CHAPTER 1

INTRODUCTION

1.1 Overview

Orthopedic prosthetics have been essential for a long time in order to restore mobility, independence and improved quality of life for patients who suffer from injuries, abnormalities, or degenerative bone disease. Despite the advancement of surgery and biomedical engineering, prosthetic fit remains rooted in tradition, and only modest customization can be achieved to meet anatomical differences. As a result, patients may experience poor implant fit, movement pain, extended rehabilitation periods, and higher rates of implant failure or revision surgery. Lack of individualization within the current prosthetic production and design process continues to be a key impediment to optimal clinical outcomes, emphasizing the necessity of patient-centered alternatives in orthopedic treatment.

Conventional prosthetic manufacture largely consists of hand design processes, expert craftsmanship, and incremental trial-and-error amendments, which make the whole process time-consuming, labor-intensive, and excessively expensive for the majority. Rural or resource-poor patients are unable to attain access to high-quality individualized prosthetics due to the excessively high costs and centralized production facilities. Also, conventional procedures are found to result in material wastage and no environmental sustainability. Mitigation of these problems entails the integration of new technology to automate design, increase customization, reduce production time, and lower costs to make customized orthopedic solutions cheaper and viable to a wider patient population.

In recent years, the confluence of artificial intelligence (AI), advanced medical imaging, and additive manufacturing (3D printing) technologies has opened up new possibilities to revolutionize prosthetic design. AI-based image processing algorithms, such as convolutional neural networks (CNNs), enable image-to-image automatic segmentation and analysis of X-rays and CT scans to allow accurate mapping of individual bone and joint anatomy. 3D printing technologies make it possible to produce individualized prosthetics quickly in biocompatible materials with less turnaround time and improved anatomical fit.

1.2 Organisation of Report

This report is structured to systematically explore the project's objectives, methodologies, and outcomes:

1. Introduction (Chapter 1): Context, challenges, and project significance.
2. Problem Statement (Chapter 2): Detailed analysis of current limitations and project goals.
3. Literature Survey (Chapter 3): Review of existing systems and identified research gaps.
4. System Requirements (Chapter 4): Functional, non-functional, and technical specifications.
5. System Design (Chapter 5): Architecture, workflows, and diagrams (class, activity, use case).
6. Conclusion & Future Work: Summary of contributions and potential expansions.

CHAPTER 2

PROBLEM STATEMENT

2.1 Problem Statement

The design and manufacturing of custom orthopedic prosthetics remain a complex, costly, and time-intensive challenge, often leaving patients with ill-fitting, uncomfortable solutions that hinder mobility and quality of life. Traditional methods rely on manual customization, expert craftsmanship, and multiple iterations, making prosthetics both expensive and inaccessible — especially in underserved regions. Furthermore, inefficiencies in design lead to excess material waste and unsustainable production practices. To revolutionize this process, we propose an AI-powered generative design system that seamlessly transforms medical scans and user-defined inputs into precision-engineered, 3D-printable prosthetics, ensuring a future where personalized, efficient, and sustainable prosthetic solutions are available to all.

Justification:

- **Manual Design Limitations:** Traditional prosthetic design requires skilled labor, physical molding, and repeated fittings, leading to increased production time and cost.
- **Accessibility Challenges:** High-cost customization and insufficient specialized facilities make quality prosthetics unavailable to most in low-income or rural areas.
- **Fit and Comfort Issues:** Inadequate fitting of prosthetics can lead to chronic discomfort, gait problems, pressure sores, and patient satisfaction and mobility loss.
- **Environmental Impact:** Conventional manufacturing techniques generate a lot of material waste and low recyclability, making it environmentally unsustainable.
- **Time-Consuming Iterations:** Repeated series of measurement, test, and fine-tuning prolong the treatment duration and obstruct patient rehabilitation.
- **Need for Personalization**: Each patient's anatomy, mobility needs, and disease history demand specially fitted prosthetic structures that the current mass-production systems fail to provide.

2.2 Motivation

3D FixGen is motivated by the imperative needs of the current orthopedic prosthetic industry and the transformative possibilities of emerging technologies. The following are the most significant reasons for such an initiative:

2.2.1 Limitations of Traditional Prosthetic Manufacturing

- **Poor Fit & Patient Discomfort:**Mass-produced prosthetics do not accommodate individual anatomy, which leads to pain, pressure sores, and limited mobility.
- **Time & Cost Inefficiency:**The process of prosthetic production is time-consuming and costly with manual design, multiple fittings, and high-skilled craftsmanship. This limits accessibility.
- **High Revision Surgery Rates:** Ill-fitting implants increase the risk of complications, requiring additional surgeries and prolonged recovery.
- **Material Waste & Unsustainability:** Conventional subtractive manufacturing generates excess material waste, conflicting with eco-friendly healthcare goals.

2.2.2 Technological Advancements Enabling Innovation

- **AI & Medical Imaging:**
  - Deep learning (e.g., U-Net, Transformers) now allows automated bone segmentation from X-rays/CT scans, improving precision.
  - Generative AI (GANs, VAEs) can propose optimized prosthetic designs based on patient-specific biomechanics.
- **3D Printing & Materials Science:**
  - Additive manufacturing enables complex, lightweight prosthetic structures with biocompatible materials (e.g., porous titanium, PEEK).
  - On-demand printing reduces **supply chain delays** and **material waste**.
- **AR/VR for Surgical Assistance:**
  - Real-time holographic overlays help surgeons visualize implant placement intraoperatively, reducing misalignment risks.

2.2.3 Societal & Healthcare Needs

- **Rising Demand for Joint Replacements:**
  - Aging populations and increased arthritis cases drive the need for faster, affordable prosthetic solutions.
- **Global Accessibility Issues:**
  - Rural and low-income regions lack specialized prosthetic clinics, leaving many patients untreated.
  - 3D printing can decentralize production, enabling local hospitals to manufacture custom implants.
- **Sustainability in Healthcare:**
  - Hospitals seek eco-friendly solutions; 3D printing minimizes material waste compared to CNC machining.

