UDK 004.356:616.718.4 ISSN 1580-2949
Original scientific article/Izvirni znanstveni članek MTAEC9, 57(3)283(2023)

BIO-PRINTING OF FEMUR MODEL: A BONE SUBSTITUTE FOR BIOMEDICAL RESEARCH

BIOTISK MODELA STEGNA: KOSTNI NADOMESTEK ZA BIOMEDICINSKE RAZISKAVE

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Prejem rokopisa – received: 2023-03-21; sprejem za objavo – accepted for publication: 2023-04-25

doi:10.17222/mit.2023.831

This paper deals with the development of a medical support model that can be used as a prototype to study the anatomy of the femur and for biomechanical research experimentation related to bone plates. CT scan data of the femur bone are converted into a 3D model using MIMICS software and imported into a finite-element model for analysis. The materials selected for the fabrication of the femur model were PEEK and CF PEEK (infused with chopped carbon fibre). The femur bone model was analysed using ANSYS® WORKBENCH® 2021 R2 with different material properties. By conducting a subsequent FE analysis, the optimal material was finally arrived at. Using 3D-printing technology, the 3D model of the femur was fabricated by using a material spool with better properties suited for the femur bone. The FE results were compared with the experimental results of the fabricated femur model and the results of the CF PEEK bone model closely matched the properties of real human femur, and it can be used as a femur bone substitute for biomechanical investigations of bone plates instead of using a real femur.

Keywords: Femur bone, 3D printing, FE analysis, PEEK, ANSYS

V članku je opisan razvoj modela medicinske podpore. Uporabi se ga lahko kot prototip za študij anatomije stegna in eksperimentalne biomedicinske raziskave, ki se nanašajo na kostne ploščice. Podatke iz posnetkov računalniške tomografije (CT)stegenske kosti so pretvorili v model 3D z uporabo programskega orodja MIMICS in ga nato uvozili v programsko orodje na osnovi metode končnih elementov (MKE), s pomočjo katerega so izvedli končno analizo. Za izdelavo modela stegna je bil izbran polietereterketon (PEEK)in PEEK z vlitimi nasekanimi ogljikovimi vlakni. Model kosti stegna so analizirali s programskim orodjem ANSYS® WORKBENCH® 2021 R2 z uporabo podatkovnih baz za lastnosti različnih materialov. Z nadaljnjo analizo MKE so določili optimalni material. Na osnovi analiz so izdelali modelno stegensko kost iz najprimernejšega materiala. Rezultate analize MKE so primerjali z eksperimentalnimi rezultati izdelanega modela stegna. Ugotovili so, da se model kosti izdelane iz materiala CF PEEK dobro ujema z lastnostmi realnega človeškega stegnain se ga zato lahko tudi uporabi kot nadomestek za biomehanske raziskave kostnih ploščic.

Ključne besede: stegenska kost, 3D tisk, o metoda končnih elementov, polietereterketon ,programsko orodje ANSYS

1 INTRODUCTION

Bones are hard tissues that make up the main part of human vertebrates. Bones protect different parts of the body, support loads, produce red blood cells and white blood cells, store minerals, and provide body structure and support to enable movement.[1,2] The femur is the largest bone in the body and is present in the thigh. Different kinds of trauma can damage the femur, causing it to fracture into two or more pieces. This might happen to the part of the femur head, the femur shaft, or the condylar part of the femur. In certain types of femur fractures, even though the femur has broken, its pieces would still line up correctly. In other types of fractures, the injury moves the bone fragments[3] out of position.

Rapid Prototyping (RP) is a scientific advance that creates models out of 3D software systems (CAD). Unlike the subtractive method, where material is removed to fabricate the product, 3D printing (3DP) relies on an additive-level correlation method that adds material layer by layer to the substrate to build a complete model. Since it takes a long time to make models, molds, and prototypes in the production field, various complicated processes are used to reduce the production time. The industry has initiated 3DP victimisation technology to provide exquisite models, molds, and prototypes.[4] In the subtractive method, tool movements are planned for material removal from the workpiece to achieve the specified form. Compared to subtractive methods like turning and machining, AM technology has the greatest capability to induce complicated geometries like anatomical structures. RP provides cost-effective models of the styles that will be used to understand the merchandise before the fabrication process of high-priced prototypes. RP techniques include stereolithography (SLA), selective optical maser sintering (SLS), fused-deposition modeling (FDM), and laminated object manufacturing (LOM).[5] The FDM technique is preferred for the current work, as mostly strong polymers can replicate the femur bone and the easy availability.

