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Design, Analysis and Optimization of Patient-Specific Implant Fixation Position Using FEA and Fabrication Via RP Techniques

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Abstract

Patient anatomy specific orthopaedic implant design and fabrication and identifying the suitable position to fix the implant on bone fracture are the challenging one to the surgeons to overcome existing shortcomings of current implant designs. In this work, a 3D finite element model of the left tibia bone of an adult male is developed from Computed Tomography (CT) scan image. Proximal tibia fracture type B1 as per Association of Orthopaedic (AO) is simulated on the bone model. The geometry specific implant is obtained, by extracting the surface features of the bone in order to promote better bone ingrowths and uniform stress distribution. Finite Element Analysis (FEA) is performed to evaluate and compare the mechanical properties such as stress, strain and displacement for the bone and implant. The same FEA is carried out for implant fixed at different positions. The results obtained from FEA are used to achieve the design objective such as low stress and displacement combination of implant and bone are identified. The obtained implant CAD model from FEA results is converted into .stl format which is a de facto standard, the most common interface between CAD and Rapid Prototyping (RP) systems. Then the implant model is fabricated using RP-Fused Deposition Modeling (FDM) technique. The FDM implant model is used to verify and validate the design of the implant.

Key words: CT, MIMICS, CATIA, HyperMesh, implant, FEA, RP.

Introduction

Rapid Prototyping (RP) is an exceptional innovation in Engineering. RP, an integrated product development process creates the total management, operations, engineering, manufacturing, test and business environment that enables this to happen. Initially conceived for design verification and part verification, now it meets the demand for a wide range of applications, from building prototypes with material properties close to those of production parts, to fabricating model for medical application (Uma Maheswaraa). The medical industry has made great strides in offering healthcare services. Many of these are related to various technologies such as imaging system, laser scanning, robotics and rapid prototyping that are either coming of age or are now affordable for implementation. The medical industry and particularly orthopedics has certain applications, while not necessarily unique, are extremely well suited to these technologies and may foster their integration and expansion (1). The great advantage of RP technology is the precise reproduction of objects from a 3D medical image data set as a physical model which can be looked at and touched by the surgeon (2 & D' Urso)

Rapid Prototyping and more recently Rapid Manufacturing (RM) as a part of Engineering Assisted Surgery enables manufacturing of customized implants and prostheses prior to surgical procedures (Lohfeld). The applications of RP extended to direct fabrication of custom fit patient specific implants within short time and economically (3). Since 3D medical data are often represented in slices as in CT and RP systems also creates models from slices, this is an obvious application area (4). Rapid prototyping makes it possible to manufacture a patient specific implant that precisely fits a patient at reasonable cost. The advent of Rapid manufacturing techniques, such as Electron Beam Melting (EBM), Direct Laser Metal Sintering, direct SLS, etc., does not have any shape limitations and does not generate material waste.

Finite Element Analysis (FEA) is a well established tool for determining stresses inside the bone subjected to hypothetical loading conditions and also can simulate various boundary conditions, which are very difficult to replicate in experiments (5 & 6). This information is considered by a number of investigators as a key factor for understanding bone functional behaviour in many research and clinical applications (7). However, an accurate finite element simulation of in-vivo conditions requires proper physiological data such as geometry and bone density that can be related to material properties of bone region (3). Non invasive data acquisition methods such as Computed Tomography (CT) imaging have become useful tool for assisting physicians with surgical planning of complicated orthopaedic procedures. This image data can be used in manual segmentation of the bone to generate idealized surfaces for creating finite element model. Already, attempt in developing a patient-specific biomechanical model of the human tibia bone for the purpose of comparing the benefits of custom implant design against the conventional implant design (8 & 9).

The implants are often anatomically shaped or contoured designs versus basic geometric shapes and produced as a family in a range of sizes that can be selected at surgery to match the patient requirement (10). The pre-bent implant results in more compressive contact across the fracture site without gapping. Gap may result in micro movements with subsequent bone resorption and loss of fixation. An implant must be sufficiently long and strong and should be fixed with an adequate number of screws to provide rigid fixation for successful treatment of a fracture (11). The screw should not be inserted too close to the fracture line because it split the pilot hole into the fracture and cause additional comminuting.

Custom implants are necessary for those situations when an off-the shelf standard size is not suitable. These are usually complex cases involving trauma or disease resulting in bone deformity or loss (12). A custom implant is produced on a prescription basis and is unique for each patient. Most commonly used implants for fracture fixation are often limited by their biological and mechanical constraints (1). The Biomechanical considerations while designing the implants, improves the longevity of the implant and provides stability to the bone – implant construct. Sharing of load by implants creates favourable mechanical conditions for healing.