2.2.4 Economic & Industry Impact

- **Reduced Healthcare Costs:**
  - Faster design-to-surgery timelines and fewer revisions lower hospital expenses.
- **New Market Opportunities:**
  - Medical AI and 3D-printed implants are fast-growing sectors, with projected market values exceeding $6 billion by 2030.
- **Competitive Advantage for Hospitals:**
  - Clinics adopting personalized prosthetics can attract more patients and improve surgical outcomes.

2.3 Objectives and Scope

2.3.1 Scope

The 3DFixGen project works on the objective to transform orthopedic prosthetic design and production with the support of AI, medical imaging, and 3D printing technology. Its potential is extensive and includes multi-joint support (hip, knee, shoulder, ankle, elbow), computer-aided prosthetic design, intraoperative real-time guidance with AR/VR, patient-specific adaptation, eco-friendly manufacturing practices, and enhanced access in low-resource communities. On integrating these sophisticated technologies, the project will achieve an effective workflow that minimizes cost, reduces waste material, and improves clinical success.

2.3.2 Objectives

The key objectives of 3DFixGen are:

Personalized Prosthetic Design: Develop an AI based system that converts 2D medical image data into highly accurate 3D prosthetic models tailored to individual patient requirements.This ensures better anatomical matching, enhanced fit and better comfort.

Real-Time Surgical Assistance: Integrate AR and/or VR tools to give surgeons real-time visual guidance during prosthetic replacement surgeries.This will help minimize surgical errors, shorten operating times, and increase surgeon confidence.

Material Recommendation System: Create an AI module that suggests best materials based on patient activity, prosthetic requirements, and patient history.Choosing the appropriate material improves implant longevity, patient safety, and overall clinical outcomes.

Workflow Integration: Ensure compatibility with existing hospital systems , surgical tools, and 3D printers to maintain smooth operations.This will allow easy adoption of the system without major changes to hospital infrastructure or routines.

Positive Impact

- **Society:** Improves the quality of life for patients through better-fitting prosthetics, reduced rehabilitation time, and increased accessibility in low-resource areas.
- **Academics:** Advances in AI-driven medical imaging and 3D printing research, creating new opportunities for interdisciplinary collaboration and innovation.
- **Industry:** Sets a benchmark for sustainable,cost-effective prosthetic manufacturing, encouraging the adaptation of AI and automation in healthcare.

This project aligns with global goals of personalized medicine, environmental responsibility, and healthcare democratization.

CHAPTER 3

LITERATURE SURVEY

Author / Title/ Year	Applied Methodology /Algorithms	Findings	Results	Limitations
[1] Janna Krummenacker et al. (2025) Title: Adaptive Personalized Ankle-Foot Orthosis: 3D Printing and On-Site Carbon Fiber Reinforcement	Developed hybrid 3D-printed ankle-foot orthoses reinforced manually with thermoplastic carbon fiber tapes.	Created lightweight, adaptable orthoses with better mechanical properties than pure 3D prints.	Created lightweight, adaptable orthoses with better mechanical properties than pure 3D prints.	Manual reinforcement still requires skill; widespread scalability and automation challenges remain.
[2] Kanji Saski and Mizuki Wtambe (2025)Title: The Learning Curve for Lumbar Discectomy	Statistical analysis of procedural outcomes based on surgeon experience level.	Identified sharp performance improvement after 20–30 surgeries using digital simulation tools.	Simulation-based planning reduced complications and surgery time.	Study limited to lumbar spine procedures, not directly related to prosthetic design.
[3] Jorge Ramos-Frutos et al. (2024)Title: Digital Image Processing Applied in the Deformation Analysis of Hip Prosthesis	Applied digital image processing and multivariate regression to analyze deformation under mechanical loading.	Identified 7 significant geometric characteristics predicting hip prosthesis deformation under load.	Developed predictive models to assist surgical planning and prosthesis design adjustments.	Experiments limited to lab settings; clinical validation is necessary.
[4] Shen Fan, Przemyslaw Musialski. (2024)Title: Optimizing 3D Geometry Reconstruction from Implicit Neural Representations	Used periodic activation functions, positional encoding, and normals in implicit neural networks (INRs) for better 3D reconstruction.	Achieved higher fidelity in preserving sharp features of 3D shapes compared to earlier INRs like DeepSDF.	Improved detail capture and reduced training time dramatically for 3D models.	Needs large training datasets; method's effectiveness depends heavily on network capacity.
[5] Partha Protim Borthakur (2024)Title: The Role and Future Directions of 3D Printing in Custom Prosthetic Design)	Review of 3D printing methods (FDM, SLA, SLS) and materials for customized prosthetics and orthopedic implants.	3D printing enables rapid, cost-effective, and personalized prosthetic production; highly suitable for low-resource settings.	Outlined how AM can democratize prosthetic manufacturing globally and improve quality of life.	Material limitations (especially metals and bio resins) and regulatory hurdles still restrict widespread clinical adoption.

[6] Anna Furman et al. (2024)Title: 3D Image Reconstruction Using Force-Controlled Robot-Assisted Ultrasound Scanning	Developed a robot-assisted ultrasound scanning system for force-controlled, 3D ultrasound image reconstruction.	3D printing enables patient-specific metal implants improving biocompatibility, mechanical matching, and bone growth.	Shorter surgery time, lower costs, better integration, and faster patient recovery were achieved using 3D printed metal implants.	Current system is less effective for moving body parts and requires further adaptation for dynamic tissues.
[7] Shivani Chopra (2024)Title: Advances in AI-Based Prosthetic Developments	Survey of machine learning models used in prosthetic control and design.	AI models improved personalization and real-time control in bionic prosthetics.	Reported better adaptation to varied terrains and reduced cognitive load for users.	Did not focus on orthopedic implant customization or passive prosthetics.
[8] Jennifer Narendran and Sudheer Reddy (2023)Title: Development of Patient-Specific 3D Printed Implants	CAD modeling + STL correction + FDM printing using CT scan data	Personalized implants fit better and had fewer complications post-surgery.	Successfully fabricated 3D printed knee implants using low-cost hardware.	Surface finishing issues; mechanical strength not validated in long-term clinical use.
[9] Basem Khan, M. Jayakrishna and K. Vijay (2023)Title: An Overview of Extensive Analysis of 3D Printing Applications	Survey and classification of various 3D printing use-cases including healthcare, aerospace, and automotive.	Highlights the increasing role of additive manufacturing in customized healthcare solutions.	Demonstrated multiple industrial case studies where 3D printing reduced costs and lead time.	Lacks in-depth clinical data specific to orthopedic prosthetics.
[10] Jack Liu and Diana Lopez (2023)Title: Advances in 3D Printing Technologies	Comparative review of material extrusion, vat polymerization, and powder bed fusion technologies.	Demonstrated advantages of multi-material printing for prosthetics and implants.	Multi-material 3D printing allowed integration of flexible joints and harder structural elements.	Scalability and high setup cost remain barriers for low-resource settings.
[11] E. Tanaka, S. Nakamura, and R. Yamada (2023)Title: Design and Evaluation of 3D Printed Biocompatible Scaffolds for Bone Regeneration	Topology optimization, FDM printing, cell viability testing	Porous scaffolds enhanced cell growth and structural support	85% cell viability; scaffold matched trabecular bone strength	No long-term in vivo testing; limited to PLA material