So far, the most widely used polymer filaments are Acrylonitrile Butadiene Styrene (ABS) and polylactic

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acid (PLA).[6] PLA filaments have a better prospect than ABS because they are perishable, bio-absorbable, and renewable thermoplastic polyesters with great mechanical strength and methodability.[7,8] Polycarbonate is also widely used in 3D printing due to its good strength and stiffness properties.[9,10] PEEK materials are now widely used in a variety of surgical and medical fields. PEEK is biomechanically similar to that of human bone, and it is becoming more useful and provides more accurate and stable results.[11,12] Lately, carbon-fiber-reinforced 3D-printing filaments have been introduced into the biomedical field as the carbon fiber provides an increase in strength and mechanical properties of the filament.[13] Spinal cages, bone-fixation screws, and cardiac and neurological leads have all used carbon-fiber-reinforced PEEK in the past. Carbon-fiber-reinforced PEEK has recently been used in orthopedic implants and it is ideal for articulating implants, such as knee and hip replacements and bone plates.[14]

3D printing is a perfect technology for manufacturing implants and medical devices. The major reasons are low-cost additive manufacturing and that the medical implant producers have great independence in designing new implants and prototypes, allowing them to customise new medical implants based on the market's needs in a much shorter time. Medical 3D printing was once imagined to be a dream project. But time and investment brought it to reality. Today, 3D printing represents a huge specific implant, enabling the opportunity for pharmaceutical or healthcare companies to help create more rapid production of medical implants and change the way doctors and surgeons plan procedures.[15,16]

Femur CT scan data referred by a physician is used for the femur modeling. The finite-element analysis of the femur is carried out using thr material test data results of the 3D-printing filament. Despite the abundance of research in 3D modeling and finite-element simulations of the femur, this paper presents a new approach to the 3D printing of femur models and provides ample suggestions for bone-plate research. There is a lot of research going on right now in the field of orthopedic implants. There are many computerized methods for analyzing the implants, but the experimental analysis needs real people or animal specimens. The 3D-printed femur bone provided in this can be used to experiment with the bone plates.[17,18]

This present work is implemented in the following four phases.

- Phase 1: 3D Modelling of Femur Bone using CT scan data via. MIMICS Software and SOLIDWORKS®2020 software.
- Phase 2: Finite-element modelling and simulation of femur bone.
- Phase 3: 3D printing of femur-bone model using CF PEEK.
- Phase 4: Experimentation on femur-bone model to validate the results

2 MATERIALS AND METHODS

The main objective of the present paper is to fabricate a femur-bone model with the nearest similar property of the human femur. CT scan, MIMICS Software, SOLIDWORKS® 2020, ANSYS WORKBENCH® 2021 R2 and CURA slicing software are used during the course of this work.

2.1 Materials

Carbon-fiber-reinforced 3D filaments are being used in the work as they possess better strength when compared to the normal filaments. The materials[19] that are best suited for 3D printing and have better property resemblance to human bone, i.e., PEEK and CF PEEK (reinforced with chopped carbon fibers), are preferred here. The filaments were purchased from the filament manufacturer 3DXTECH Additive Manufacturing and the technical data sheet of the material characteristics was also provided by the filament manufacturers.

3D printing was chosen as the femur structure was very complex and difficult to fabricate using the conventional manufacturing processes. **Table 1** indicates the material properties of the materials in the present study. The material properties were collected from the filament manufacturer.

