Finite element analysis for evaluation of post implant axial loading condition of femur fracture fixation plate made of shape memory alloy for optimum healing.

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ABSTRACT

Bone is known to remodel in the existence of a screw though bone-plate screw design had gone through numerous modifications over the time. Once screws are removed, it has been seen that holes usually remain in the bones, which may cause risks of secondary bone fractures. In consideration of such problems, shape memory alloys arise as an effective material to be used for fracture fixation plate. The stiffness of shape memory alloys basically nitinol (NiTi) is relatively close to bone and also possess the higher degree of biocompatibility as compared to stainless steel and titanium alloy. Some previously reported researches also utilizes shape memory alloy for fracture fixation. However, they are not sufficient to explain the post implant loading requirements to provide optimum mechanical environment around the fracture site. So, this study is based on finite element analysis and considering the different design parameters like length of plate, circumferential angle, number of ribs etc. based on the objective function and evaluation of axial loading required for optimum healing of callus afterwards.

Keywords: Fracture fixation plate, shape memory alloy, optimum mechanical environment, FE analysis.

1. INTRODUCTION

Bone is the main constituent of the skeletal system and it differs from the connective tissue primarily due to its rigidity and strength. A strong and stiff bone enables the skeleton to maintain body shape, to protect the internal organs, to provide a frame for the bone marrow, and to transmit force of the muscular contraction from one part of the body to another during movement. Fatigue and impact loads are the most common reasons for bone fracture. Fractured bones need to be fixed surgically for its healing and proper functioning as early as possible. Different techniques are used in the clinical treatment of long bone fractures. Most of the simple fractured long bones are treated by conservative non-operative methods of external immobilization. Another method to treat fractures is by intramedullary rod fixation. Muller et al.[1] have advocated open reduction and internal fixation using bone plate and screws. The role of bone-plate and screws is to hold the fragments of the bone in position till the bone heals. Several advancements in design of bone-plate screw had been done although bone is known to remodel in the presence of a screw but it has been seen that once screws are removed, the holes usually remain in the bones, which may cause risks of secondary bone fractures [2]. Large difference in stiffness of plate material and bone causes the osteoporosis and stress shielding [3]. In consideration of such problems, shape memory alloys emerges as an effective material to be used for fracture fixation plate. So our aim is to analysis of shape memory alloy as an effective approach to overcome these problems.

1.2 HEALING MECHANISM OF BONE AND CONCEPTUAL MODEL

Fracture healing is commonly described as a 4-phase concept: 1) inflammation phase, 2) soft callus formation (cartilage form), 3) hard callus formation (woven bone), and 4) bone remodeling (Fig.1.3). The first step is the inflammatory phase where several cells and materials prepare the fracture area for healing. The second step is the formation of soft callus (cartilage) around the fracture area. The third step is the conversion of soft callus to hard callus (cartilage to woven bone), and the final phase 4) is the remodeling of bone, where woven bone changes to lamellar bone (Pivonka and Dunstan, 2012[4]; Einhorn and Gerstenfeld, 2015[10]; Claes et al., 2012[6]; Pivonka and Komarova, 2010[5]).

In the present work, conceptual model proposed by Elliott et. al[7]. is adopted for the bone healing and remodeling. Elliott et. al. proposed a unified theory of bone healing and non-union. Elliott et al. considered the whole fracture to be a “bone-healing organ ,”which works as a functional unit and responds to biological and mechanical stimuli. They combined Wolff's law, Perren's strain theory and Frost's “mechanostat” model to create their own model of bone homeostasis, healing, and nonunion (BHN conceptual model). Using BHN, the behavior of “bone healing organ” was determined with respect to the mechanical strain applied to the organ. In BHN, the bone is in homeostatsis when under tolerable strain (much less than 2%) i;e left to the point B of Fig. . For strains greater than 2% and less than 10%, a fracture occurs and is considered to be the beginning of the “bone-healing organ” i;e in between points B and C . Finally, for strains above 10%, the “bone-healing organ” stops and fails to heal, leading to nonunion i;e right to the point C. .