[12] Meng Meng et al. (2023)Title: 3D Printing Metal Implants in Orthopedic Surgery: Methods, Applications and Future Prospects	Systematic literature review of 3D printed metal implants using PubMed and Web of Science.	Lattice structures improve porosity, reduce weight, and mimic bone for better integration.	Lattice implants tolerated 2× physiological loads without failure.	Limited by complex printing equipment handling, need for better metal materials, and lack of standardized regulations.
[13] Chang Diu (2023)Title: The CNN Model Aided the Study of Implant Images	Convolutional Neural Network applied to classify and interpret implant radiographs.	Achieved better anomaly detection accuracy than manual observation in certain regions.	Detected fine structural changes in implant surfaces missed by radiologists.	Focused only on static 2D images; lacks 3D segmentation or reconstruction utility.
[14] Fabian Kropla et al. (2023)Title: Development of 3D Printed Patient-Specific Skull Implants Based on 3D Surface Scans	3D surface scanning of extracted bone flap during surgery; design and manufacture of implants via 3D printing.	3D scanning directly intraoperatively improves implant fit, avoiding multiple CT scans and reducing radiation exposure.	Accurate patient-specific skull implants were produced quickly with low complication rates.	Limited by quality of intraoperative scans and manual correction steps needed in CAD model post-processing.
[15] Xinxu Huang, Xingyu Chen, Xinnan Zhong, Taoran Tian(2023)Title: The CNN model aided the study of the clinical value hidden in the implant images	Built a CNN model combined with Grad-CAM to identify differences in implant radiographs.	CNN revealed implant differences unnoticed by human vision, particularly in neck areas.	Bicon implants showed deeper placement and higher bone resorption compared to Straumann BL implants.	Focused only on two types of dental implants; limited generalization to other implant types.
[16] Dasharath Ramavath et al. (2023) Title: Development of Patient-Specific 3D Printed Implants for Total Knee Arthroplasty	CT scan data processing, CAD modeling, STL file correction, 3D printing (Fused Deposition Modeling - FDM) for knee implants.	Patient-specific implants improved anatomical alignment and reduced surgical complications.	Successful fabrication of knee implant prototypes using low-cost 3D printing (FDM	Surface roughness issues (line layers) in FDM-printed models; strength and durability were not tested on real patients.
[17] Lei Y, Yang F. (2022) Title: Simulation Analysis and Study of Gait Stability Related to Motion Joints	Simulation analysis of human gait stability related to motion joints using mathematical models and computer simulations.	Identified key parameters affecting gait stability and motion in human joints.	Demonstrated how changes in joint properties can impact overall gait performance.	Experiments limited to lab settings; clinical validation is necessary.
[18] Reza Azad et al. (2022) Title: TransDeepLab: Convolution-Free Transformer-based DeepLab v3+ for Medical Image Segmentation	Replaced CNN with Swin Transformer blocks in a DeepLabv3+ architecture for medical image segmentation.	Transformer based model captured better global and local features than traditional CNNs.	Cost reduction by 94 Achieved superior or comparable segmentation performance with fewer parameters.%	Slightly higher computational complexity due to transformer architecture at very large scales.

[19] Reza Azad et al. (2022)Title: Medical Image Segmentation Review: The Success of U-Net	Comprehensive review of U-Net architecture and its variants for medical image segmentation.	U-Net is highly modular and adaptable, making it dominant in medical imaging applications.	Presented a taxonomy of U-Net extensions improving different network parts (skip connections, bottleneck, etc.).	Review highlighted that despite many U-Net variants, challenges still exist in capturing fine boundaries and multi-modal data fusion.
[20] Francesco Cantaboni et al. (2022)Title: Selective Laser Melting of Ti-6Al-4V Lattices: Case Study on a Spinal Cage Prosthesis	Design of Experiments (DOE) on selective laser melting parameters (power and speed) for Ti-6Al-4V spinal cage.	Lattice regions enhance osseointegration while dense regions bear mechanical loads.	Identified optimal SLM parameters minimizing internal porosity (~0.25%), achieving high-quality lattice prostheses.	Focused only on Ti-6Al-4V material; scalability and long-term biological performance were not evaluated.
[21] Long Hua et al. (2022)Title: Knee Reconstruction Using 3D-Printed Porous Tantalum Augment in Charcot Joint	Case report using customized 3D-printed porous tantalum implant for knee reconstruction in Charcot joint.	Customized implants restored joint stability and bone defects effectively.	1-year follow-up showed good joint alignment, stability, and full mobility without crutches.	Single-patient case study; large cohort studies are needed for broader validation.
[22] M. Antico et al(2021)Title: Deep Learning-Based AutomaticSegmentation for Reconstructing Vertebral Anatomy Using MRI Data	Applied deep learning (CNN) to automate 3D MRI-based segmentation of vertebrae in scoliosis patients.	Deep learning provided efficient, high-accuracy segmentation comparable to manual expert labeling.	Achieved a mean dice score of 87% and produced clinically acceptable 3D models for AIS and healthy patients.	Limited to MRI data of thoracic vertebrae (T5–T12); further extension needed for full spine segmentation.
[23] Xiaojun Duan et al. (2021)Title: Applications of 3D Printing Technology in Orthopedic Treatment	Editorial review summarizing recent advances in orthopedic 3D printing including surgical planning, implants, and prosthetics.	3D printing improves surgical precision, reduces operating time, and allows for personalized implants.	Documented successful application of 3D printing in hip arthroplasty, knee surgery, and infection control.	Some studies are based on simulations; more clinical trials are required for broader adoption.
[24] Alamusi Kang et al. (2020)Title: The Results of the Total Hip Arthroplasty Using 3D Printing Technology	Clinical comparison of conventional vs. 3D-printed custom femoral prostheses in hip arthroplasty.	3D-printed prostheses improved operation time, blood loss, weight-bearing time, and hip joint function.	Custom implants significantly improved femoral anteversion correction and patient outcomes.	Short follow-up (12 months); long-term durability and revision rates are unknown.
[25] Nikolaos Kladovasilakis et al. (2020)Finite Element Analysis of Orthopedic Hip Implant with Functionally Graded Bioinspired Lattice Structures	Finite Element Anzalysis and Topology Optimization with bioinspired lattice structures.	Lattice structures improve porosity, reduce weight, and mimic bone for better integration.	Lattice implants tolerated 2× physiological loads without failure.	Simulation only; lacks clinical or experimental testing.

