Design of Hydroxyapatite-Polyetheretherketone Fixation Plates for Diaphysis Femur Fracture

Abhishek Soni, Bhagat Singh

***Abstract*—**In this study, scanned data of a damaged femur diaphysis are used to generate three dimensional model of the bone. Further, customized implant of Hydroxyapatite-Polyetheretherketone (HA-PEEK) material for this damaged bone is prepared using CAD modeling. Damaged bone and implant have been assembled to prepare the intact bone. This assembled model has been analyzed to evaluate the stresses and deformation developed during the static loading. It has been observed that these stresses and deformation are very less thus imply that the proposed method of preparing implant is appropriate.

***Keywords*—**Customized implant, deformation, femur diaphysis, stress.

I. Introduction

ACCIDENTS with heavy impacts result in fatal fracture and high-energy trauma in femur diaphysis. Mostly, preferred treatment of femur diaphysis fracture (FDF) is Intramedullary (IM) nailing [1]. Though the success rate of this treatment is high, still there are certain some possibilities of complications such as: malunion, non-union, leg length discrepancy, infection and other potential complications [2].

FDF non-union after primary nail treatment has been observed in 0.9% to 7.5% of cases [3]. Major reasons of non-union are diabetes, obesity, unstable fixation and infection etc. In the present work, study has been focused on unstable fixation. For providing stable fixation, anatomic reduction must be achieved and fixation must be able to resist the high shear forces across the fracture with motion, weight-bearing and muscle tone. Higher shear forces develop stress shielding across the fixation screw and intake bone. It also increases the risk of unstable fixation due to loosening of the screws [4].

In last few decades, researchers have proposed a methodology consisting of a framework of design and analysis of a customized counter fit implant for preventing shear force and stress shielding with a constant compression force over fractured region [5]. Customized counter fit implant has been designed with the help of Reverse Engineering (RE) technique. There are various stages in RE such as: scanning of physical dimensions of an object, processing of scanned data, utilizing the data to create a 3D model of the object and finally this model is physically fabricated using additive manufacturing technique.

Researchers have developed various physical dimensional scanning techniques. These techniques are broadly categorized as contact and non-contact type. In the field of medical applications generally non-contact type of imaging techniques are employed such as: computed tomography (CT), magnetic resonance imaging (MRI), ultrasonography (USG) [6]. CT scan is generally performed for hard tissues like bone [7]. This CT scan data are available in DICOM file format. Many researchers have invoked RE technique for developing customized counter fit implants, prosthetics and medical models for different uses [8].

In this study, we have used CT scan data of fractured femur bone to develop and analyze customized orthopedic implant. Limitation of using traditional orthopedic implant is that it requires modifications (bending and shaping) for better counter fit on the fractured/damaged region of the bone depending on the anatomy of a specific patient. Aforementioned implant modification can be done only after incision and observing the fractured region, thereby increasing surgery time as well as the risk of infection [9]. Moreover, this tailoring and alteration in the shape of implants affects its mechanical strength and ultimately resulting in unstable fixation [10]. If the intactness of the implant and damaged bone is not perfect then it may lead to failures and pain [4]. These limitations have motivated the researchers to design a patient-specific counter fit implants.

Proposed work is to simulate the behavior of bone and customized implant system under physiological loading conditions. Moreover, it is a non-invasive technique for analysis of stress distribution and deformation.

II. Methodology

Initially, a patient-specific CT scan data of fractured femur bone in Digital Imaging and Communications in Medicine (DICOM) file format are obtained. The data are invoked to create a 3D geometric model using RE approach in Materialise Mimics software, which is stored in the form of standard tessellation language (STL) format. Then 3D CAD Model is prepared using the STL model. Thereafter, fracture is reduced digitally and a counter fit implant is designed pertaining to the morphology of the fractured region. Then assembled 3D CAD model of the reduced fracture bone along with the implant is prepared (clinical setup). Finally, in order to ascertain the strength of the implants and intactness of the fractured bone, biomechanical analysis has been performed on the clinical setup.

