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Study to Establish Machining Route for Metallic Prosthesis through Conventional Route

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ABSTRACT

The hip replacement or hip arthroplasty is an orthopedic surgery in which a damaged or dysfunctional hip joint is surgically replaced with a suitable artificial hip prosthesis. During this surgical procedure, a stem is inserted into the patient’s femur for stability; and the head of the femur is replaced with a ball and socket joint is replaced by an artificial cup. Literature survey reveals that various types of methodologies were used by researchers for the development of the hip prosthesis and while after surgery different complications were arise with the patients like mismatch, aseptic loosening, improper load distribution, and discomfort due to change of morphology of human being. It is present status the availability of specific prosthesis for specific patients are very difficult. Due to the high complexity of customized hip implant results in low production rates. Hence it is understood that there is a requirement of machinablity study for manufacturing of customized hip prosthesis. The one part of study is to concern with the design of different types of hip prosthesis like solid, hollow (with and without internal rib structures) to reduce the effective stiffness and due to the hollowness of prosthesis, stiffness increases which will ultimately results in increase the strain at the proximal femur in comparison to solid femur as well as weight of hip prosthesis is drastically reduced. The machining of hip prosthesis is being carried out by taking the CT scan data of the patient using MIMICS software. The data then analyzed with suitable load in ANSYS after that the CAD model of femoral stem was prepared by using the measured data. The blank size of the prosthesis is first calculated. Then the critical profile machining of top and bottom stem is being carried out using 3-Axis CNC vertical milling machine “Mikron” CNC and the parting operation by using wire cut EDM machine by preparing the necessary programme based on the profile of the prosthesis. However, in this study the machining of hip prosthesis is being carried out through conventional route to stress on economical benefits for low cost manufacturing strategy.

Introduction

The objective was to develop state of art prosthesis for hip / knee and finger and to create state of the art facilities to manufacture and measure. Under this work package the CSIR- CMERI proposed to manufacture the metallic biomedical prosthesis like Hip, Knee & Spinal implant through conventional route, creation of the manufacturing set up, dimensional inspection of prosthesis and report preparation. CSIR-CMERI worked in this area in association with nodal laboratory CSIR-CGCRI and has developed expertise. Selected metallic prosthesis of hip, knee and spinal joint have been developed from CT data, using MIMICS, 3D CAD and FEA packages. Different types of new design of femoral stem were developed, like solid, hollow and hollow with internal ribs. Initially the machining work was carried out with the existing manufacturing facility at CSIR-CMERI. To establish the machining route the preliminary machining of the implants was tried out with Al 6061 materials, considering the criticality of the profile. Finally machining of the implant was carried with Stainless Steel (316L) and Titanium alloy materials (Ti6Al4V). Later on a new CNC Vertical Milling (Model-MCV350) facility was created and a few critical metallic implants were successfully developed. The fabricated prosthesis was then finally put under metrological inspected for dimensional accuracy of the profiles and it was found that the important matching dimensions were well within accepted limit**.** These activities had been communicated to the nodal lab CSIR-CGCRI on regular basis during different task force meetings and the task force gave satisfactory remarks with the progress.

FEA of intact femur bone to find stress and strain pattern:-

- CT data of Hip were processed in MIMICS.
- Suitable loading was imparted in ANSYS.
- Stress and strain of this intact femur bone were found out.

CAD Modeling of Prosthesis (femoral stem):-

CAD model of femoral stem was prepared with 6 different types of geometry

- Solid with collar,
- Solid without collar,
- Hollow with collar
- Hollow without collar
- Hollow with Collar having internal stiffener.
- Hollow without collar having internal stiffener.