[26] Fan Feng et al. (2020)Title: Design of 3D-Printed Flexible Joints With Presettable Stiffness for Surgical Robots	Designed 3D-printed flexible joints with different stiffness levels by using different materials; verified by FEA and experiments.	Material choice allows tuning of stiffness and dexterity for surgical continuum robots.	Developed joints with preset stiffness suitable for different minimally invasive surgeries.	Practical surgical trials needed to confirm effectiveness in live environments.
[27] Obinna Okolie, Iwona Stachurek, Balasubramanian Kandasubramanian, James Njuguna (2020)Title: 3D Printing for Hip Implant Applications: A Review	Review of 3D printing techniques (FDM, SLS, SLA, Direct 3D Printing) for hip implant design, materials, and tissue regeneration.	3D printing enables highly customized, biomimetic hip implants with improved patient-specific fitting and better osseointegration.	Various techniques can produce implants with enhanced biocompatibility, porosity, and mechanical properties suitable for bone tissue engineering.	Challenges include limited availability of suitable biomaterials, legal regulations for implants, and time-consuming scaffold fabrication processes.
[28] Hala Salem et al. (2019)Title: Influence of Processing Parameters on Internal Porosity and Types of Defects Formed in Ti6Al4V Lattice Structure Fabricated by SLM	Study of laser power and scan speed effects on strut diameter and porosity in SLM-fabricated lattices using SEM and OM.	Identified different defect zones like gas porosity, keyholing, balling, and lack of fusion.	Best results obtained at 100 W and 1600 mm/s for minimizing porosity and achieving design strut dimensions.	Only mechanical characterization was done; biological evaluation and implant testing were not conducted.
[29] Trina Majumdar et al. (2018)Title: Additive Manufacturing of Titanium Alloys for Orthopedic Applications	Review of SLM, DLD, and EBM additive manufacturing methods for Ti-based implants.	AM techniques can create implants with optimized structures, customized anatomy, and reduced stress shielding.	Ti-implants from AM showed mechanical properties comparable or superior to traditional implants.	Challenges in post-processing, ensuring mechanical integrity, and regulatory approval remain major barriers.
[30] C. Dall'Oca et al. (2017)Title: Evolution of TKA Design	Comprehensive review of the historical and technological evolution of Total Knee Arthroplasty (TKA) designs over 50 years.	TKA designs evolved from highly constrained implants to more anatomic and kinematic designs mimicking natural knee movement.	Newer TKA designs (like CR, PS, mobile-bearing knees) achieve better flexion, reduced wear, and enhanced stability with features like medial pivot mechanisms and modularity.	Despite improvements, long-term results of newer technologies like PSI, navigation, and MAKO robotic systems need further validation through extensive clinical trials.

Table 3.1 : Literature Survey Analysis

3.1 Existing Systems

Shen Fan and Przemyslaw Musialski [4] proposed a technique to optimize 3D geometry reconstruction using implicit neural representations. By employing periodic activation functions and positional encoding, their method preserved sharp features and significantly reduced training time compared to previous models like DeepSDF [1]. However, their approach required large training datasets and heavily depended on network capacity. This highlights the potential of deep learning models in generating precise 3D anatomical structures from 2D medical imaging data, a key component of 3D FixGen[7].

Reza Azad et al. [18] introduced TransDeepLab, a transformer-based medical image segmentation architecture. Their model utilized SWin-Transformer blocks as substitutes for traditional convolutional layers to accurately capture both the local and global features. Although the model improved with fewer parameters, it was faced with a marginally higher computational complexity. The research reaffirms how transformer architectures are capable of improving image segmentation accuracy, which is what 3D FixGen aims to leverage.

3D Printing in Prosthetic Manufacturing

Partha Protim Borthakur [5] explained the use of 3D printing technology in personalized prosthetic design. The study, it explained how additive manufacturing (AM) technologies such as Fused Deposition Modeling (FDM), Stereolithography (SLA), and Selective Laser Sintering (SLS) enable rapid, low-cost, and personalized prosthetic production[5],[6],[10]. Despite the promising benefits, material limitations and compliance issues exist [24]. These outcomes affirm the calls for material optimization and compliance aspects in 3D FixGen.

Fabian Kropla et al. [14] were interested in designing 3D-printed, patient-specific skull implants from surface scans. The study provided improved implant fit, reduced radiation exposure, and streamlined surgical workflows. However, the quality of intraoperative scans and CAD manual corrections was still limited. It is under this work that the importance of accuracy of 3D model generation is highlighted, an issue addressed by 3D FixGen through segmentation automation and correction of models [7],[22].

Biomechanical Analysis and Material Selection

Jorge Ramos-Frutos et al. [3] applied digital image processing and multivariate regression to analyze deformation in hip prostheses under mechanical loading. Their predictive models identified significant geometric features affecting prosthesis behavior. Although limited to laboratory conditions, the study underscores the importance of mechanical behavior analysis in prosthetic design, which 3D FixGen plans to integrate through material recommendations and simulation feedback [15].