2.2 Rapid prototyping

Rapid prototyping is a set of techniques used to rapidly manufacture scale models of physical parts or assemblies using three-dimensional computer-aided design

Table 1: Material Characteristics

Properties	Standard	Carbon Fiber PEEK	PEEK
Density (g/cc)	ISO 1183	1.39	1.32
Tensile Strength (MPa)	ISO 527	126	105
Tensile Modulus (MPa)	ISO 527	10,100	3980
Tensile Elongation (%)	ISO 527	1.9	7
Flexural Strength (MPa)	ISO 178	145	141
Flexural Modulus (MPa)	ISO 178	11,200	2850
Glass Transition Temperature (Tg) (°C)	DSC	143	143
Deflection Temperature at 0.45 MPa (66psi) (°C)	ISO 75	305	140

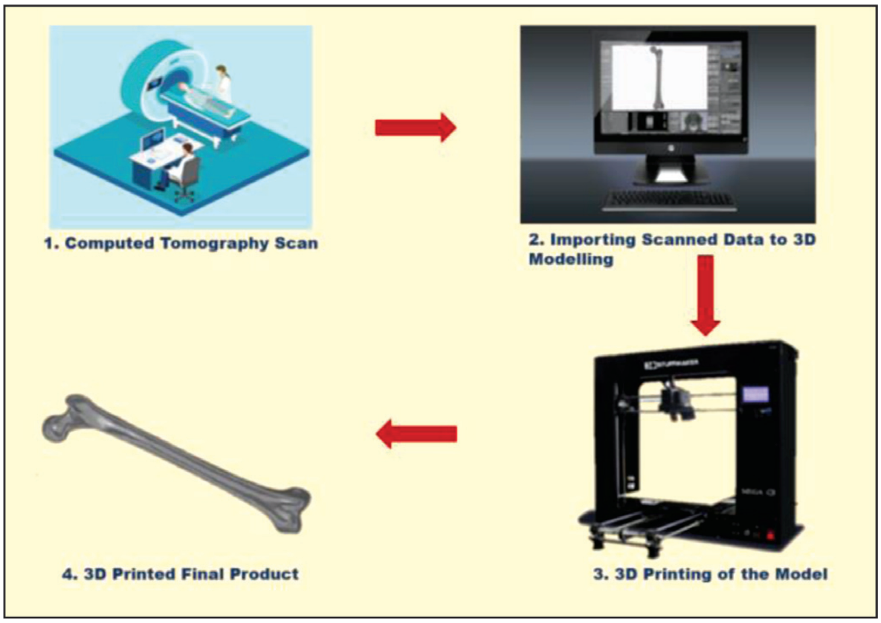

Figure 1: Schematic of the methodology

(CAD) data. The construction of parts or components is usually done with 3D printing or additive layer fabrication technology. **Figure 1** represents the entire methodology incorporated into the present study for the 3D printing of the femur-bone model.

2.3 3D modeling using CT scan data

The CT scan data of the femur were used to create a 3D model of the femur bone. A CT scan using CT equipment was performed on a 33-year-old male. The knee in the neutral position was scanned where the least tension or pressure on tendons, muscles, and bones was felt. The scans were performed with a slice distance of 2 mm and were made up of 1816 cross-sectional cuts. The images were exported in DICOM format from the CT equipment. The DICOM images from the CT scan were then processed with the Materialize Interactive Medical Image Control System (Mimics) 10.01 software to generate the primary 3D model using the density-segmentation techniques. The primary 3D models that were generated were then processed and assembled as geometrical data files. Finally, the model was saved as a .stl file. Loads, boundary conditions, material constitutive models, kinematic constraints, and mesh discretization processes were then used to prepare the model for analysis.[20–22]

The SOLIDWORKS® 2020 software package was used to smooth the 3D model. **Figure 2** shows the smoothened bone model in the SOLIDWORKS® 2020 environment after being imported from MIMICS software and the cross-sectioned model of the femur bone to view the cavity in the femur bone.

CURA slicing software was used to slice the model to enable 3D-printing capabilities. Cura software converts digital 3D models into printing instructions for a given 3D printer to build an object.

2.4 Finite-Element Analysis of Femur-Bone Model

The 3D model of the femur bone was imported into the FE model and the entire finite-element computations[23] were made using the ANSYS WORKBENCH® 2021 R2 software package.