2. WORK METHODOLOGY

This work is purely analytical and performed using finite element software ANSYS MAPDL 17.1. The shaft portion of the femur is considered where the plate is implanted for the fracture fixation. The average diameter of femur shaft portion is 15mm and considered length is 105.3mm. The two models of femur are used for two different objectives of the present work. One model is used for the optimization of different design parameter of the bone plate. Femur bone is modeled as simple cylindrical shape with diameter 15mm and length 107mm The second model is used for the effectiveness of bone plate and includes the initial grown callus at the fractured site. Hence, three parts are there for the second model i;e callus in between the two fractured ends of the femur. Femur model is divided in three parts using boolean operation i;e two fractured ends of length 53 mm each and callus of length 1mm in between two ends of the fractured femur. The design of bone plate made of shape memory alloy is assembled with the bone without screws by its embracing capability at the body temperature. Bone plate basic design is taken from the literature [32][36] and it consist shaft and ribs. For femur fracture fixation plates, contact pressure is an important design factor that makes its assembly with bone. So, the maximum contact pressure is set as the objective function for selecting the different design parameters of plate. The design parameters that influence the contact pressure are selected as circumferential angle (θ), thickness *(t),* and internal diameter *(d).* The width of each rib of plate is considered as 5.5 mm and the distance between the ribs is 8 mm. Three reference values as given in table [39] for three design parameters.

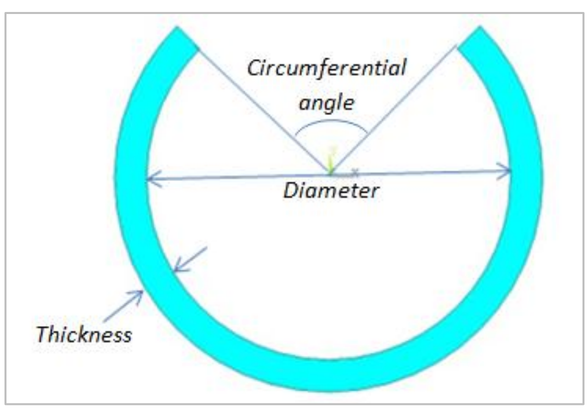


Figure 1 Shape memory embracing fixator designs from literature.

Table. 1 Dimension of different parameter of plate

PARAMETER	VALUE
CIRCUMFERENTIAL ANGLE	1. 210^0
	2. 240^0
	3. 270^0
THICKNESS	1. 2.0 mm
	2. 2.2 mm
	3. 2.4 mm
DIAMETER	1. 27 mm
	2. 28 mm
	3. 29 mm

L9 table of Taguchi method of optimization is considered to select the

Geometry	Circumferential angle	Thickness	Diameter
G1R1M1	210	2.0	27
G2R1M1	210	2.2	28
G3R1M1	210	2.4	29
G4R1M1	240	2.0	29
G5R1M1	240	2.2	27
G6R1M1	240	2.4	28
G7R1M1	270	2.0	28
G8R1M1	270	2.2	29
G9R1M1	270	2.4	27

combinations of different parameters which can consider effect of each parameter. The nine cases which are selected as per the L9 table of Taguchi method of optimization are tabulated and shown in table 2.

Table 2 Considered geometries as per L9 table.

2.1 MATERIAL PROPERTIES

In the present work femur bone is assume as homogeneous, isotropic and linear material. The fracture gap fills with a curing tissue (callus) as healing process i;e the callus moduli vary throughout the healing period as given in the table 3 along with the femur bone properties.

Table 3 material properties of bone and callus at different healing stages.

Component name	Material name	Young's modulus						Poisson's ratio
Callus	Callus	Healing Stages						0.36
		1^{st}	2^{nd}	3^{rd}	4^{th}	5^{th}	6^{th}	
		100 MPa	200 MPa	400 MPa	800 MPa	1 GPa	1.5 GPa	
Fractured bones	Cortical bone	16GPa						0.36

Shape memory alloys are both biofunctionabale and biocompatible. There are various shape memory alloys commercial available. But the shape memory alloys which have the young's modulus close to the modulus of femur bone and also capable of possessing shape recovery at the human body temperature.

Table 4 shape memory alloys material properties.

Material properties	SMA1[9]	SMA2[8]	SMA3[8]
Young's Modulus (Austenite Modulus), E_A	60,000 MPa	75000 MPa	70000 MPa
Poisson's Ratio, ν	0.33	0.3	0.3
Hardening Parameter, h	500 MPa	4000 MPa	500 MPa
Reference Temperature, T	0 5 ℃	263 K	289 K
Elastic Limit, R	300 MPa	70 MPa	120 MPa
Temperature Scaling Parameter, β	7.5 MPa/℃	7 MPa/K	8.3 MPa/K
Maximum Transformation Strain, ξ	0.08	0.07	0.07
Martensite Modulus, E_M	60,000 MPa	75000 MPa	70000 MPa
Shape recovery temperature	37℃	310 K	311 K

2.2 MESH AND BOUNDARY CONDITION

In this analysis model is supposed to undergo large deformation and large strain. So, Solid 185 with 8 nodes is selected for meshing both bone plate and CAD bone model. The element size for plate is taken as 0.5 mm and bone is meshed with element of size 2 mm.