Fabrication of custom fit implants using CAD model is possible with RP. The most commonly used material for implant is Titanium for long term usage (9 & 13). The elastic modules of Titanium are approximately half that of Stainless Steel and six times that of bone. The mechanical properties of titanium are closer to those of bone. The high cost of titanium implant is compensated for by the fact that a second operation is often unnecessary and prolonged absence from work is avoided (14). The effective utilization of RP can be achieved by earlier FEA study for various situations and conditions to enhance the patient specific implant features (15).

3d Bone Model Developed From Ct Image

The methodology used to fabricate the patient specific implant from CT images as shown in fig (1) is discussed in this paper. CT imaging is a useful method together with three dimensional physiological data such as geometry and density of bone in vivo. This image data can be used in manual segmentation of bone to generate idealized surfaces for creating finite element models.

The MIMICS, an image processing software package is used to convert the CT data into a series of contours to simulate outer cortical and intramedullary cancellous surfaces by segmentation and 3D rendering objects. The input data of the modeling process represented by tomography slices in DICOM format belongs to 23 year old adult male with a body weight (BW) of 80 Kg. For extracting the cortical and trabacular tibia bone features, threshold value is adjusted from 226 to 1956 Hounsfield units in the MIMICS. Then region growing is used to separate the region of interest (ROI) from the selected object. To check the result, 3D model has to be calculated. The accuracy of the model is comprised by 3 times smoothing.

Then Med CAD module in the MIMICS is used to export the 3D model data from imaging system to the CAD system as IGES file format. The transfer from solid to surface is done by the polylines, which determine the cortical and trabacular contour. For each section polylines have been generated, so that 1677 polylines are obtained from tomography slices. This IGES format is imported into CAD software CATIA as polylines. CATIA is used to process the data in order to create Non Uniform Rational B-Splines (NURBS) surfaces, which are easily handled by Finite Element software (2). After editing the data such as blending, joining, smoothing, filling gaps, etc. on the splines, the curves are wrapped as closed surfaces.

