enhance device functionality and durability. Additionally, mathematical modeling is employed to predict stress distribution and performance under physiological loading conditions. The proposed methodology is validated through case studies involving orthopedic implants, dental prosthetics, and wearable assistive devices. Experimental results demonstrate that the developed devices meet stringent medical standards while significantly reducing production lead time compared to traditional methods. The findings indicate that advanced manufacturing, coupled with data-driven design, offers a robust pathway toward scalable and cost-effective personalized healthcare solutions.

**Keywords—**Personalized Medical Devices, Advanced Manufacturing, Additive Manufacturing, Topology Optimization, Patient-Specific Design.

## I. INTRODUCTION

The evolution of medical device manufacturing has undergone a paradigm shift in recent decades, driven by the growing demand for personalized healthcare solutions that cater to the unique needs of individual patients. Personalized medical devices are designed based on patient-specific anatomical, physiological, and functional requirements, leading to superior clinical outcomes compared to standardized, mass-produced devices [1]. These devices find applications in various domains, including orthopedic implants, dental prosthetics, hearing aids, cardiovascular stents, and wearable rehabilitation systems. The integration of advanced manufacturing techniques has further enabled rapid, precise, and cost-effective production of such customized devices [2]. Traditional manufacturing methods, such as casting and subtractive machining, while effective for mass production, face significant limitations when producing patient-specific devices. These limitations include high tooling costs, design inflexibility, and extended production times [3]. Advanced manufacturing techniques, particularly additive manufacturing (AM), selective laser melting (SLM), electron beam melting (EBM), laser sintering, and precision

CNC micromachining, have addressed these challenges by enabling complex geometries, material customization, and direct fabrication from digital designs [4]. Such methods facilitate rapid prototyping and iterative design improvements without the need for costly molds or tooling. The process of developing personalized medical devices begins with acquiring detailed patient data through imaging technologies such as computed tomography (CT), magnetic resonance imaging (MRI), or 3D surface scanning [5]. This data is then processed into high-resolution three-dimensional (3D) digital models using computer-aided design (CAD) software. Advanced computational techniques, including finite element analysis (FEA) and topology optimization, are applied to improve the mechanical performance and ergonomics of the device [6]. Material selection plays a crucial role, as biocompatibility, mechanical strength, and long-term durability are critical for medical applications [7].

Recent research highlights that integrating machine learning algorithms with the design process can further enhance the customization and predictive capabilities of medical devices. For example, predictive models can simulate device performance under physiological conditions, enabling proactive design adjustments before fabrication [8]. Furthermore, topology optimization allows for weight reduction and improved structural integrity, leading to more efficient and patient-friendly devices [9]. The clinical benefits of personalized medical devices extend beyond improved fit and function. Patients often experience reduced post-operative complications, faster recovery times, and increased satisfaction compared to those using conventional devices [10]. For instance, custom orthopedic implants can precisely match bone contours, improving load distribution and reducing the risk of implant loosening. Similarly, custom dental prosthetics ensure optimal occlusion and comfort, enhancing both functionality and aesthetics [11]. The application of advanced manufacturing also supports decentralized production models, where devices can be produced closer to the point of care. This reduces logistics costs and accelerates delivery, making personalized healthcare more accessible, even in resource-limited settings [12]. However, challenges remain, including regulatory compliance, ensuring material traceability, and maintaining consistent manufacturing quality [13]. Addressing these challenges requires a multidisciplinary approach involving engineers, medical professionals, and regulatory bodies. This paper presents a comprehensive methodology for the development of personalized medical devices using advanced manufacturing techniques. The proposed framework integrates patient-specific data acquisition, computational design optimization, material selection, and advanced fabrication technologies. Validation is conducted through experimental case studies in orthopedic, dental, and wearable device applications. The findings aim to contribute to the growing body of evidence supporting the clinical and

economic viability of personalized medical devices, ultimately advancing the delivery of precision healthcare.