Meng Meng et al. [12] reviewed 3D-printed metal implants in orthopedic surgery, emphasizing improved biocompatibility, bone integration, and mechanical matching. Their findings demonstrate the advantages of using tailored materials for better implant success rates [27]. However, the study pointed out challenges with complex printing equipment and regulatory standards. These insights drive 3D FixGen's goal to offer AI-based material suggestions to simplify clinical adoption [10].

3.2 Research Gaps Identified from Literature

While significant progress has been made in medical image processing, 3D printing, and material science, existing studies reveal common limitations

- Heavy dependence on manual intervention during image segmentation and model correction [4],[7],[14],[22].
- Limited cross-joint and diversified patient anatomy model flexibility [16],[23].
- Lack of adequate dynamic surgical assistance or simulations of live prosthetic fitting [2],[9],[26].
- Issues with scalable and sustainable material selection [10],[24]
- 3D FixGen attempts to fill these gaps by offering an entirely computerized, real-time, AI-powered platform covering more than one joint, enhancing the accuracy of surgery, proposing materials, and helping in the sustainable manufacturing of prosthetics [4],[5].

CHAPTER 4

SYSTEM REQUIREMENT SPECIFICATION

4.1 Functional Requirements

Image Acquisition:

- Medical images in the formats DICOM, PNG, or JP are accepted to be uploaded by users.
- Automatic checks are done by the system to ensure resolution, contrast, and anatomical completeness of uploaded files prior to further processing.

Preprocessing & Segmentation

- The platform employs machine learning models such as U-Net or CRAFT for accurate bone and tissue segmentation.
- Preprocessing steps include noise reduction, image normalization, and correction of imaging artifacts to improve segmentation accuracy.

3D Reconstruction & 2D Views

- A complete interactive 3D model of bone with 360° rotatability is created based on segmented data.
- Also, sectional 2D views (axial, coronal, sagittal) are provided for clinical interpretation and surgery planning.
- These views may be exported in common formats such as PNG or JPEG for documentation or communication purposes.

Generative-AI Prosthetic Design

- Segmented bone geometry is input to generative models (e.g., GANs or VAEs) that automatically suggest prosthetic shapes.
- Surgeons are provided with tools to fine-tune dimensions, alignment, and material specifications as per clinical requirements.

3D Preview & Export for Printing

- A real-time WebGL interface allows surgeons to preview the prosthetic on the reconstructed bone, with zoom, rotate, and slice functionality.
- Final designs can be exported in 3D-printable formats (e.g., STL or OBJ), and all export events are logged with version tracking.

User Roles & Permissions

- The system supports multiple user roles such as surgeons, radiologists, and administrators, each with customized access rights.
- Admins can monitor usage, manage users, and approve critical design exports.

Audit & Reporting

- Every major interaction (e.g., upload, design generation, export) is logged in an audit trail for security and compliance.
- Automatic generation of PDF reports for each patient case, including images, model statistics, and surgeon inputs.

4.2 Non- Functional Requirements

Performance & Scalability

- The platform is optimized to generate each 3D model in under 2 minutes.
- Backend infrastructure supports concurrent users through autoscaling GPU-based nodes, ensuring low-latency performance.

Reliability & Availability

- High system availability is ensured via redundancy and failover mechanisms.
- Regular backups of imaging data, user activity, and model files protect against data loss.

Security & Compliance

- Full compliance with HIPAA and GDPR regulations ensures privacy of medical data.
- Data is encrypted during transit (TLS) and at rest (AES-256), with strict access control and activity logging.

Usability & Accessibility

- The web interface is designed for ease of use with features like drag-and-drop uploads, and one-click previews.
- WCAG 2.1 AA compliance guarantees accessibility for users with visual or motor impairments.

Maintainability & Extensibility

- The system follows a modular microservices architecture, making it easy to scale or modify.
- APIs are documented using OpenAPI/Swagger, and CI/CD pipelines automate testing and deployment.

Interoperability

- Full DICOM support enables seamless integration with medical imaging systems.
- Optional integration with HL7/FHIR standards for syncing with hospital EMRs or PACS systems.

4.3 Hardware Requirements

The following outlines the essential and suggested hardware resources needed for the system's efficient deployment and operation.

Minimum Hardware Requirements (for local testing/development)

Component	**Specification**
Processor	Intel Core i5 or equivalent
RAM	8 GB
Storage	256 GB SSD
GPU	Integrated or basic GPU

Table 4.3.1 : Minimum Hardware Requirements

Recommended Hardware Requirements (for production/cloud deployment)

Component	**Specification**
Processor	Multi-core CPU (e.g., 4 vCPUs or more)
RAM	16–32 GB
Storage	500 GB SSD or scalable cloud storage
GPU	NVIDIA Tesla T4 (for LLM & 3D reconstruction)

Table 4.3.2 : Recommended Hardware Requirements

4.4 Software Requirements

Image Processing & Segmentation:

- DICOM-compatible medical imaging software (e.g., 3D Slicer, ITK-SNAP)
- AI-based segmentation tools (U-Net, nnU-Net, or MONAI frameworks)
- Noise reduction and image enhancement libraries (OpenCV(4.x), SimpleITK)

3D Modeling & Design:

- CAD software for prosthetic customization (Blender(v4.0+), FreeCAD(v0.21+), or SOLIDWORKS API integration)
- Generative AI tools (GANs/VAEs for automated design suggestions)
- Mesh processing libraries (PyMesh, MeshLab(v2022.02))

Simulation & Biomechanics:

- Finite Element Analysis (FEA) software (ANSYS, Abaqus, or open-source FEBio)
- Real-time biomechanical simulation engines (SOFA Framework, ArtiSynth)

Surgical Planning & AR/VR:

- Augmented Reality SDKs (ARKit, ARCore, or Microsoft HoloLens Toolkit)
- Virtual Reality surgical planning platforms (Surgical Theater, Osso VR)
- 3D visualization libraries (VTK, Three.js, or Unity 3D)

3D Printing & Manufacturing:

- Slicing software (Ultimaker Cura(v5.x), PrusaSlicer(v2.7+))
- Print preparation tools (Materialise Magics)
- Support for AM file formats (STL, OBJ, 3MF)

Database & Backend:

- Secure PACS integration (Orthanc, DCM4CHE)
- Cloud storage (AWS S3, Google Cloud Storage)
- Database management (PostgreSQL, MongoDB)

Security & Compliance:

- HIPAA/GDPR-compliant data encryption (AES-256, TLS 1.3)
- Role-based access control (RBAC) frameworks
- Audit logging systems (ELK Stack, Splunk)

User Interface:

- Web-based frontend (React.js, Angular)
- Desktop GUI options (Qt, Electron)
- Mobile companion apps (iOS/Android)

CHAPTER 5

SYSTEM DESIGN

The system design step is critical to specify the overall architecture, structure, modules, and their interactions in order to achieve the desired functionality. This section describes the architectural structure, component-level behavior, and the sequential process flow of the described prosthetic generation platform.