In order to perform analysis, nodes of plate shaft portion are made constraint by constraining all degree of freedom and nodes at one end of the femur shaft portion are made constraint by constraining all degree of freedom while the axial load will be applied through the second end of femur. Two frictional contact pairs with frictional coefficient 0.2 are defined between the plate and bone. CONTACT 172 and TARGET 162 elements are used to define the contacts. The contact is defined as surface to surface contact. Initially the diameter of bone is more than the plate. So, firstly plate is expanded by applying load on both the ribs. The plate is then mounted over the bone and then assembly is made as plate try to recover its shape. So, it is required that contact pair 2 should be deactivated until the ribs are expanded by displacement loading. This is

Finite element analysis steps

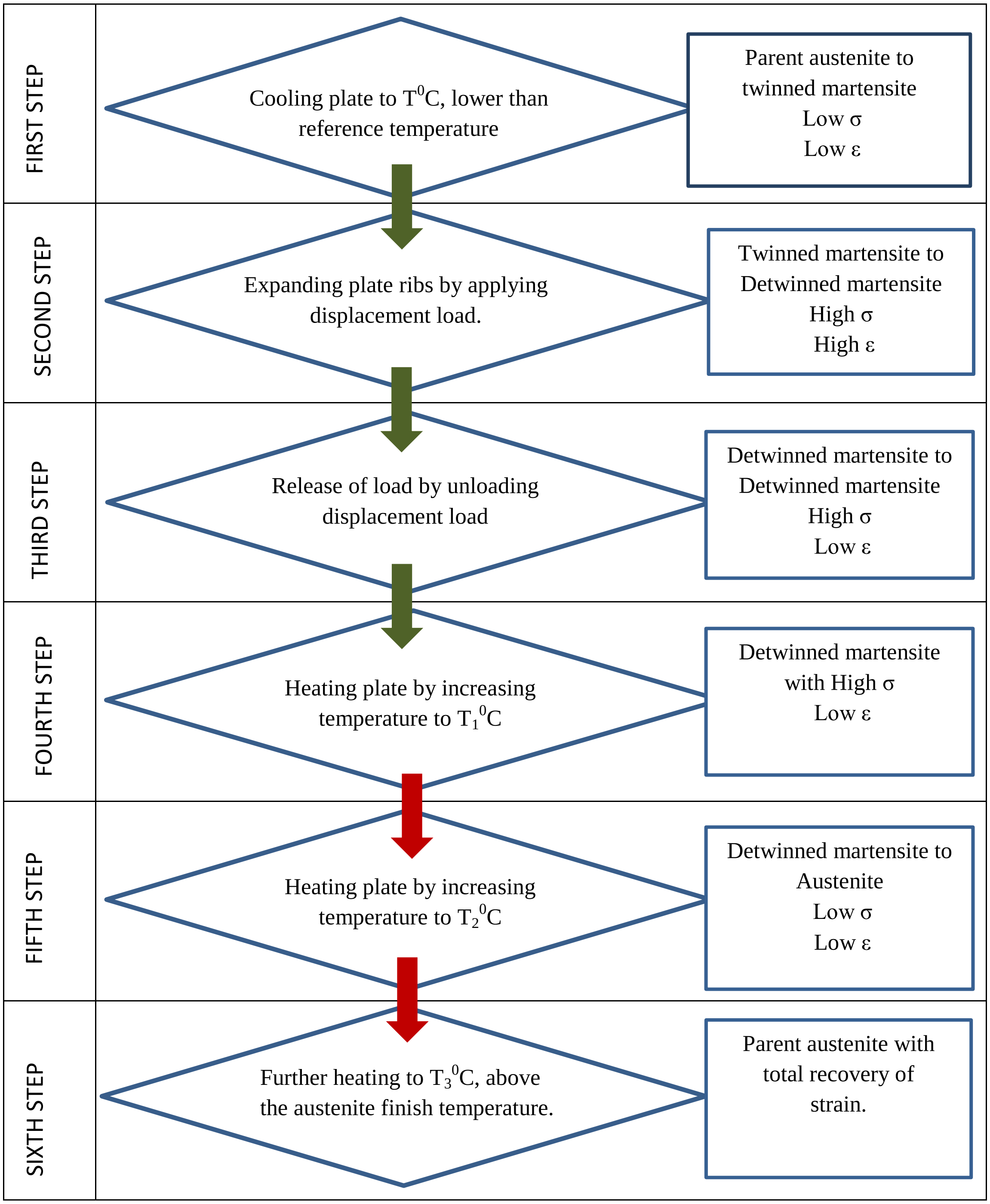
Material Phase Transformation

done by using EKILL and EALIVE command for the contact elements of contact pair 2. The elemental component named CONTACT is made which includes elements of contact pair 2. This elemental component facilitates in selecting all element for activating or deactivating rather selecting elements individually. In the similar way nodal components FX-, FX+ and BL are also made to applying loads on selected nodal component rather selecting individual node.

FX- and FX+ consist of nodes of ribs on which displacement load is applied in negative and positive x-direction respectively while BL is nodal component consist nodes of bone on which axial load is applied. The nodal coordinate system of all nodes of the nodal component FX- and FX+ are changed to active coordinate system when real geometry of bone is used. The active coordinate system is rotated by 60^0 about the negative z axis to generate same opening for the bone plate under the application of displacement loading along positive and negative x- axis.

The shape memory effect of shape memory alloys in ansys is based on the 3-D thermomechanical model for solid phase transformations. Hence temperature and structural loads are applied to simulate the shape memory effect. The loading is done in six load steps. Each load step is simulated as time step loading where time interval of each load step is taken as 1 second. Time step loading is done by writing code in ansys parametric design language. APDL code for time step loading