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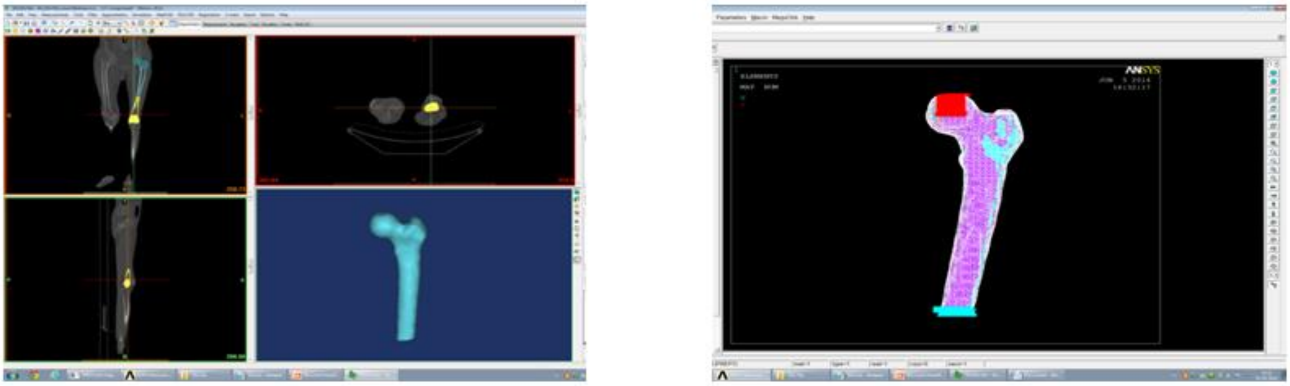
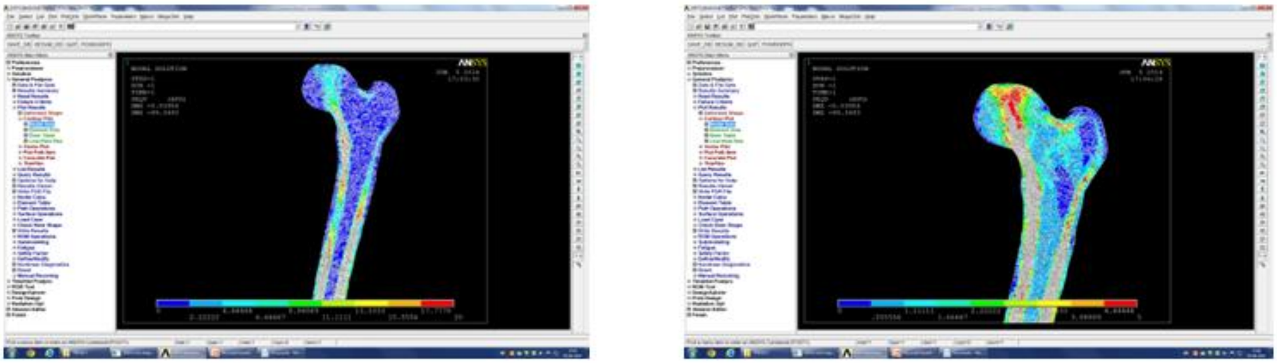
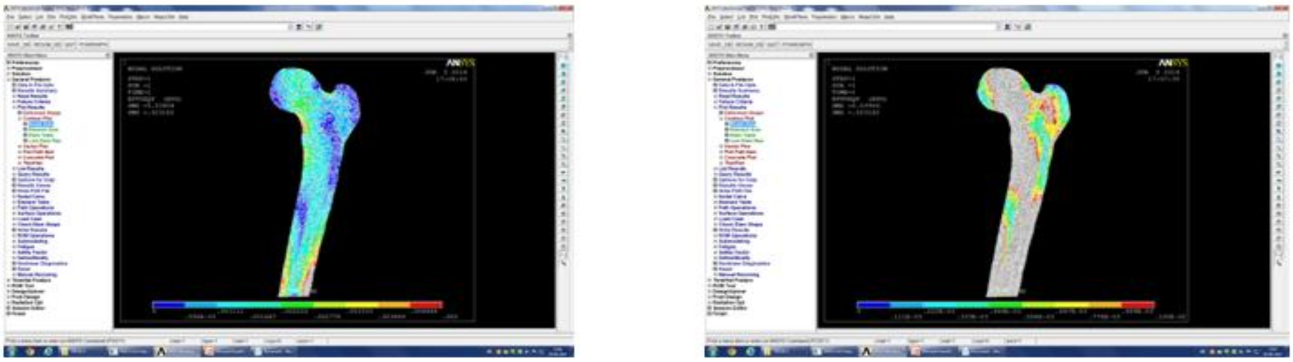