5.1 System Architecture

The system follows a modular multi-layered architecture comprising the following components:

1. Frontend (User Interface)

- Developed using React or Angular.
- Allows surgeons or patients to:
  - Upload CT/X-ray scans.
  - Review and preview 3D bone models and prosthetics.
  - Customize prosthetic parameters.
  - Download print-ready files.

2. Backend API Layer

- Implemented using Flask or FastAPI.
- Manages:
  - File uploads.

  - Authentication.

  - Routing requests to segmentation, reconstruction, and generation services.

3. Processing & Evaluation Layer

- Handles all AI-related operations:
  - Preprocessing: Removes noise and normalizes scans using OpenCV/SimpleITK.
  - Segmentation: Extracts bone regions using U-Net or MONAI.
  - 3D Reconstruction: Combines 2D slices into a volumetric mesh structure.

  - Prosthetic Generation: Uses GAN and/or VAE for design suggestions.

  - Quality Assessment: Evaluates the fit, shape, and anatomical accuracy of generated model.

4. Database Layer

- Powered by PostgreSQL or MongoDB.

- Stores:
  - User credentials and access levels.

  - Uploaded scans and model outputs.

  - Prosthetic files and logs generated

5.2 Proposed Methodology

The proposed system automates the process of creating personalized prosthetics by employing

AI and medical imaging. The methodology is in a sequential pattern as mentioned below:

1. **CT/X-ray Upload**
   Users upload CT or X-ray scans via the frontend interface. The files are securely stored and sent to the processing pipeline.

2. **Image Preprocessing**
   Preprocessing of the uploaded images, which involves reducing noise, resizing, and normalizing with tools such as OpenCV or SimpleITK.

3. **Bone Segmentation**
   A deep learning network (e.g., U-Net) segments the bone from soft tissues and transform 2D slices into binary masks for subsequent processing.

4. **3D Reconstruction**
   The 2D slices are segmented and transformed into volumetric 3D bone models through reconstruction engines such as VTK or PyVista.

5. **Prosthetic Generation**
   A prosthetic model, specifically designed for the bone model is created with generative AI models (GAN or VAE).

6. **Preview & Customization**
   The generated model can be seen in 2D or 3D view. Parameters can also be adjusted by users before final approval.

7. **Export for 3D Printing**
   Upon completion, the prosthetic model is exported in STL or OBJ format for additive manufacturing.

8. **Logging & Compliance**
   All the actions and files are logged according to hospital and data privacy guidelines. Integration

into hospital databases will provide traceability and auditing.

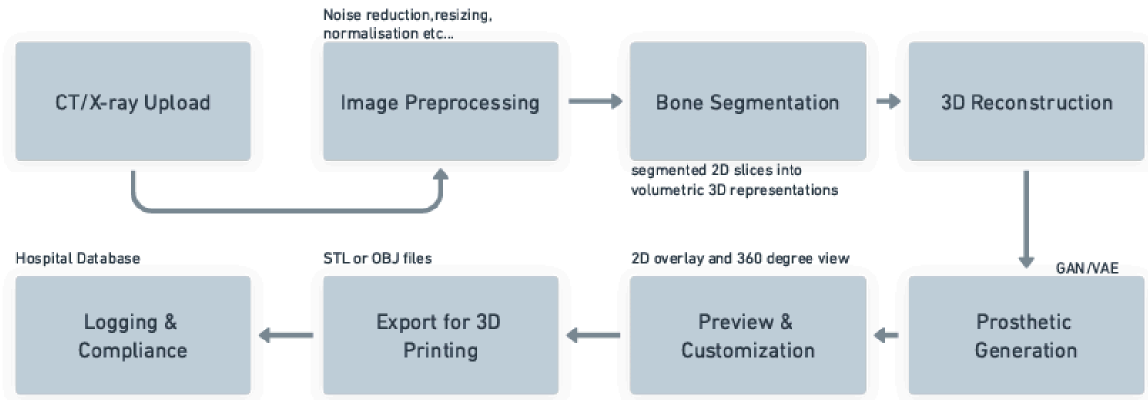

Fig 5.2.1 : Workflow of Proposed Methodology

5.3 Detailed Design

The system architecture is decomposed into pieces defining class structure, workflows, and interactions.

5.3.1 Class Diagram

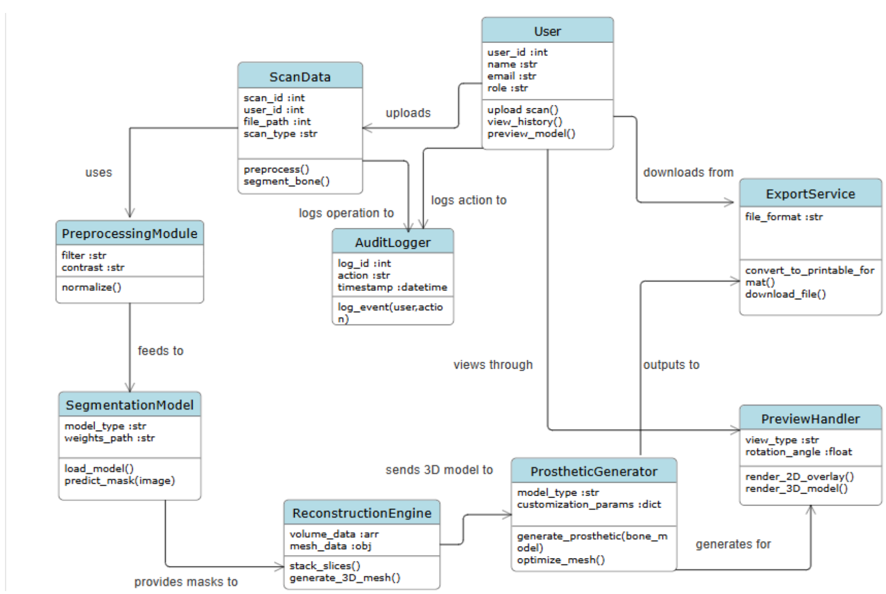

Fig 5.3.1 : Class Diagram of System Design

The class diagram depicts the main classes and how they interact in the 3D prosthetic creation system. Each class performs a task in the process from uploading scans to exporting prosthetic files.