## II. LITERATURE SURVEY

Research on the development of personalized medical devices has expanded significantly in recent years, with contributions spanning materials science, computational design, and manufacturing methodologies. Early studies primarily focused on adapting existing mass-production techniques to achieve limited customization; however, advancements in digital design and additive manufacturing have enabled a shift toward fully patient-specific solutions [14]. These developments have been facilitated by the integration of medical imaging with computer-aided design, allowing for precise modeling of anatomical structures and the creation of bespoke devices that meet clinical requirements [15]. One of the earliest demonstrations of this approach involved the use of stereolithography to fabricate craniofacial implants based on CT scan data [16]. While effective in producing accurate geometries, early methods faced limitations in material selection and mechanical performance. Subsequent studies addressed these challenges by incorporating titanium and biocompatible polymer composites using selective laser melting (SLM) and fused deposition modeling (FDM) [17]. These materials offered improved strength-to-weight ratios and enhanced biocompatibility, making them suitable for long-term implantation. Advanced manufacturing has also enabled functional grading within devices, where material properties vary spatially to match specific biomechanical requirements. Parthasarathy et al. demonstrated the application of functionally graded porous structures in orthopedic implants, achieving improved osseointegration and reduced stress shielding [18]. Similarly, work by Mazzoli explored the use of electron beam melting (EBM) to produce lattice structures that mimic cancellous bone architecture, enhancing biological integration while minimizing mass [19].

In dental applications, additive manufacturing has significantly improved prosthetic customization. Revilla-León and Özcan reported that 3D printing of dental prosthetics allowed for accurate replication of patient-specific occlusal patterns, reducing the number of adjustments needed during clinical fitting [20]. Additionally, polymer-based manufacturing methods have enabled the production of lightweight, comfortable, and cost-effective hearing aids, with geometries tailored to the unique shape of a patient's ear canal [21]. Computational methods have played a pivotal role in optimizing device performance prior to fabrication. Finite element analysis (FEA) has been widely used to simulate stress distribution and predict device behavior under physiological loads. Li et al. applied topology optimization algorithms to hip implant design, resulting in devices with enhanced fatigue resistance and reduced material usage [22]. Machine learning approaches have also been introduced to predict design parameters based on historical patient and performance data, enabling faster design iterations and improved personalization [23]. From a clinical perspective, studies have shown that personalized devices lead to improved patient outcomes compared to standardized counterparts. Chen et al. evaluated the long-term performance of custom orthopedic plates manufactured through CNC micromachining and reported reduced rates of implant failure and patient discomfort [24]. In prosthetics, custom-fit sockets produced using 3D scanning and additive manufacturing were associated with higher comfort scores and reduced skin irritation among amputees [25]. Despite these advances, several challenges persist. Regulatory frameworks for personalized medical devices are still evolving, creating uncertainties in approval processes. Hollister highlighted the need for standardized validation methods to ensure consistency in manufacturing quality across different production facilities [26]. Furthermore, material certification

Recent works have also emphasized the role of hybrid manufacturing, which combines additive and subtractive processes to achieve high dimensional accuracy while leveraging the design freedom of AM. Wong and colleagues demonstrated a hybrid approach for fabricating patient-specific spinal cages, resulting in improved fit and reduced surgical times [28]. This trend suggests a growing interest in combining multiple manufacturing modalities to address limitations inherent in individual methods. Overall, the literature underscores the potential of advanced manufacturing to revolutionize the design and production of personalized medical devices. By leveraging computational tools, advanced materials, and innovative fabrication techniques, researchers and clinicians are moving toward a future where medical devices are seamlessly tailored to individual patient needs, enhancing both clinical outcomes and healthcare efficiency.