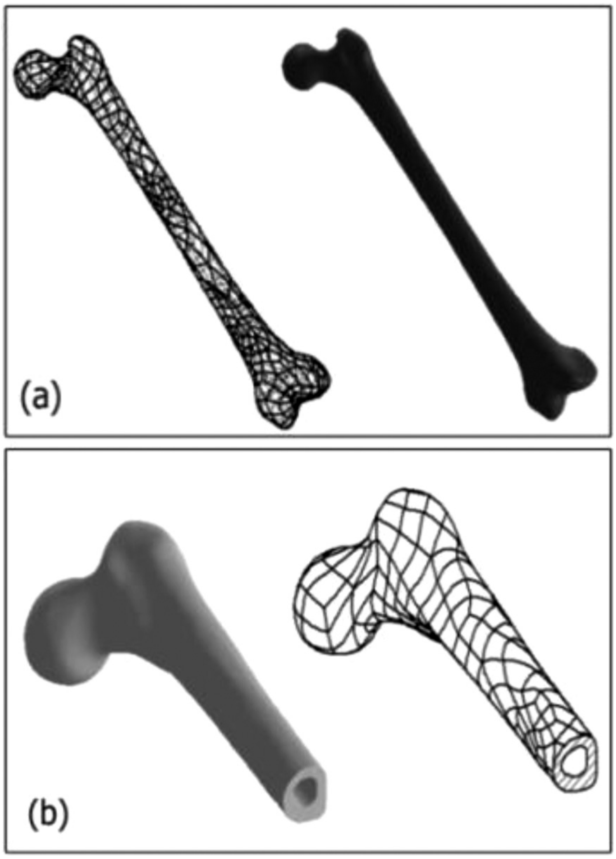

Figure 2: a) 3D model and b) cross-sectioned model of femur

2.4.1 Preprocessing

In the preprocessing stage, the 3D modeling of the femur bone model, assigning material models, material properties, meshing, applying appropriate loads and boundary conditions were carried out in chronological order. Separate finite-element models are developed with different material models and material properties, i.e., femur bone,[2] PEEK and CF PEEK (**Table 1**). Different materials were taken into account in the FE model for the purpose of analyzing a better material for the femur bone.

The femur bone modeled using SOLIDWORKS®2020 software was imported into ANSYS WORKBENCH® 2021 R2. The model was assumed to be isometric for the analysis[24]. The material properties were imported to ANSYS from the data available in **Table 1**. A fine mesh was considered for the femur-bone analysis with 8-node tetrahedral elements. A mesh-convergence study was conducted to confirm that that FEA model converged to a solution.[25] The mesh convergence was done by increasing the number of elements from 12000 to 4716336. The maximum deformation results were compared for the mesh convergence. The maximum deformation results were almost constant for all the material properties after the fine meshing. The mesh size that was selected for this work was 5 mm and the numbers of elements was 206,216 (**Figure 3a**).

2.4.2 Solving

After completing the meshing, boundary conditions were applied to the femur similar to the loads acting on the human femur while standing and walking. The lower end of the femur model was distally fixed and the load was given from the femoral head. ISO 7206-4:2010 was used for the loading conditions of the femur model. ISO 7206-4:2010 specifies the test parameters and the requirements of the endurance limit of stemmed femoral components tested experimentally.[26] The boundary conditions (**Figure 3b**) are considered by fixing the lower end of the femur model and a compressive load is given from the top. The load value as per ISO standard is 2300 N, and it is applied from the top of the femoral head and the load type is a compression load. A static structural analysis was carried out in three parts: femur bone,[2] PEEK, and CF PEEK.