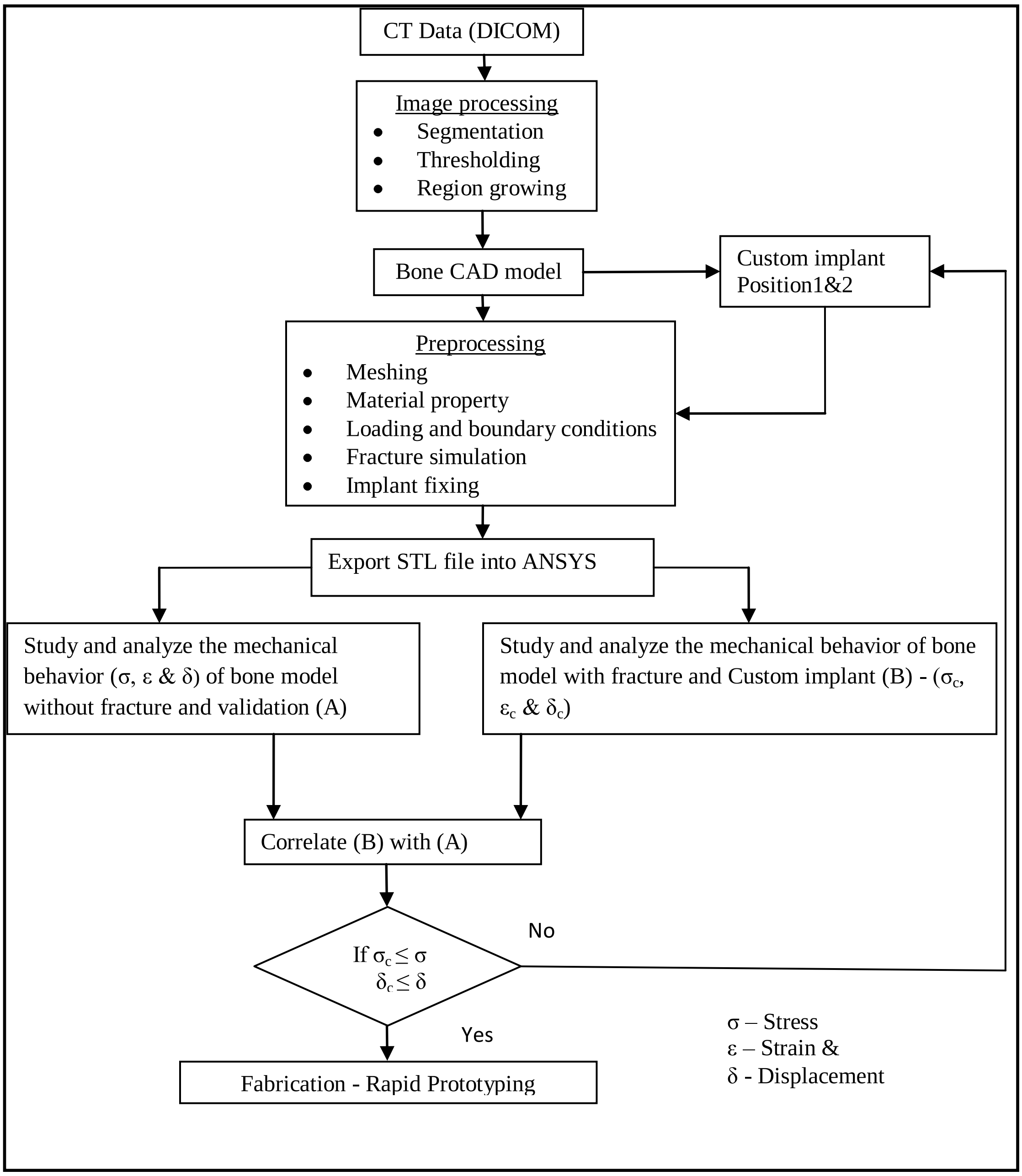


Figure 1: Methodology used to Analysis and fabrication of the customized implant from CT images

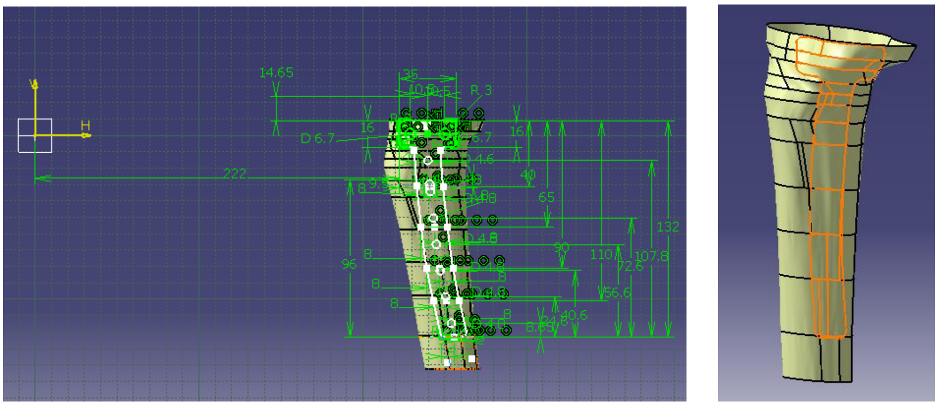


Figure 2: Patient specific implant modeling using CATIA

The CAD model of the bone developed from the CT image is used to develop the patient specific implant for proximal tibia fracture type B1 as per Association of Orthopaedic (AO). In order to promote better bone ingrowths and uniform stress distribution, it was decided to construct the custom implant by extracting the surface features of the bone. The inner surface of the implant should be parametric as well as it should nearly define the external surface of the bone to get an even load distribution and uniform thickness. The inner parametric surface i.e., bone-implant interface is generated and it closely follow, the shape of the section curves of the tibia bone model. Parameterization feature helps to change the dimension and location of the implant as shown in the fig 2. Thus created implant is exported into IGES format. The final model of the implant has a length of 135 mm and 2.5mm thickness.

Repairing and Reconstruction of Tibia Bone

Then the IGES file is imported into HyperMesh software, to clean up imported geometry containing surfaces with gaps, overlaps and misalignments that prevent high-quality mesh generation. By eliminating misalignments and holes, and suppressing the boundaries between adjacent surfaces, the overall meshing speed and quality is improved. The model is meshed to 3 mm element size and the quality is checked. Element type and Boundary conditions are applied to these surfaces for future mapping to underlying element data. FE model is developed for the entire length of the Tibial bone measured 415 mm in length.