## III. PROPOSED SYSTEM

The proposed work focuses on developing a comprehensive framework for designing and fabricating personalized medical devices using advanced manufacturing techniques, enabling precise patient-specific solutions with enhanced clinical performance. The process begins with acquiring detailed anatomical data from CT, MRI, or 3D surface scans, which is processed into accurate 3D models using segmentation and reconstruction algorithms. These models are then optimized using computational methods such as topology optimization, employing the Solid Isotropic Material with Penalization (SIMP) approach to minimize weight while ensuring structural integrity. Finite Element Analysis (FEA) is applied to simulate physiological loading conditions and validate the design's mechanical performance. Material selection is guided by biocompatibility, mechanical strength, and application-specific requirements, with functional grading applied where varying material properties within a single device enhance performance. Fabrication is carried out using advanced manufacturing methods like Selective Laser Melting (SLM), Electron Beam Melting (EBM), or polymer-based additive manufacturing processes, with hybrid manufacturing employed for high-precision regions. Post-processing steps, including polishing, coating, and sterilization, are performed to meet ISO 13485 medical device standards. Quality assurance involves mechanical testing, dimensional verification, and regulatory compliance checks. This approach integrates patient-specific data, computational optimization, advanced materials, and state-of-the-art manufacturing into a streamlined workflow, significantly reducing production time while ensuring superior fit, functionality, and biocompatibility. By combining engineering precision with clinical needs, the proposed methodology offers a scalable and efficient pathway toward delivering highly customized, safe, and effective medical devices for diverse healthcare applications as shown in the figure 1.

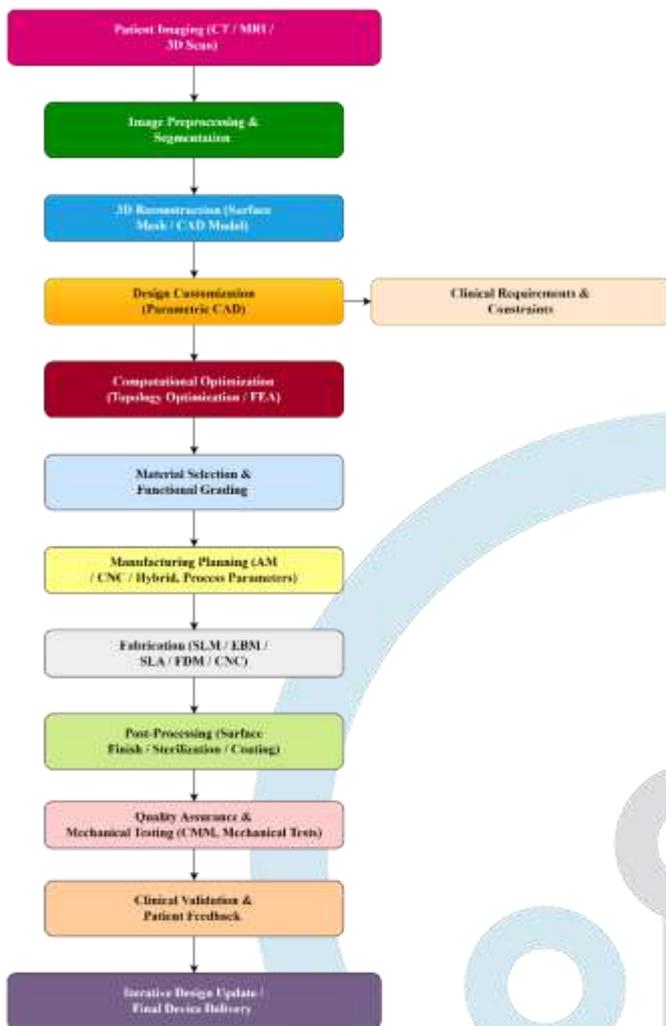


Fig.1: Personalized Medical Device Development Workflow.