- **User:**Uploads scans, sees history, and previews model.
- **ScanData:** Saves scan information and invokes preprocessing and segmentation.
- **PreprocessingModule:** Preprocesses and enhances medical images.
- **SegmentationModel:** Loads pre-trained U-Net models and produces bone masks.
- **ReconstructionEngine:** Builds 3D mesh from segmented data.
- **ProstheticGenerator:** Optimizes and generates prosthetic models based on GAN/VAE.
- **PreviewHandler:** Renders 2D/3D visual previews of the prosthetic.
- **ExportService:** Converts models to printable formats (STL/OBJ) and enables download.
- **AuditLogger:** Logs user actions for compliance and traceability.

5.3.2 Activity Diagram

The activity diagram depicts the sequential workflow of the 3D prosthetic generation platform. It outlines the end-to-end process from uploading medical scans to downloading the final 3D printable prosthetic model.

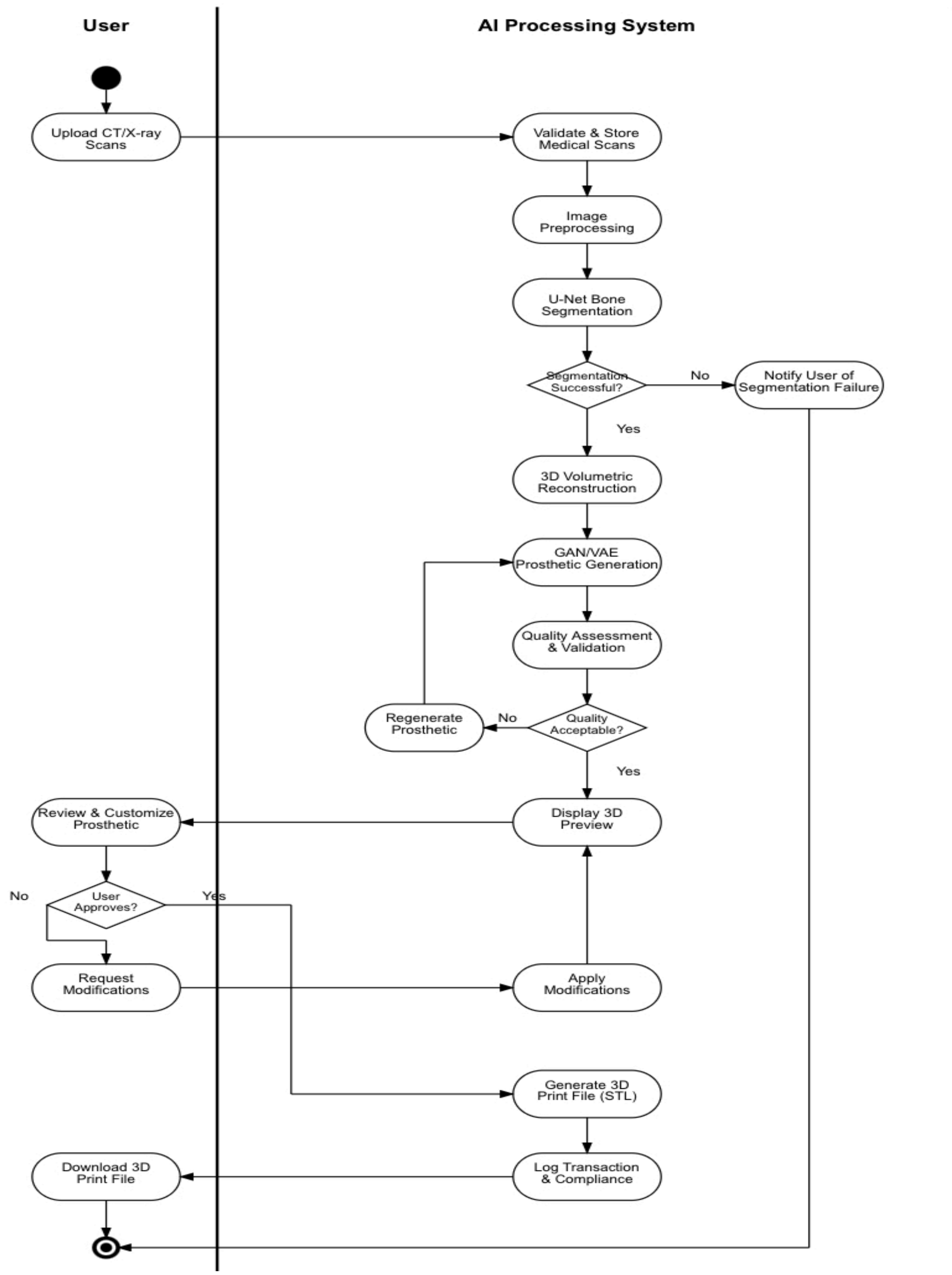

Figure 5.3.2 – Activity Diagram of System Design

- User uploads CT/X-ray scans via the frontend.
- The system checks and saves the scans in a secure backend.
- Image preprocessing is carried out (e.g., noise reduction, resizing).
- Bone segmentation is accomplished with a U-Net model.
- If segmentation fails, notification to the user is sent.
- Successful segmentation results in 3D volumetric reconstruction.
- Prosthetic generation is achieved with GAN/VAE models.
- Generated prosthetic is subjected to quality inspection:
- If poor quality, the system initiates regeneration.
- A 3D preview is presented for inspection.
- The user might accept the prosthetic or request adjustments.
- If adjusted, the system implements updates and rebuilds the model.
- The 3D print file (STL) is created once approved.
- Transaction and compliance logs are maintained.
- Lastly, the user downloads the 3D file to print.