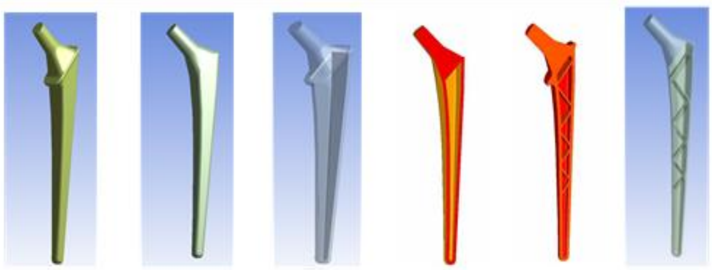
CT scan Data



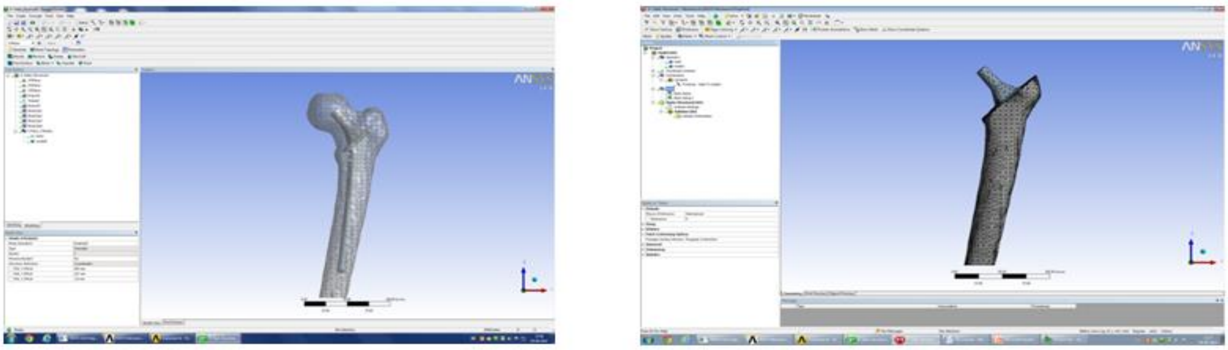
Stress Pattern in intact femur



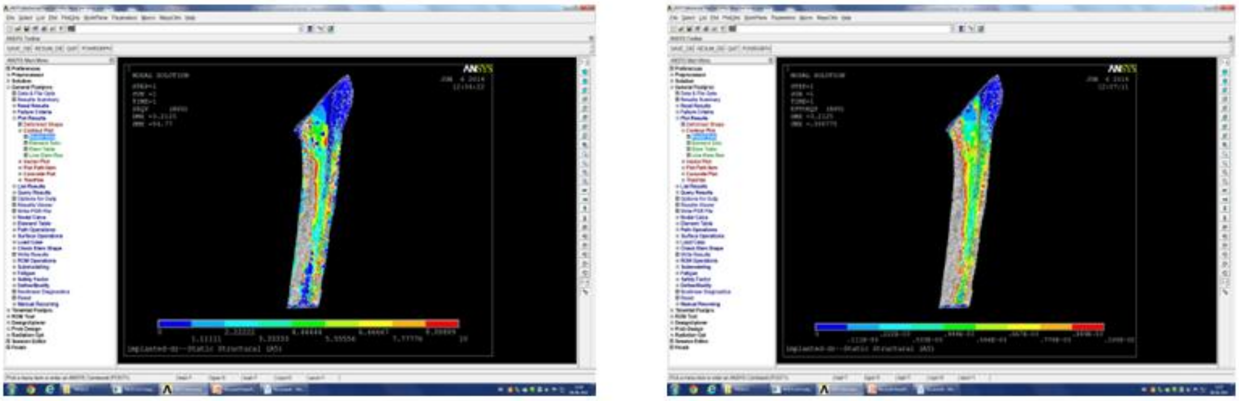
Strain Pattern in intact femur



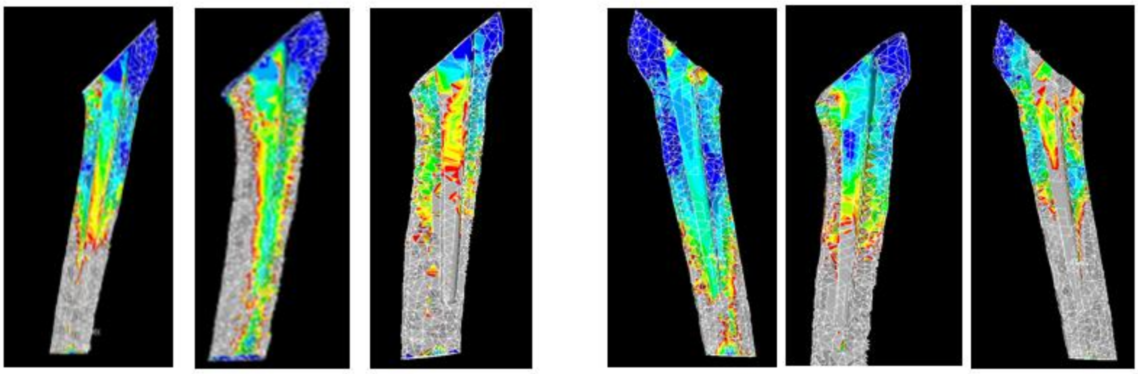
CAD Models of femoral stem



Placement of Prosthesis in proper place and meshing in ANSYS



Experimental Stress and Strain Pattern in bone



SOLID Titanium Hollow Titanium H-Int-st-Ti

VON MISES STRAIN PATTERN With and Without Collar

Top and bottom views of the developed Hip Prosthesis

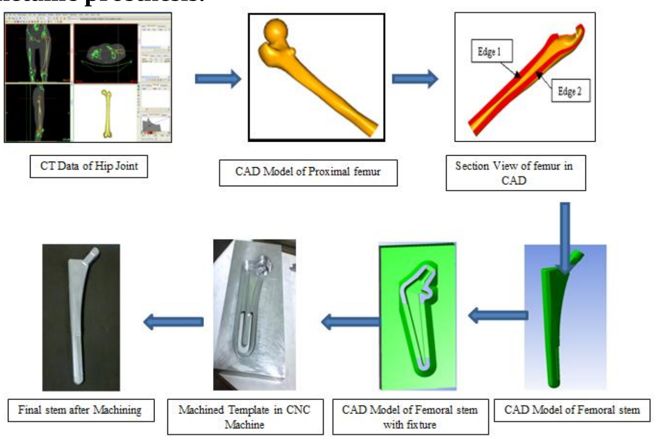
FEA of the femur bone after implanting into femoral stem:-

- Six different types of Prosthesis structures (A-F) were assigned.
- Each case was analyzed with SS alloy and Ti Alloy materials.

Experimental Details:

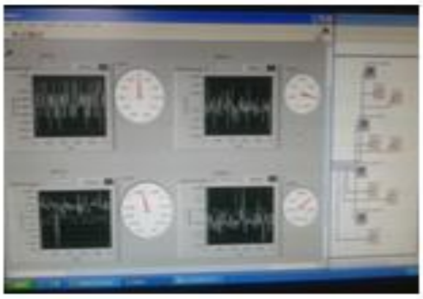
CT data of hip joint of a few Indian patients was studied in detail in Materialise's Interactive Medical Image Control System (MIMICS). Based on the CT of femur canal, outer shape of femoral stem was designed in CAD. Three different types of femoral stem design were prepared in CAD; solid, hollow and hollow with internal rib structures. The FEA of implant was carried out in ANSYS for each case with assigned material as SS316LVM and Ti6Al4V. The stresses generated in femur were compared with the strength of intact femur bone of different bone quality. Similarly for Knee joint and spinal joint selected implants were designed. All these implants were manufactured and put under metrological inspection for dimensional accuracy.