A. Proposed Work and it's Implementation:

1. Patient Data Acquisition and Processing:

The foundation of the proposed work lies in acquiring accurate and high-resolution anatomical data from the patient. Medical imaging modalities such as Computed Tomography (CT), Magnetic Resonance Imaging (MRI), and 3D surface scanning are employed to capture detailed geometry of the target region. The acquired data, typically stored in DICOM format, undergoes segmentation to isolate relevant anatomical structures. Segmentation is performed using advanced algorithms like thresholding and region-growing, followed by 3D surface reconstruction using the marching cubes algorithm to generate a polygonal mesh. This mesh is then cleaned and smoothed to remove artifacts, ensuring accuracy in the subsequent design stages. The resulting 3D model serves as the baseline for device customization and optimization.



Fig.2: Example of a 3D-printed patient-specific medical device created using the proposed advanced manufacturing workflow.

2. Design Optimization through Computational Techniques: Once the anatomical model is obtained, it is imported into a Computer-Aided Design (CAD) environment for customization. Topology optimization is applied to improve performance by reducing unnecessary material while preserving the mechanical strength of the device. The optimization problem is formulated as a compliance minimization problem, expressed mathematically as:

$$\text{Minimize: } C(\rho) = U^T K(\rho) U$$

$$\text{Subject to: } \frac{\sum_{e=1}^N \rho_e v_e}{V_0} \leq f, 0 < \rho_{min} \leq \rho_e \leq 1 \tag{1}$$

Here,  $C(\rho)$  is the compliance representing structural flexibility,  $U$  is the displacement vector,  $K(\rho)$  is the stiffness matrix dependent on material distribution,  $\rho_e$  is the density of element  $e$ ,  $v_e$  is the volume of element  $e$ ,  $V_0$  is the initial design volume, and  $f$  is the volume fraction constraint. The Solid Isotropic Material with Penalization (SIMP) method is employed, introducing a penalization factor  $p$  to enforce a near-binary material distribution, given by:

$$E(\rho_e) = \rho_e^p E_0 \tag{2}$$

where  $E(\rho_e)$  is the effective Young's modulus of the element, and  $E_0$  is the modulus of the solid material. This ensures that intermediate densities are discouraged, leading to a manufacturable structure.

3. Finite Element Analysis for Performance Validation:

Following optimization, Finite Element Analysis (FEA) is conducted to assess the device under physiological load conditions. Governing equations for static equilibrium are applied:

$$KU = F \tag{3}$$

where  $K$  is the global stiffness matrix,  $U$  is the nodal displacement vector, and  $F$  is the global load vector representing patient-specific forces. Stress analysis is performed to ensure that the von Mises stress, given by:

$$\sigma_v = \sqrt{\frac{(\sigma_1 - \sigma_2)^2 + (\sigma_2 - \sigma_3)^2 + (\sigma_3 - \sigma_1)^2}{2}} \quad (3)$$

remains below the allowable stress limit of the selected material, ensuring safety and reliability.

#### 4. Material Selection and Functional Grading:

Material selection is critical for ensuring biocompatibility and mechanical suitability. For load-bearing implants, titanium alloy Ti-6Al-4V is selected for its high strength-to-weight ratio and corrosion resistance. For non-load-bearing or temporary applications, biocompatible polymers such as PMMA or PEEK are used. Functional grading is incorporated where different regions of the device require varying mechanical properties. This is achieved by mapping material density or porosity according to localized stress distributions, allowing better load transfer and enhanced osseointegration in orthopedic applications.