A. Finite element Model Generation

Initially, the patient's fractured femoral bone has been

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scanned using CT scan technique and stored in DICOM format. DICOM file format is generally used in medical imaging for storing, handling and transmitting anatomical information. Anatomical information stored in DICOM file format comprises of various images taken with reference to three mutually perpendicular planes viz. top view (axial), side view (sagittal) and front view (coronal).

The DICOM file of the fractured femur bone has been imported into medical image processing software Materialise Mimics software for converting the stacks of 2D images into a 3D model. In order to develop 3D CAD model for analysis, the 3D model created using the DICOM file has been saved in STL file format which is universally accepted and almost compatible file format for 3D printing. This STL file may contain some noise and errors like inverted normal, gaps etc. which needs to be identified and accordingly rectified before further proceedings. These identified errors have been rectified and further re-meshing of STL model has been done using MeshLab software. MeshLab is advanced mesh processing software with features of automatic as well as manual filtering, cleaning, editing, rendering and conversion of irregular meshed region. The STL file obtained from Materialise Mimics software has been loaded into MeshLab. Here, it has been checked for errors such as: duplicate facets, unreferenced vertices, null faces, small isolated pieces and non-manifold faces. These errors have been removed and small holes were filled up automatically as presented in Fig. 1.

Fig. 1 Error free model of femoral shaft

After removal of errors in MeshLab software STL model has been imported into SolidWorks 2016 software. In this software 3D CAD model of the fractured femur bone has been created using the STL model as shown in Fig. 2. This 3D CAD model has been studied and further in consultation with an orthopedic surgeon customized implant has been modeled accordingly in SolidWorks 2016 software as shown in Fig. 3. This implant has been designed keeping in mind that it will keep the fractured bone intact and also provide stable support under static physiological loading conditions. Moreover, location of drilled hole in the implant for tightening the screws plays very important role. The location of holes should be neither very near nor very far from the fracture line. However, traditional implants have pre-countered holes and thus positioning of implant along with the screws posed various hindrances. Moreover, traditional implants are available in standard sizes only. So, it has to be tailored before fixing it on the bone. These limitations can be overcome by designing a customized implant.

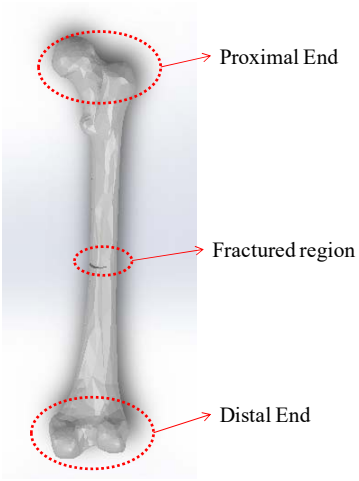

Fig. 2 3D CAD model of the fractured femur bone

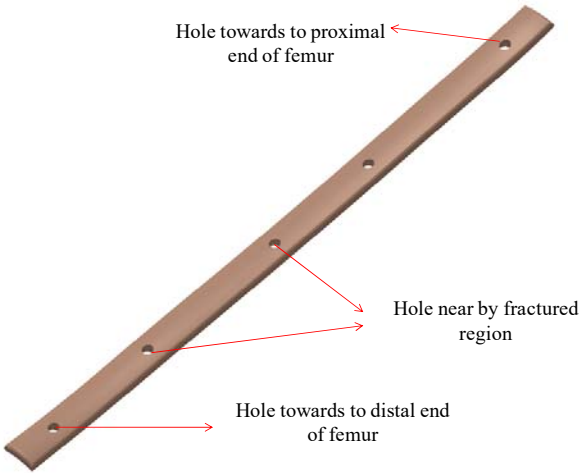

Fig. 3 Customized implant designed for fractured bone

Further, implant screws have been designed in the same software on the basis of bone and implant dimensions. In the present work, five implant screws have been designed for proper fixation on the fractured bone. Finally, clinical setup has been prepared by assembling the fractured bone along with the customized implant and screws in a proper way as shown in Fig. 4.