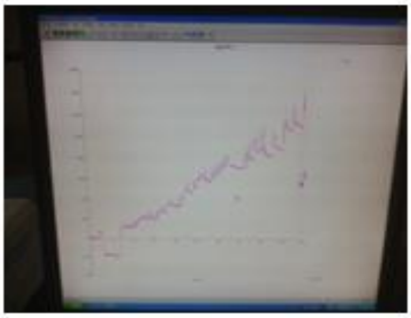
Establishing machining route for development of the metallic prosthesis.



Experimental Load Test of the fabricated hip prosthesis

In addition to these activities, to have an idea about acceptability of the results generated from computational FE analysis, mechanical load testing was also carried out. The femoral stem along with the strain gauges were inserted in the canal of the collected cadaveric femurs. A special mechanical fixture was built in which the implanted cadaveric femur could be held in the vertical position with the help of a number of bolts. The entire fixture along with implanted femur was kept on a force sensing platform. Suitable vertical load was applied at the top surface of implant neck. The Dynamometer was connected to a computer for monitoring this load on implant. The trends of values are same in case of theoretical FE data and experimental data. Thus, in the present investigative study, it can be said that the theoretical FE data pattern are qualitatively validated with experimental data.





It indicates that the boundary conditions, material properties and entire procedure followed during the theoretical FE analysis were in correct directions.

Experimental Metrological data:

i) Hip prosthesis.

Sl No	Actual Dimension	Measured dimension	Remarks
1	195.0	194.32	
2	173.2	173.19	
3	12	11.94	
4	13.6	13.54	
5	R 4.0	R 4.10	
6	9.44	9.39	
7	28.47	28.50	
8	23.40	23.96	

Sl No	Actual Dimension	Measured dimension	Remarks
1	5.16	5.06	
2	5.75	5.72	
3	6.74	6.73	
4	7.98	7.99	
5	8.0	8.20	
6	9.59	9.60	
7	1.54	1.53	

Note: The manufactured metallic implants were put under metrological inspection for measurement of some of the important dimensions. It was found that important matching dimensions were within accepted limit.

Results & Discussions:

The designed implants were initially put under computational stress Analysis. In case of hip joint, the computational stress analysis revealed that hollow prosthesis has lesser stress shielding effect than the solid prosthesis. The effect is further improved by using Ti Alloy in place of SS alloy as prosthesis material. Furthermore it has been found that there is no significant difference in generation of strain on femur between collarless prosthesis and collared prosthesis. All the developed metallic prosthesis were finally inspected at metrology lab of CSIR-CMERI for dimensions and it is found that the results obtained are very close to the developed CAD Model from CT Scan data of the patient. Hence it is said that through this experimental study a new machining route has been established for the machining of such types of critical metallic biomedical prosthesis through conventional route.

Major Conclusions:

1) CSIR-CMERI was engaged in fabrication of the metallic biomedical implants. During the project work selected metallic implants have been fabricated and the machining route has been established.

2) A CNC set up has been created at CSIR-CMERI for machining of critical shapes of selected metallic prosthesis.

3) An improved design of Hollow femoral stems was developed, having reduced stress shielding effect and increased life of implantation.

3) The critical shape of metallic implants for knee joint could be manufactured with new CNC set up.

4) Metallic anterior cervical plates for spinal joint could be also fabricated with this manufacturing set up.

5) Metrological inspection shows that all important geometrical dimensions of implants could be maintained through established machining route.