The model is divided into three regions named as thick shaft region as cortical bone, bone marrow inside the cortical as cancellous and spongy region in proximal and distal end of the bone as trabacular. During normal walking stance phase at full extension the peak load acting on the human tibia region is 3 times body weight of the person (16 & 17). A loading condition of 2400N (BW-80kg) is applied on the proximal region which is splitted into 60% (1470N) of weight in the medial region and 40% (980N) in the lateral region of the model. The load is approximately distributed in the middle of the medial and lateral regions. The linear elastic, orthotropic and heterogeneous material property is assigned for the cortical region (18

& 19). The linear elastic, isotropic and homogeneous material property is assigned for both trabacular and cancellous (20) bone regions. Poisson’s ratio (υ) for all the three regions is considered as 0.3. The bulk modulus (G) for cortical bone was calculated using the formula given in the equation 1,

$$E = 2G\,(1+\upsilon) \tag{1}$$

Where E is young’s modulus. The degrees of freedom of the nodes in the distal end of the bone were totally constrained. The B1 type fracture is created on the proximal lateral side of the bone and the implant is fixed with fractured bone.

Finite Element Analysis (FEA)

The models are imported into ANSYS software to perform the analysis. Element type, real constant, material property, thickness of implant and component manager is assigned for implants. The implant material property is assigned as linear elastic, homogeneous and isotropic (21 & 22). It is made of surgical Titanium (Ti6Al4V) have an elastic modulus of 120 Gpa and Poisson’s ratio of 0.3. The interaction between the two fractured pieces is defined as ‘bonded’ augmented Lagrange contact without separation after contact. Bone and implant hole is constrained in all degrees of freedom. The finite element analyses were solved using a Pre Conjugate Solver (PCS).

Results and Discussion

Based on non-linear contact analyses of proximal tibia bone fracture with custom implant at two positions, a comparative study is done in terms of displacement, induced stress, bone-implant interface stress and contact stress at fractured interface surface. All the FEA plots are scaled at the same stress level.

Displacement of bone and implant

For the custom implant configurations, the overall deflection has been found to be approximately 2mm which is less than deflection of intact tibia. This may be due to the stiffness of the implants which is not allowing more deflection. The lateral deflection of a custom implant configurations for the position 1 and 2 are 0.76 mm and 0.61 mm respectively. But the intact tibia lateral deflection is 1.58 mm in posterior side. The lateral deflection of bone-implant configuration is much less than intact tibia, probably due to location of implant on the tension side of the tibia. In both the configurations all the holes in the implants are constrained except the hole near the fracture site. Hence the deflection of implants alone not shows much of difference between them. In both overall and lateral deflections, the position 2 of custom implant is less than position 1.

The higher the stiffness of an implant resulted the smaller the deformation and the smaller the displacement of the fracture fragments resulted to the minimum strain on the repairing tissue. Hence, a reduction in strain which promotes healing.

Principal Stress Distribution

In intact condition, the stress distribution is approximately 13.4 MPa on the tibia bone and near the distal end of the bone is maximum of 47 MPa and. The tibia bone act as a column supporting the body weight and as a beam resisting bending moments. In the case of implanted tibia, the stress distribution on the entire region was negative and the maximum stress is at the implant region. So the implant bears the maximum load and function according to the tension band principle to resist very large amounts of tensile forces. Custom implant shows uniform stress distribution probably due to patient specific geometry of the implant. The table.1 shows the comparison of maximum and minimum principal stresses of implanted bone with intact tibia bone.

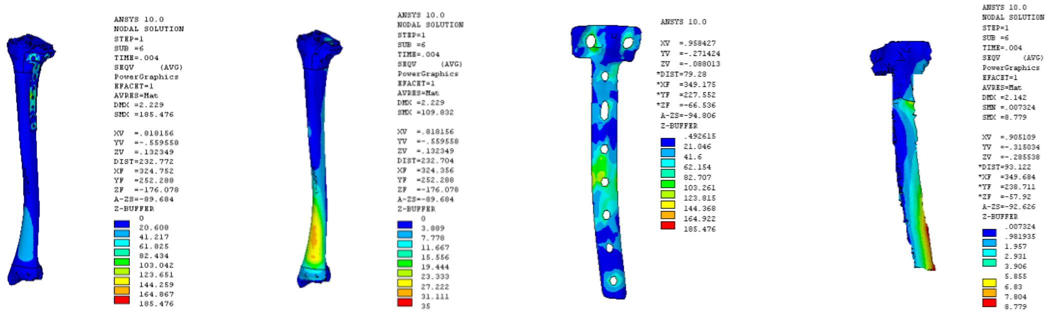
Table 1: Maximum and minimum principal stresses of the tibia model with implants and intact