B. Biomechanical Evaluation Using Finite Element Analysis

Clinical setup has been imported into ANSYS workbench software for biomechanical evaluation. In this work, stresses and deformations developed in the implant and damaged bone have been analyzed considering Von–Mises and Rankine's

(Maximum Principal Stress) stress criteria under static physiological loading condition. Moreover, aforementioned analysis has been done for implant of biocompatible material HA-PEEK. The detailed analysis has been presented in the ensuing text.

Fig. 4 Prepared clinical setup

Mesh Preparation: Meshing is an operation to divide the region of analysis into small size elements for evaluation. In the present work, mesh model for the fractured femur bone has been created using model wizard in ANSYS Workbench 14. Element considered for meshing purpose was tetrahedral. The number of tetrahedral elements and nodes used for the fractured femur diaphysis model were 19,496 and 33,732, respectively.

Boundary Conditions: Boundary conditions considered for finite element analysis of clinical setup are as follows:

a. Distal end of the femur has been fixed considering the human bone to be inflexible
b. A fixed loading condition has been applied on the proximal end of the femur.

Loading Conditions: In the present work, static load analysis has been done. It has been assumed that a person is standing straight and weight of the person is 1000 N. This load is transmitted equally the through pelvic bone at the head of femur. Thus it has been assumed that 500 N load is acting vertically downward on each femur neck of the person. Biomechanical evaluation of clinical setup has been performed for biocompatible material HA-PEEK. Properties of this material have been mentioned in Table I.

TABLE I
IMPLANT MATERIAL PROPERTIES

Material	Young Modulus (GPa)	Ultimate Strength (MPa)	Poisson's Ratio	Density (g/cm^3)
HA-PEEK	6.8	71.46	0.38	1.851

III. RESULTS AND DISCUSSIONS

A. Stress Analysis

Stress analysis has been done considering Von–Mises and Rankine's (Maximum Principal Stress) stress criteria. It has been observed that average Von-Mises stresses developed over the whole region of clinical setup for HA-PEEK was approximately 2.41 MPa as shown in Fig. 5. However, on analyzing the stresses developed in the implant and screws, it has been noted that stress is raised up to 12.06 MPa. This stress was maximum in the screw thread of the nearest screw from the fractured region towards the distal side. This stress is higher in this region because of stress concentration. Moreover, this stress is also developed because of contact pressure between the bone and the screw threads. Similarly, stress distribution has been analyzed considering maximum principal stress criterion for HA-PEEK as shown in Fig. 6. Overall stress distribution in the clinical setup was uniform and about 2.88 MPa. However, stress developed in the screw near the vicinity of fractured region was higher and observed to be 12.38 MPa.