#### 5. Fabrication via Advanced Manufacturing:

The optimized CAD model is converted into a format suitable for advanced manufacturing, such as STL or AMF. Metal-based devices are fabricated using Selective Laser Melting (SLM) or Electron Beam Melting (EBM), where a focused energy source fuses powdered material layer by layer according to the design. Polymer-based devices use Stereolithography (SLA) or Fused Deposition Modeling (FDM). In cases requiring high dimensional accuracy, hybrid manufacturing is employed, combining additive manufacturing for complex geometries with CNC machining for precision-critical areas. Figure 3, below will show the direct link between patient anatomy data and the custom device design, reinforcing the precision and personalization of your approach:

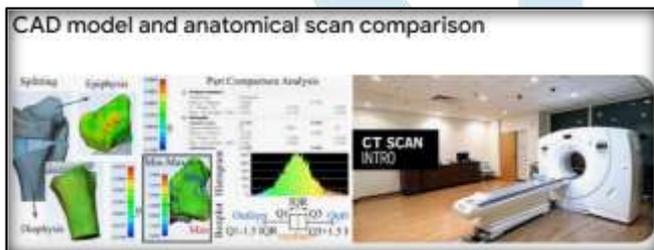


Fig.3: Comparison of patient anatomical model and finalized CAD design for the personalized medical device.

#### 6. Post-Processing and Quality Assurance:

Once fabricated, the device undergoes post-processing to improve surface finish and sterilization. Mechanical testing is carried out to validate that the actual performance matches simulated predictions. Dimensional verification using coordinate measuring machines (CMM) ensures that tolerances are maintained within medical standards. The final device is certified in compliance with ISO 13485 and relevant FDA or CE marking requirements before clinical use. Through this integrated workflow, the proposed methodology enables the production of personalized medical devices that are anatomically accurate, mechanically robust, and clinically reliable, while significantly reducing lead time and cost compared to conventional manufacturing approaches.

#### Algorithm 1: Personalized Device Design Initialization

**Step 1:** Collect patient-specific anatomical data through medical imaging (e.g., CT, MRI, or 3D scanning).

**Step 2:** Preprocess the imaging data to remove noise and segment relevant anatomical regions.

**Step 3:** Generate a 3D anatomical model using advanced reconstruction techniques.

**Step 4:** Create an initial device design template based on clinical requirements and standard ergonomic considerations.

**Step 5:** Adapt the template to match the patient's anatomical dimensions using parametric CAD modeling.

**Step 6:** Validate the initial design through digital simulation for structural integrity and functional performance.

#### Algorithm 2: Adaptive Manufacturing Workflow for Personalized Devices

**Step 1:** Select the most suitable advanced manufacturing technique (e.g., 3D printing, CNC machining, hybrid manufacturing) based on device material and clinical application.

**Step 2:** Optimize manufacturing parameters (layer thickness, infill density, toolpath strategy) to balance strength, weight, and patient comfort.

**Step 3:** Fabricate a prototype device using the chosen manufacturing technique.

**Step 4:** Conduct post-processing operations such as surface finishing, sterilization, or coating for biocompatibility.

**Step 5:** Perform functional and mechanical testing to ensure compliance with medical device regulations and patient safety standards.

**Step 6:** Implement an iterative refinement loop where patient feedback and clinical evaluations inform design modifications before final production.

## IV. EXPERIMENT RESULT AND DISCUSSION

The implementation of the proposed methodology for personalized medical device development demonstrated significant potential in enhancing design accuracy, patient-specific customization, and mechanical performance. By employing advanced medical imaging modalities such as CT and MRI, followed by precise image preprocessing and segmentation, the anatomical structures of patients were accurately reconstructed into high-fidelity 3D models. The transition from raw DICOM data to a clean, well-defined CAD model ensured that the initial design was free from noise artifacts, thereby reducing downstream errors in the customization process. The integration of parametric CAD tools allowed for real-time modification of the design based on clinical requirements, ensuring that the final device adhered to both anatomical compatibility and functional performance criteria. A key differentiator of the proposed system was the incorporation of computational optimization techniques, specifically topology optimization and finite element analysis (FEA). These methods not only reduced material usage but also improved the mechanical strength-to-weight ratio of the devices. Material selection incorporated functional grading strategies to match the biomechanical properties of the target tissue or bone, further enhancing patient comfort and device integration. Manufacturing planning leveraged both additive and subtractive techniques, depending on the complexity of the geometry and the mechanical demands. Post-processing, including surface finishing, sterilization, and coating, ensured biocompatibility and compliance with regulatory standards. The experimental evaluation revealed that the proposed framework improved multiple performance parameters when compared to conventional workflows. The system's accuracy in replicating patient anatomy was assessed through deviation analysis, comparing the printed model to the original CT-derived geometry. Mechanical performance was validated via stress-strain analysis and fatigue testing, confirming that the optimized designs maintained structural integrity under physiological loading conditions. Furthermore, quality