Stress distribution	**Intact**	**Custom implant**	
		Position-1	**Position-2**
Max principal stress (MPa)	47 to-14	225 to -12	182 to -5.5
Min principal stress (MPa)	-72 to 6	-207 to 11	-160 to 7.7

In the minimum principal stress distribution, the entire model shows that the minimum stress distribution at the anterior distal end of the bone and maximum stress distributed on the implants. This implies that implants are load sharing component and minimizes the stress induced on the bone, due to accurate fit with the bone. The stress distribution pattern shown in the custom implant of position-2 is more advantageous than the position-1, because the more even stress distribution on the implant which induces the bone growth instead of bone resorption.

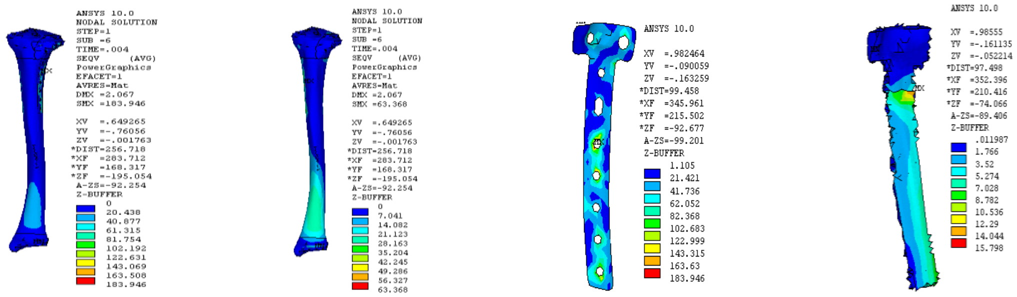
Von Mises stress distribution

The Von Mises stress distribution on bone was analyzed for user specified range from 0 to 35 MPa to compare the stress distribution pattern on bone when the custom implant fitted at both the position. In both the cases, the more stress is found in the distal region and it is nearly 20 MPa to 31MPa as shown in the fig 3b & 4b. The stresses experienced by the position 1 & 2 custom implants were 185 MPa & 162 MPa respectively as shown in the fig 3c & 4c. The stress distribution patterns on the custom implants are evenly distributed all over the region of the implant. This minimizes the implant failure if the surgeon goes for surgical procedures like bending and reversing the implant for appropriate fixation. When a fractured bone is fixed with an implant, both bone and implant shares the limb load. The bone is relieved of some of its original load by the implant.



(a) (b) (c) (d)

Figure 3: The Von Mises stress distribution on a) fractured bone with custom implant-position 1, b) Bone alone, c) implant alone and d) bone-implant interface



(a) (b) (c) (d)

Figure 4: The Von Mises stress distribution on a) fractured bone with custom implant-position2, b), Bone alone, c) implant alone and d) bone-implant interface

For this reason, the custom implant may probably be suitable to the patients by modeling the exact geometry of the bone using the CT data. The bone-implant interface region in the fig 3d & 4d shows that there is stress distribution on the cortical region only and not in the proximal side. The even stress distribution as evident from interface region may reduce the uneven bone remodeling that can lead to premature loosening.