2.4.3 Post Processing

The post-processing capabilities of ANSYS® were utilized for generating the equivalent stress plot and total deformation plot for the femur bone with various material properties. A detailed post-processing result was generated in the FE analysis. **Figure 4** represents the finite-element method results of the equivalent stress, equivalent strain and total deformation of femur bone model using the femur bone property, PEEK and CF PEEK material properties, respectively. From the results it is inferred that CF PEEK had good compression properties as per the ISO 7206-4:2010 standard FE analysis, and moreover the compression property closely matched

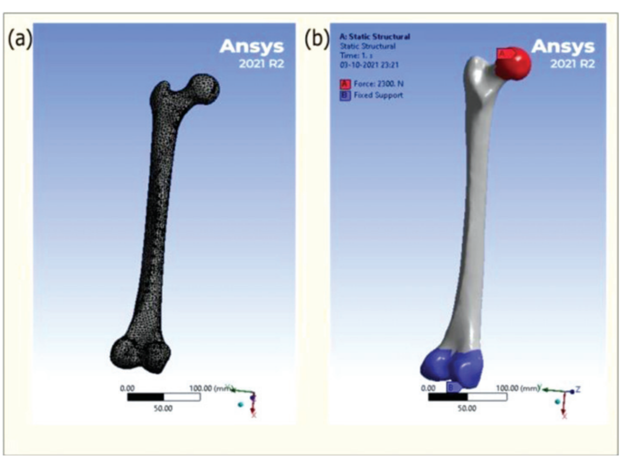

Figure 3: Processing of femur model in ANSYS WORKBENCH® 2021 R2

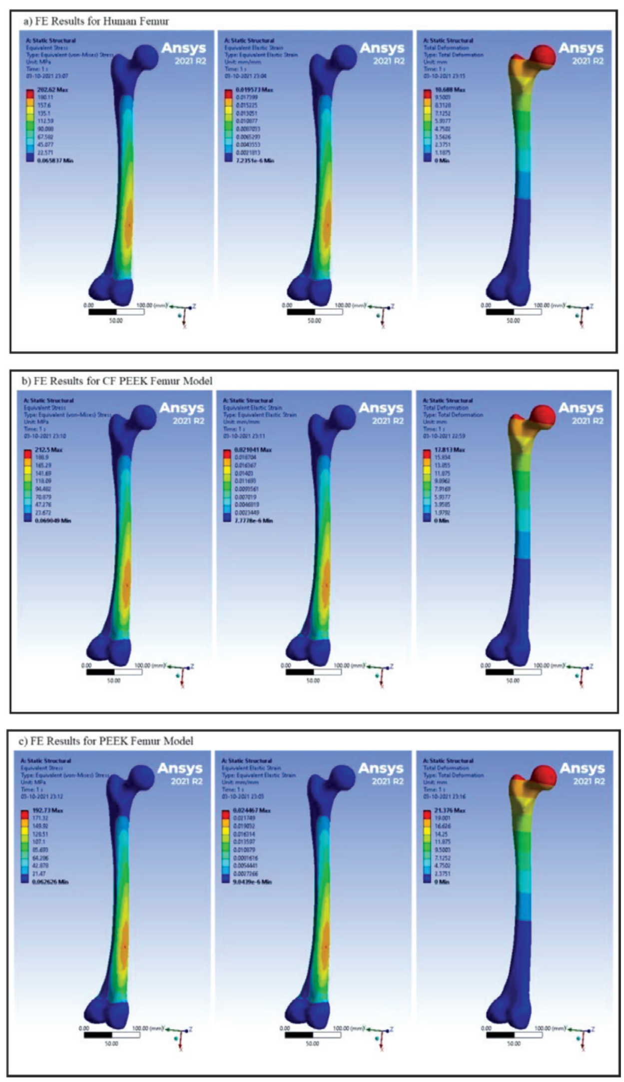

Figure 4: Equivalent stress, equivalent strain and total deformation of femur model with different material properties

to that of the human femur. So, a CF PEEK filament was used to 3D print the femur-bone model.