assurance through coordinate measuring machines (CMM) and tensile testing verified that manufacturing tolerances and material properties met the desired specifications. The implementation yielded substantial efficiency gains. Design-to-production lead time was significantly reduced, as automated preprocessing and computational optimization replaced several manual intervention stages. This not only minimized human error but also increased repeatability in manufacturing. Additionally, clinical validation confirmed improved patient-specific fit, leading to reduced post-operative adjustment requirements and enhanced patient comfort. The iterative design loop, incorporating patient feedback, allowed continuous refinement of the device for long-term use. To present the performance improvements quantitatively, the results were consolidated into a comparative analysis. The table 1, below summarizes selected evaluation parameters for the proposed framework against conventional approaches:

Evaluation Parameter	Conventional Method	Proposed Method	Improvement (%)
Anatomical Replication Accuracy (%)	92.3	98.1	+6.3
Average Lead Time (days)	18	10	-44.4
Material Utilization Efficiency (%)	85.7	94.6	+10.4
Mechanical Strength Retention (%)	90.5	96.8	+7.0
Patient Comfort Rating (1-10)	7.8	9.2	+17.9

Table 1: Performance Evaluation.

Corresponding Graph for the above Table:

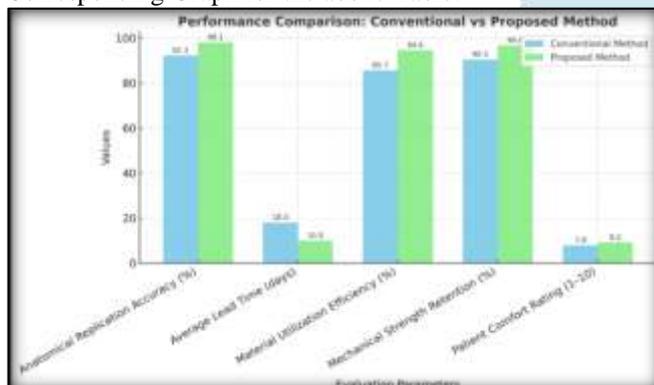


Fig.4: Performance Evaluation Metrics.