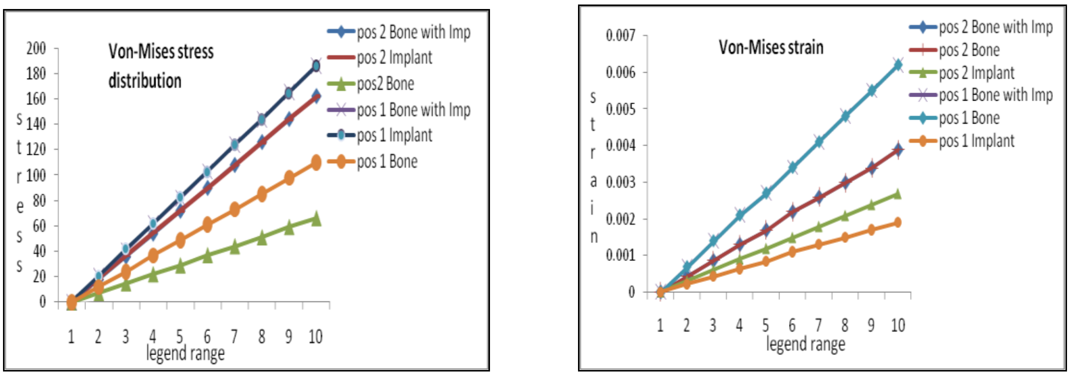
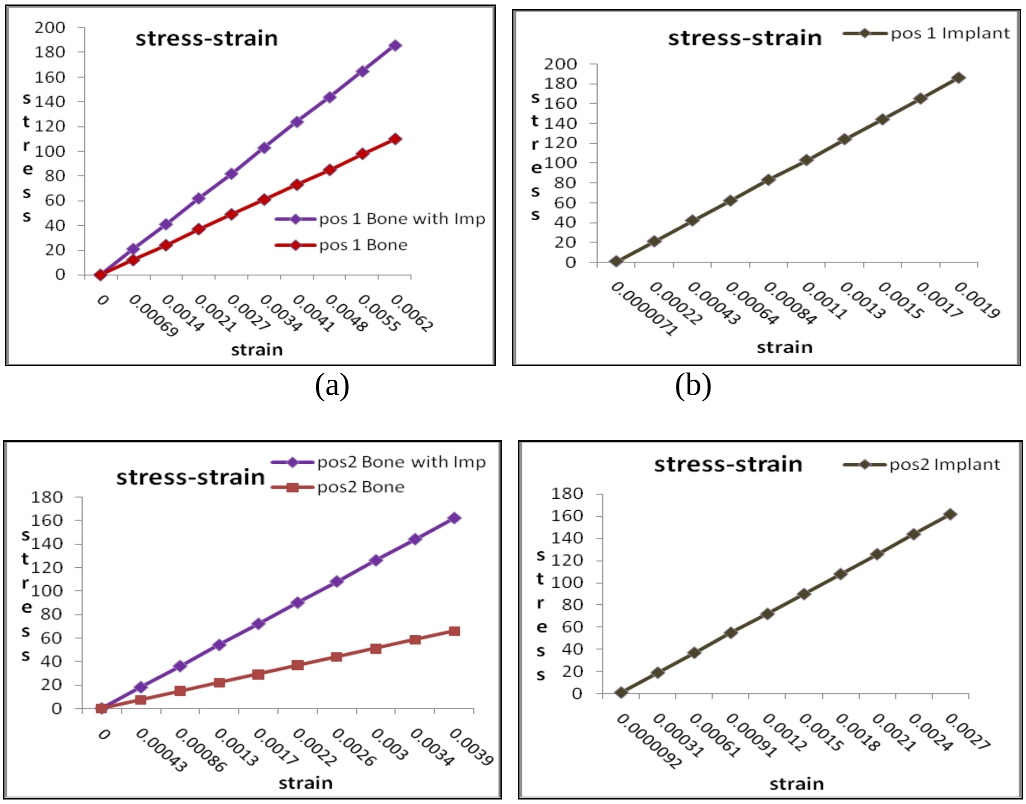


Figure 5: Von-Mises stress and strain Vs legend range for bone, implant and bone with implant at positions 1 & 2

Fig 5. Shows that the stress distribution on bone with implant and implant are same in both the position and stress on bone is less than the implant and bone with implant. This implies that the implant bears more stress than the bone which leads to faster healing. Stress distribution on implant and bone at position 2 is 13% and 40% less than the position 1 respectively. Strain graph shows that the strain on bone and bone with implant are same and the strain on implant is less than the bone and bone with implant. Strain on bone at position 2 is 37% less and on implant 30% greater than the position 1. When comparing the positions with stress and strain results, it conclude that at position 2, the stress and strain on the bone is less than at position 1. The stress-strain relation on bone and implant is linearly elastic and for normal walking gait phase condition, both bone and implant is within the yiele stress value (bone-200 MPa and implant -800 MPa) as shown in the fig 6.



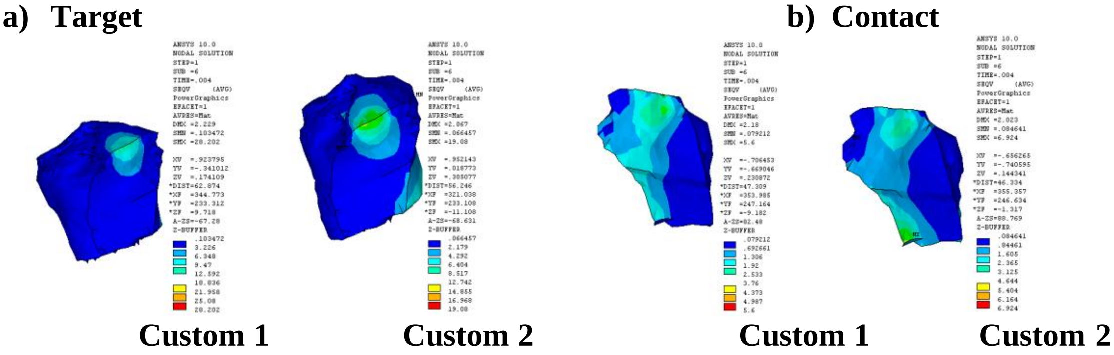
(a) (b)