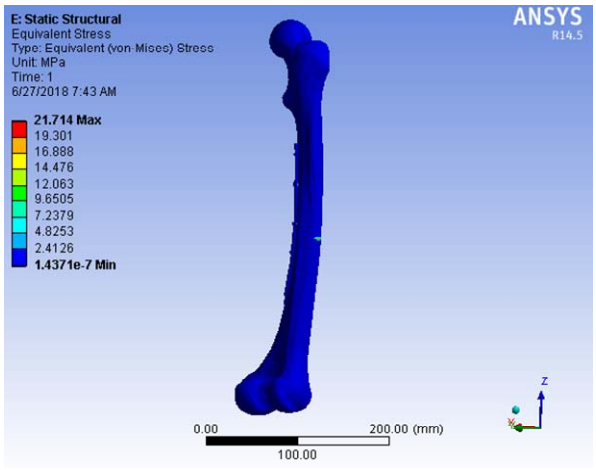

Fig. 5 (a) Von-Mises stress distribution in clinical setup

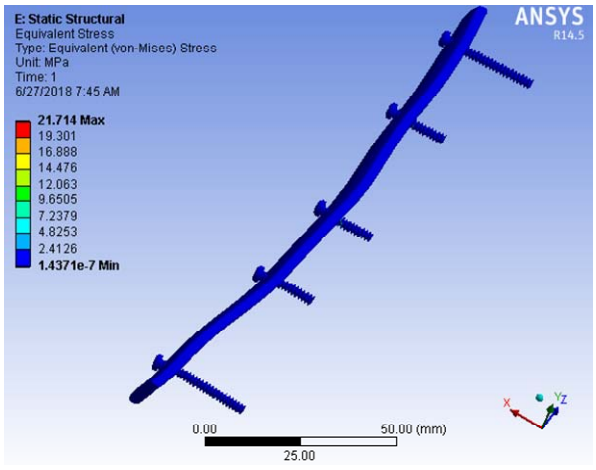

Fig. 5 (b) Von-Mises stress distribution in implant and screws

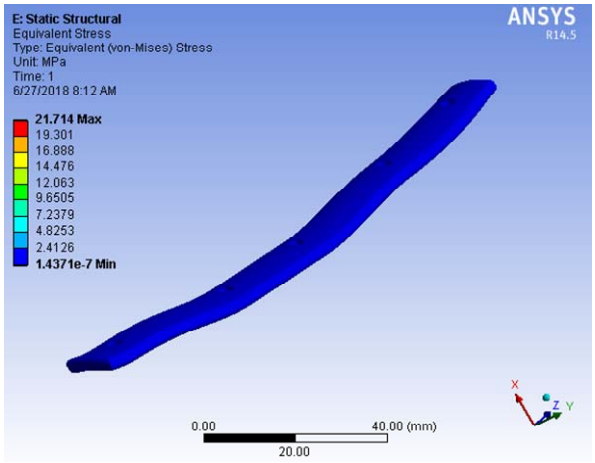

Fig. 5 (c) Von-Mises stress distribution in implant

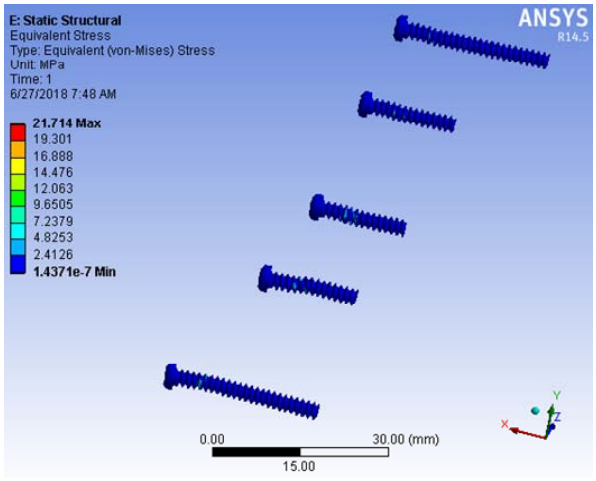

Fig. 5 (d) Von-Mises stress distribution in all screws

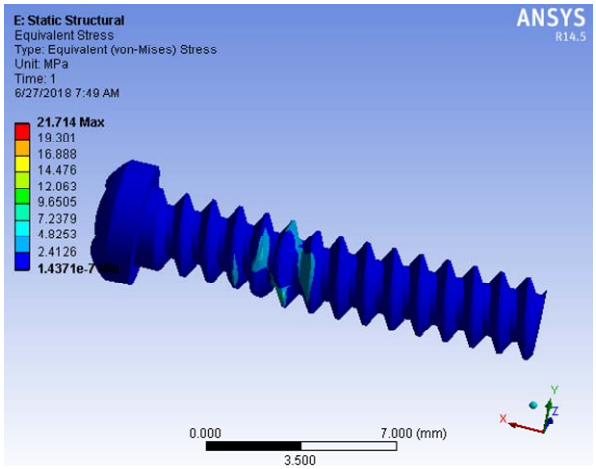

Fig. 5 (e) Von-Mises stress distribution in critical screw

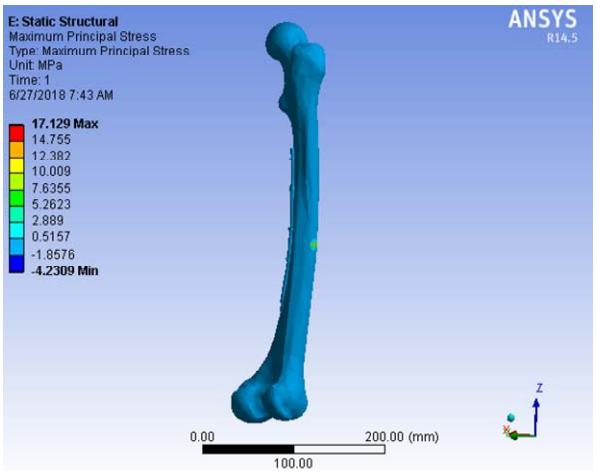

Fig. 6 (a) Maximum principal stress in clinical setup

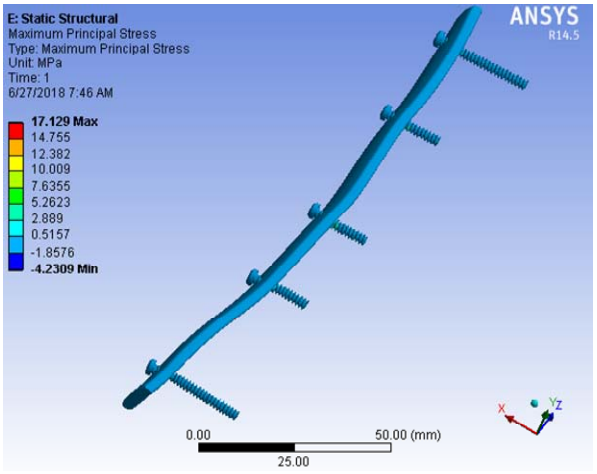

Fig. 6 (b) Maximum principal stress in implant and screws

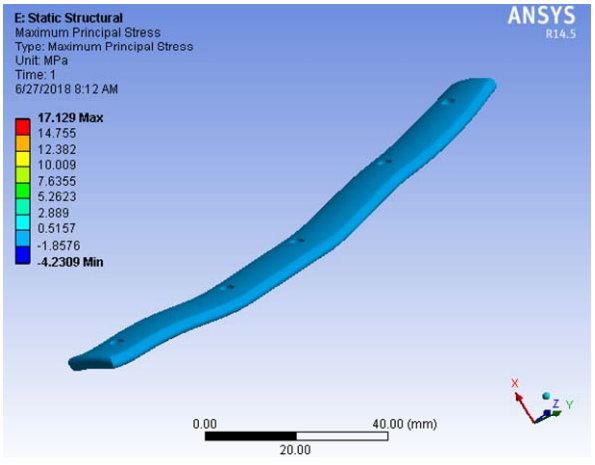

Fig. 6 (c) Maximum principal stress in implant

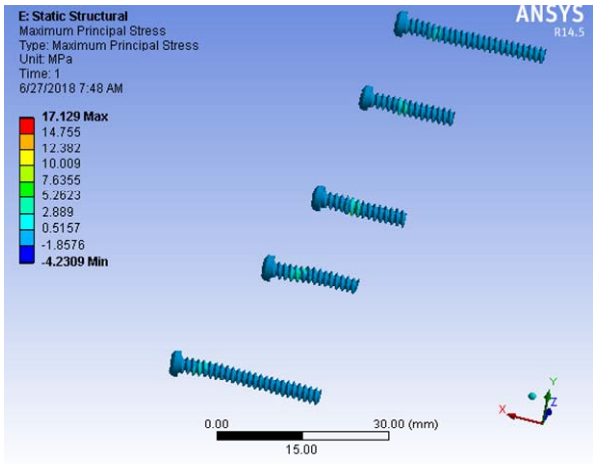

Fig. 6 (d) Maximum principal stress in all screws

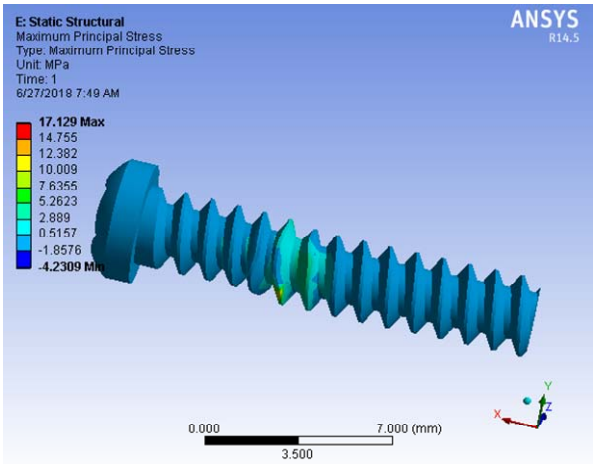

Fig. 6 (e) Maximum principal stress in critical screw

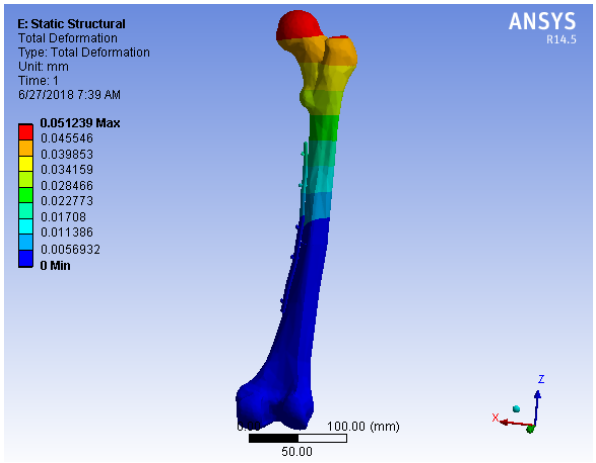

Fig. 7 Total deformation variation in clinical setup

B. Deformation Analysis