2.5 3D Printing

The femur model was 3D printed using a Pratham 5.0 3D printer and 3DXTECH CF PEEK filament spool was used for the fabrication based on the FEM results. The Pratham 5.0 3D printer was used because of its larger bed size of (500 × 500 × 500) mm. The Fusion Deposition Modelling method is used in the 3D printer to fabricate the bone model. FDM[27] is a method of 3D printing in which layers of materials blend together in a pattern to fabricate an object. Using the FDM technique the layers of CF PEEK were deposited layer by layer from the model obtained using the CURA® software (Version: Cura LulzBot Edition v3). The time taken for the fabrication of femur model with 100 % fill density was 12 h. The 3D printer has a single extruder, 100 µm to 500 µm / 0.1 mm to 0.5 mm layer resolution, 400 micron / 0.4 mm supported extruder nozzle diameter, 572 °F / 300 °C Extruder nozzle temperature and 248 °F / 120 °C build-plate temperature. The bonding between the pre-laid layer and the upcoming layer was good because the temperature held the next layer and the previous layer in a rigid form so that high strength and the mechanical properties required could arrive. This made the fabricated carbon-fibre PEEK 3D model stand firm without any flexible deformation. A CF PEEK spool was used as a fabrication material.

2.6 Compression Test on Femur Model

A servo computerized universal testing machine was used for the compression test on the 3D-printed femur bone model. The load capacity of the machine is 100–2000 kN and the displacement resolution is 0.01 mm. The results were obtained from the data-acquisition system provided with the machine. The experimental test up as per ISO 7206-4:2010 with the vertical load applied to the femur-bone model from the top of the femoral head (**Figure 5**).

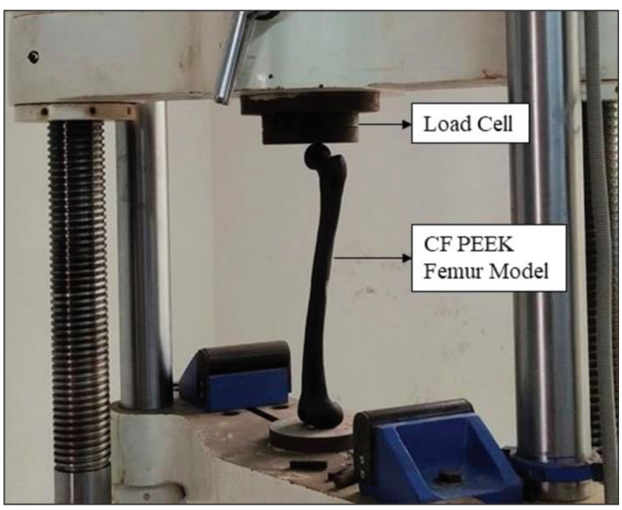

Figure 5: Compression test on 3D-printed CF Peek femur model

3 RESULTS AND DISCUSSION

3.1. FEA Results

The finite-element method results of the equivalent stress, equivalent strain and total deformation of the femur bone model using the femur-bone property, PEEK and CF PEEK material properties for ISO 7206-4:2010 loading conditions. The maximum total deformation of the femur-bone model with the properties of a real femur carries a value of 10.68 mm, which is smaller, followed by the CF PEEK material with 17.813 mm and PEEK material with 21.376 mm. The lowest deformation of the material yields a higher strength to the material. In this regard, it is numerically investigated that CF PEEK femur model is better than the other counterparts. The maximum equivalent stress for the femur-bone model with the properties of a real femur carries an equivalent stress of 202.62 MPa, CF PEEK with a value 212.252 MPa and PEEK with 192.73 MPa. From these predictions it is inferred that the CF PEEK femur-bone model has a better strength than the PEEK model. The maximum equivalent strain values of the femur-bone model with properties of real femur, CF PEEK, PEEK materials are (0.019573, 0.021041 and 0.024467) mm/mm. From these strain values it is evident that the strain values of a. real human femur and the femur model made of CF PEEK match closely when compared to that of PEEK material, making CF PEEK a better material for the fabrication of fthe emur model with the properties close to that of a human femur.

Table 2 shows the comparison of maximum equivalent stress, maximum equivalent strain and maximum total deformation of the materials that were used in the present FEA study.