(c) (d)

Figure 6: Stress-strain relation on bone, implant and bone with implant at positions 1&2

Von Mises Equivalent Stress Distribution At Target and Contact Region

Von Mises stress distribution at target and contact regions of custom implants at position 1 & 2 are shown in fig 7. The stresses at target and contact regions of position 1 are 18.8 and 3.76 MPa respectively and 12.74 and 3.125 MPa respectively for position 2. The level of the contact surface stresses is almost same for both. Both the implant positions show a more uniform stress distribution. A stable fixation is characterized by lack of motion at the fracture site even during joint movement and allows early painless mobilization with any attempt to move the limb. Hence the stress shown in the contact surfaces helps to induce the bone growth and faster healing.


a) Target **b) Contact**

Custom 1 **Custom 2** **Custom 1** **Custom 2**

Figure 7: Comparison of Von Mises Stress Distribution on Fractured Bone Surface For Standard and Custom Implants

b) Rapid Prototyping

The results obtained from FEA can be utilized to design and fabricate the patient specific custom implant accurately using one of the direct manufacturing RP techniques. EBM is one of the most suitable direct manufacturing RP techniques, which can be used for fabrication of custom implant with the low surface finish that improves the bone growth and therefore speeds up the healing process. Hence, the FEA is used to validate the implant design and RP to verify the design of the implant as shown in the fig 8.

Figure 8: Custom implant for position 1 fabricated using FDM

c) Conclusion and Future Recommendations

Finite Element Analysis was used to evaluate and compare the mechanical behaviour such as stress and deflection of a tibia bone with custom implant fixed at two various positions. The stress distribution pattern using the custom implants 1 & 2 shows that there is uniform stress distribution in the implant, bone-implant interface and contact region. When comparing the FEA results, the deflection and equivalent stress distribution of second position is less than the first position. Hence the implant fixed in the second position is considered as one of the best. This is anticipating that the longevity and stability of the implant and painless activity of the patient will be improved. The custom fit saves the surgical fixation time and improves the initial stability of the implant. Patient specific implant helps to minimize the unnecessary postoperative pain by resurfacing the healthy bone and also the requirement of biomedical instruments to perform the surgery. Now the concept of Rapid Prototyping is changed into Rapid Manufacturing. EBM can be used to fabricate direct form and fit functional implants ready to use. So the integration of FEA for validation and RP for functional implant helps to improve the overall comfort and speedy recovery of patients.

The custom fit for one material and same dimension as standard available implant is studied in this present work, it is necessary to vary the dimensions and material to get the better conclusion by performing the FEA.

References

[1] Berry. E, J. M. Brown, M. Connell, C. M. Craven, N. D. Efford, A. Radjenovic and M. A. Smith, (1997), “Preliminary experience with medical applications of rapid prototyping by selective laser sintering”, Journal of Medical Engineering Physics, vol 19, no1, pp 90-96.

[2] Petzold. R, H.-F.Zeilfofer and W.A.Kalender, (1999), “Rapid Prototyping technology in medicine – basics and applications”, Journal of Computerized Medical Imaging and Graphics vol 23, pp 277-284.

[3] Cinzia Zannoni, Raffaella Mantovani and Marco Viceconti, (1998), “Material properties assignment to finite element models of bone structures: a new method”, Medical Engineering & Physics 20, pp735-740.

[4] Baris Simsek, Erkan Erkmen, Dervis Yilmaz and Atilim Eser , (2006), “Effects of different inter-implant distances on the stress distribution around endosseous implants in posterior mandible – A 3D finite element analysis”, Journal of Medical Engineering and Physics, vol28, pp 199-213.