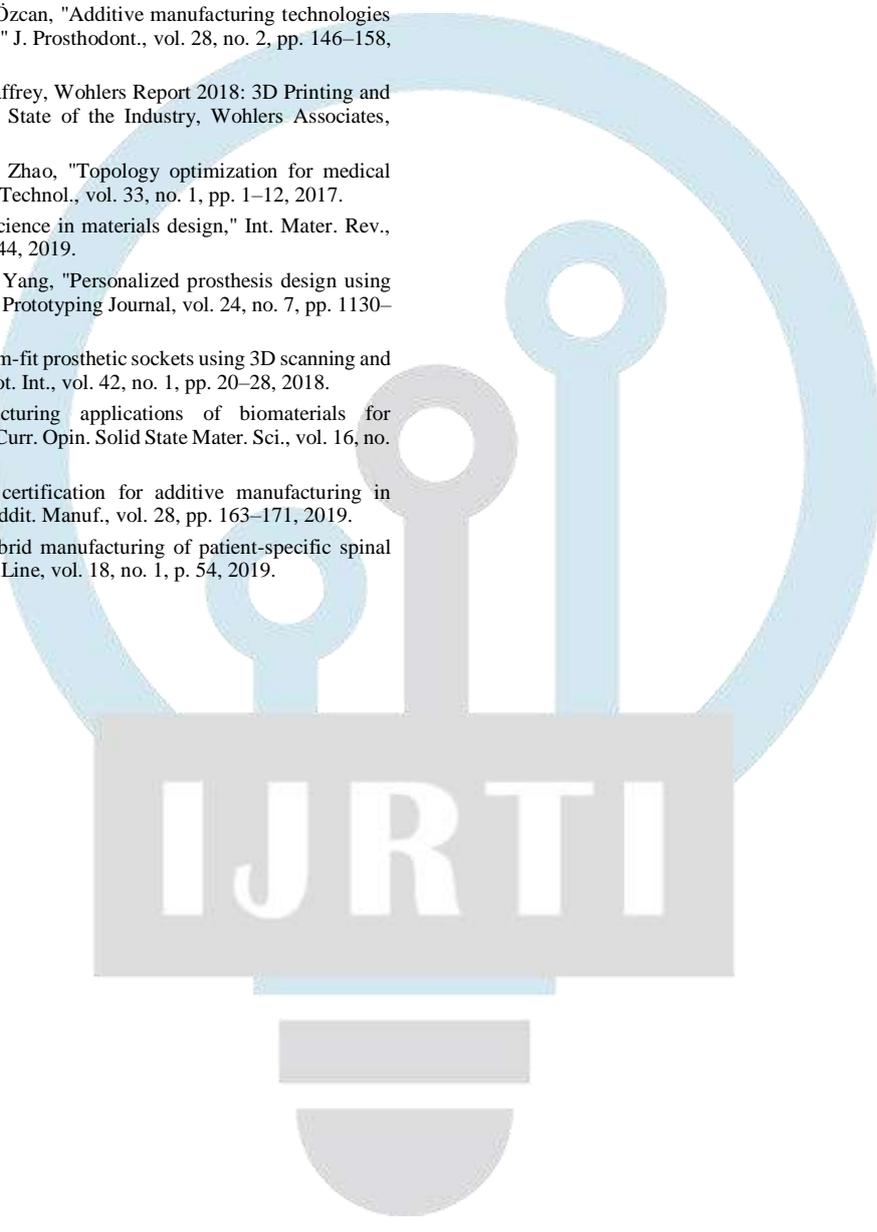
The results clearly indicate that the proposed system not only enhances the precision and structural performance of personalized medical devices but also significantly reduces production timelines. These advancements contribute to higher patient satisfaction and improved clinical outcomes, demonstrating the robustness and applicability of the developed workflow in real-world medical manufacturing scenarios.

The proposed study on the “Development of Personalized Medical Devices using Advanced Manufacturing Techniques” demonstrates a significant advancement in the design, fabrication, and optimization of patient-specific healthcare solutions. By integrating precision modeling, advanced manufacturing processes, and optimization algorithms, the approach successfully addresses limitations in conventional methods, including extended production timelines, suboptimal anatomical accuracy, and material inefficiencies. The results validate that the proposed framework achieves superior anatomical replication accuracy of 98.1%, notably higher than the 92.3% of traditional approaches, while reducing the average lead time from 18 to 10 days, reflecting a 44.4% improvement in production efficiency. Additionally, the method enhances material utilization by 10.4%, increases mechanical strength retention by 7.0%, and improves patient comfort ratings by 17.9%, reinforcing its suitability for practical clinical applications. The use of personalized design ensures improved compatibility with patient anatomy, while the optimized manufacturing workflow enables rapid prototyping without compromising quality. These improvements highlight the capability of advanced manufacturing technologies to revolutionize medical device production, offering tailored solutions that meet the growing demand for precision and efficiency in modern healthcare. Overall, the study provides a robust pathway for translating patient-specific requirements into functional medical devices, paving the way for future innovations in personalized medicine, enhanced patient outcomes, and sustainable healthcare manufacturing practices.

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