Table 2: Finite-element snalysis results

Femur model	Maximum equivalent stress (MPa)	Maximum equivalent strain (mm/mm)	Total deformation (mm)
Human Femur Bone	202.62	0.019573	10.688
CF PEEK	212.5	0.021041	17.813
PEEK	192.73	0.024467	21.376

3.2 3D Printed Femur-Bone Model

From the finite-element results, the femur bone was fabricated using CF PEEK filament material by 3D printing technology.[28,29] From the visual inspection, the fabricated femur-bone model had good strength and stiffness, with a considerable degree of elasticity. **Figure 6** shows the 3D-printed femur model using CF PEEK material and a composite bone plate that is to be screwed and biomechanically tested.

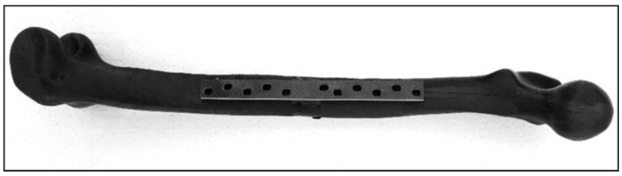

Figure 6: 3D-printed CF PEEK femur model with bone plate to be fixed for biomechanical testing

3.3 Compression-Test Results

Compression tests were conducted on the fabricated CF PEEK femur-bone model (**Figure 6**), similar to the FE method. The femur model showed an initial linear elastic response, followed by some non-linearity and showed signs of fracture at a strain of 1.9 percent, exhibiting a sudden drop in load. The CF PEEK femur model fails at a compressive stress of 208.58 MPa and a strain of 1.99 %. Failure occurred in the middle portion of the femur model, at the point of contact with the top roller in the case of intact bones. The compression strength of the human femur bone is 205 MPa. The FEM result obtained for the results of the maximum compressive stress of the femur bone was 202.62 MPa (**Figure 5a**). The result deviation is only 1.6 %. This proves the accuracy of the FEM results. The FEM results for the maximum stress value of the CF PEEK femur model was 212.5 MPa and the compressive strength obtained from the experimental value was 208.58 MPa. These results closely match the compression strength of the real human femur, and thus this CF PEEK model can be used as prototype model to study the anatomy of the human femur and can also be used by researchers to experiment on bone plates made of advanced materials. **Table 3** shows the validation of the FEM results and the experimental results with the strength of real femur.

Table 3: Comparison of FEM and Experimental results with Human Femur

Type	Compressive stress (MPa)
Real human femur[30]	205
FEM result for human femur	202.62
FEM result for 3D-printed CF PEEK femur model	212.5
Experimental result for 3D-printed CF PEEK femur model	208.58

4 CONCLUSIONS

The following conclusions are drawn from the present study:

- The materials selected for the present study were PEEK and CF PEEK. The materials were selected based on the feasibility of 3D-printing features and their current applications for orthopedic implants. In recent PEEK-made implants are largely used due to their property resemblance with human bone.
- From the finite-element analysis viewpoint, CF PEEK was found to be the better choice among the other counterparts. CF PEEK femur-bone model was fabricated using 3D printing and experimented by compression testing as per the ISO 7206-4:2010 standard to find its strength. Both the FE results and the experimental closely matched to the compressive strength of the real human femur.
- Though this CF PEEK 3D-printed model of the femur cannot replicate the exact properties of the human femur, it has better properties when compared to its other materials.
- The 3D-printed CF PEEK femur model provided an ample suggestion for experimenting with the properties of bone-plate research, since it is impossible for researchers to experiment using a real femur. It can also be used as a pilot model to study the femur bone, but this model is strictly for external usage only.
- From the newly developed femur model, the bone plates can be experimented on for mechanical strength analysis, without regard to humans or animal ethics.

Acknowledgment

The authors of this paper would like to thank Dr. M. Sekar, Principal, AAA College of Engineering and Technology, Dr. P. Nagaraj, Senior Professor & Head, Department of Mechanical Engineering of Mepco Schlenk Engineering College, Dr. P. Seenikannan, Dean and Professor & Head, Department of Mechanical Engineering, AAA College of Engineering and Technology, for their continuous support in writing this research article. The authors express their sincere gratitude to Dr. S. Ambalatharasan, MBBS, D. Ortho, DNB, Bone and Joint clinic, Sivakasi for his consistent guidance in this research paper.

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