[5] Daniel Remmler, Lorraine Olson, Ralph Ekstrom, Derek Duke, Aurelio, Matamoros, David Matthews, Christopher G. Ullrich, (1998), “Pre-surgical CT/FEA for craniofacial distraction: I. Methodology, development and validation of the cranial finite element model”, Journal of Medical Engineering and Physics, vol 20 pp 607-619.

[6] Dcosta. D, X.Hu, J.Chiang, M.Lehmicke, W.Sun, (2002), “CAD/CAE Assisted biomodeling and design of inter-vertebral implant”, IEEE, pp213-214.

[7] David Bennet, Tarun Goswami, (2008) “Finite Element Analysis of hip stem designs”, Journal of materials and design, vol 29, pp 45-60.

[8] Devika.D, Arumaikkannu.G, (2009), “Finite Element Analysis and Rapid Prototyping to enhance the patient specific implant fabrication”, International Conference proceedings TP09PUB7, RAPID2009, held on 12th-14th, May2009 organized by SME at Schaumburg, Illinois, Chicago, USA.

[9] Devika. D, Arumaikkannu.G, (2012), “Evaluation of Mechanical behaviour of Bone, Implant and Bone-Implant Interface by Numerical Simulation of Two Surgical Fixation Procedures using Finite Element

Analysis" International Journal of Computers application in technology, Vol 42 nos. 2/3, pp. 225-232.

[10] Gibson. I, L. K. Cheung, S. P. Chow, W. L. Cheung, S. L. Beh, M. Savalani and S. H. Lee, (2006), "The use of rapid prototyping to assist medical applications", Rapid prototyping journal, vol 12/1, pp 53-58.

[11] Ola LA Harryson, Yasser A Hosni and Jamal F Nayfeh, (2007), "Custom-designed orthopedic implants evaluated using finite element analysis of patient-specific computed tomography data: femoral-component case study", BMC Musculoskeletal disorder, vol 8.

[12] Ming-Yih Lee, Chong-Ching Chang, Chao-Chun Lin,Lun-Jou Lo and Yu-Ray Chen, (2002), "Custom implant design for patients with cranial defects", IEEE Engineering in Medicine and Biology, pp 38-44.

[13] Chua. C. K, (1998), "Rapid Prototyping assisted surgery planning", Journal of Advanced Manufacturing Technology, vol 14, pp 624-630.

[14] Harrington, I.J., (1976), "A Bioengineering Analysis of Force Actions at the Knee in Normal and Pathological Gait", Journal of Biomech. Engineering, vol.11, pp. 167- 172.

[15] Wei Sun, Pallavi Lal, (2002), "Recent development on computer aided tissue engineering", Journal of Computer methods and programs in biomedicine, vol 67, pp 85-103.

[16] Rho.J.Y, M.C.Hobatho and R.B.Ashman, (1995), "Relations of mechanical properties to density and CT numbers in human bone", Journal of Medical Engineering Physics, vol. 17, no. 5, pp. 347- 355.

[17] Singare.S, (2005), "Customized design and manufacturing of chin implant based on Rapid Prototyping" Journal of Rapid Prototyping, vol 11/2, pp113-118.

[18] Sowmianarayanan. S, A. Chandrasekaran and R.Krishna Kumar, (2008), "Finite element analysis of a subtrochanteric fractured femur with dynamic hip screw, dynamic condylar screw, and proximal femur nail implants – a comparative study" Journal of Engineering in Medicine, vol 222, pp 117-127.

[19] Taylor. W. R, E. Roland, H.Ploeg, D.Hertig, R.Klabunde, M.D.Warner, M.C.Hobatho, L.Rakotomanana, S.E.Clift, (2002), "Determination of orthotropic bone elastic constants using FEA and modal analysis", Journal of Biomechanics, vol 35, pp 767-773.

[20] Vamsi Krishna.B, Susmita Bose, Amit Bandyopadhyay, (2007), "Low stiffness porous Ti structures for load-bearing implants", Journal of Acta Biomatrialia, vol 3, pp 997-1006.

[21] Ashman, J.Y.Rho and Charles H. Turner, (1989), "Anatomical variation of orthotropic elastic moduli of the proximal human tibia", Journal of Biomechanics, vol.22, no. 8/9, pp. 895-900.

[22] Blecha.L.D, P.Y.Zambelli, N.A.Ramaniraka, P.E.Bourban, J.A.Manson and D.P.Pioletti, (2005), "How plate positioning impacts the biomechanics of the open wedge tibial osteotomy; A Finite Element Analysis", Journal of Computer methods in biomechanics and biomedical engineering, vol 8, no 5, pp 307-313.