Total deformation has been analyzed for biocompatible material HA-PEEK. The variation of deformation on the clinical setup has been presented in Fig. 7. From this figure it is evident that the deformation is higher near the proximal end, where load is applied. Moreover, the proximal region is a spongy bone and so deformation is higher as compared to the rest portion which is comparatively more rigid. However, the maximum deformation observed in HA-PEEK was 0.05124 mm. It is observed that the deformation is within the acceptable range. So, the customized design of the implant for this type of fracture in femur bone is quite apt.

IV. Conclusions

In the present work, a methodology has been suggested to create and analyze a clinical setup of a fractured femur bone considering CT image data. Moreover, in order to provide better fitting and overcome the stress shielding at the fractured region, a customized counter fit fixation plate has been created for the aforementioned clinical setup. HA-PEEK has been considered for the analysis. Further, static stress distribution and deformation analysis of the clinical setup have been performed for the aforementioned material. After analysis, following conclusions have been drawn:

- Stresses and stress shielding developed are found to be appreciably low as compared to its ultimate strength. Deformations are considerable in the aforementioned material. It shows that mechanical properties of implant are satisfactory for stable fixation.
- Assembled fabricated model successfully shows that the implant fits exactly over counter surface of fractured region of bone.
- Created clinical setup can be helpful for pre-operative and intra-operative planning which reduces the surgery time as well as helps in understanding the nature and severity of fracture.
- Proper fixation of designed customized implant will help in reducing the post-surgical failures and residual pain.

Proposed work will serve as a guideline for the medical practitioners to design and analyze suitable implants for the respective fractured bone. Moreover, it will enable the surgeons to select the most suitable material for these implants.

Compliance with Ethical Standards

Conflict of interest: The authors declare that they have no conflict of interest.

Ethical standard statement: This article does not contain any studies with human or animal subjects performed by any of the authors.

Informed consent: For this type of study informed consent is not required.

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