5.3.3 Use Case Diagram

The use case diagram depicts the interaction between different actors (users) and the system throughout the process of generating 3D prosthetics. It defines how patients, surgeons, admins, and the system itself are involved in the different phases of the workflow.

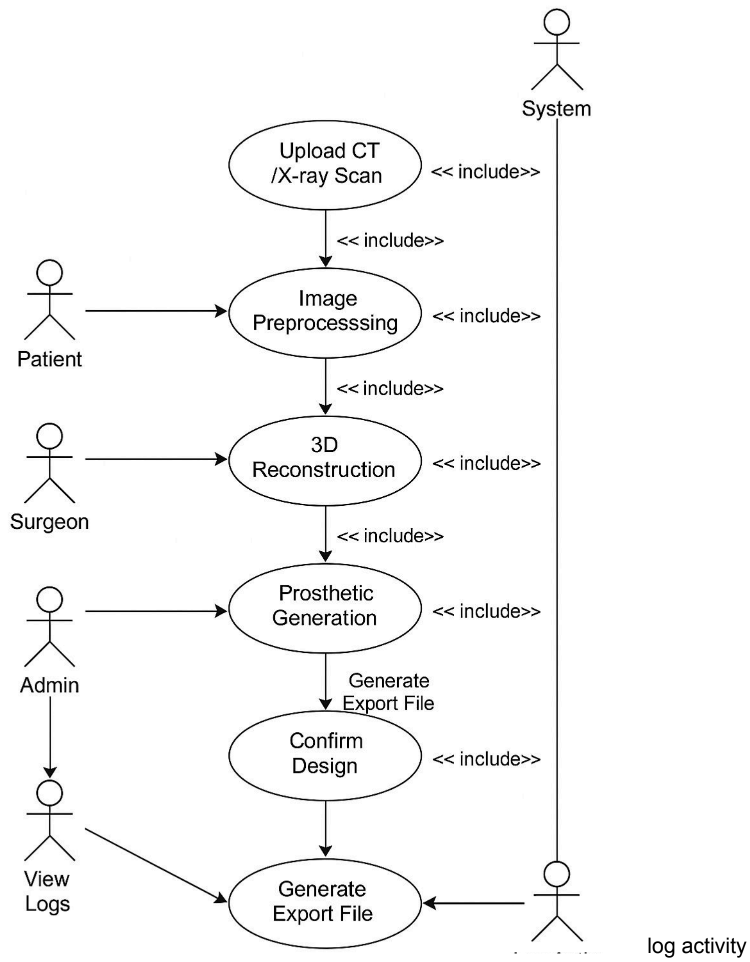

Figure 5.3.3 – Use Case Diagram of System Design

Actors Involved:

- **Patient**:Triggers the upload of the scan and preprocessing.

- **Surgeon**: Participates in 3D reconstruction and prosthetic customization.
- **Admin**:Manages prosthetic generation and confirmation.
- **View Logs**: A role for viewing system activity logs.

- **Log Activity**:Defines the system's logging facilities.
- **System**: Handles internally tasks such as uploading scans and coordinating process.

Use Cases:

- **Upload CT/X-ray Scan**: Triggered by the system resulting in image preprocessing.

- **Image Preprocessing**: Triggered by the patient to sanitize and normalize scans.

- **3D Reconstruction**:Done by the system under surgeon supervision.

- **Prosthetic Generation**:AI models create a personalized prosthetic.

- **Confirm Design**: Surgeon or admin verifies the design.

- **Generate Export File**:Final model to be printed is ready.

- **View Logs**:Admin or log viewer verifies system history.

CONCLUSION

The project is an important milestone in the evolution of orthopedic surgery through incorporation of AI in 3D printing technology. Uniform templates and manual processes make traditional prosthetic design prone to failing to satisfy personalized specifications of patients. With the use of AI and sophisticated manufacturing processes, the system bridges the gap between the current orthopedic treatment and expanding needs for customized healthcare solutions. It has a dynamic nature that increases the efficiency and precision of prosthetic design and makes it compatible with modern healthcare goals of patient-specific treatment.

The basis of this system is the transformation of 2D medical imaging data, i.e., X-ray and CT scans, into highly precise 3D anatomical models. This has the advantage of enabling surgeons to better match complex anatomical structures, with the result being the creation of prosthetics that are customized to patients. Thus, prosthetics are closer matches, enhance biomechanical compatibility, and significantly increase patient comfort following surgery. Customizing implants according to the anatomy of the individual patient also assists in reducing postoperative complications, with the advantage of shorter recovery times and greater long-term performance.

The project further encompasses AI-driven image segmentation, real-time support in intraoperative, and 3D immersive visualization functionalities, providing accurate and adaptive solutions during surgery. Dynamic visual feedback is provided to surgeons by Virtual Reality (VR) and Augmented Reality (AR) systems which will enable them to adjust prosthetic insertion in real-time. This integration enhances the accuracy of surgery as well as minimizes operating time and reduces implant malalignment risks. The integration of the technologies makes the surgery experience a more efficient, better-informed, and more interactive process, raising the bar for orthopedic quality care.

In the future, the project plans to expand its capability with predictive modeling of surgical outcomes. Surgeons will also be able to simulate other methods of surgery and forms of prosthetics and select the most suitable approach for each patient before the procedure through predictive analytics. These additions will not only increase rates of successful surgery, but also encompass the advantages of personalized medicine accessible to more people, simplifying complicated procedures into safer and faster ones.

In brief, the project epitomizes the intertwined relationship between artificial intelligence, medical imaging, and 3D printing in revolutionizing orthopedic prosthetics. By means of a fully integrated, green, patient-focused platform, it opens doors to the future of personalized orthopedic care. With the advancements in predictive analysis and robotics integration in the future, its reach only goes on to grow further, making this technology the foundation for next-generation practice in healthcare

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