Table 5 Loading steps.



3. RESULT AND DISCUSSION

3.1 EFFECT OF NUMBER OF RIBS ON CONTACT PRESSURE

The assembly of bone plate is made with bone due to the shape recovery at the human body temperature. The effectiveness of assembly is depends on the contact pressure generated between bone and bone plate. Hence, contact pressure is set as the objective function for the proper gripping of bone plate with the bone.

The number of ribs is an important parameter for the design of bone plate but as the number of ribs increases, run time for finite element analysis increases. An annular circular plate with dimension as specified in table with material properties of SMA1 is considered to investigate dependency of contact pressure on number of ribs. The displacement load of 5 mm is applied on the ribs and further temperature load of 39^0 C is applied in three stages to make assembly of plate with bone.

Table 6. Dimension of annular plate.

PARAMETER	VALUES
Thickness	2.4 mm
Diameter	27 mm
Circumferential Angle	270^0
Length	5.5 mm

The average contact pressure in case of one rib and eight ribs is 7.26 and 6.85 Mpa and run time of finite element analysis is approximately 44 minutes and 6 hours 37 minutes respectively. The difference of contact pressure is negligible in case of one rib and eight ribs. But run time of finite element analysis in case of one rib is very less compared to case of eight ribs. Hence, contact pressure is considered as independent of number of ribs to take advantage of less run time of finite element analysis. Further on, analysis for material selection and design parameters has been done with bone plate consisting only one rib.

3.2 ANALYSIS FOR SELECTION OF MATERIAL

The main objective function for proper assembly is contact pressure as discussed earlier. The design considered for material selection consists of only one rib and has dimension as specified in table. The analysis is carried out for materials as specified in table 3.1 and results are analyzed for contact pressure. Average contact pressure obtained in case of three materials is represented as a column chart as shown in Figure 4.4 The maximum average contact pressure is obtained in case of SMA1. So, SMA1 is best suited as bone plate material for the further analysis on the basis of contact pressure.

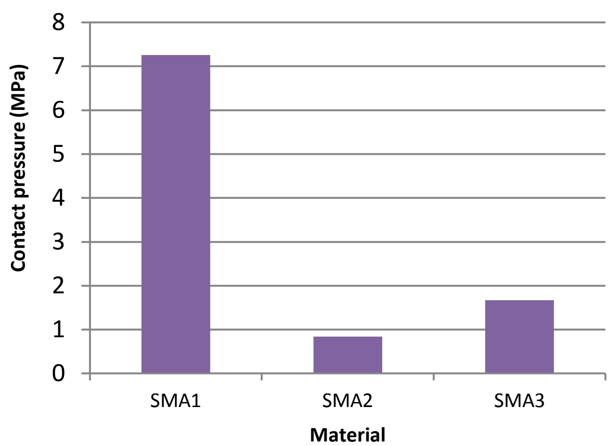


Figure 2 Column chart of average contact pressure for SMA1, SMA2 and SMA3.

3.3 DESIGN PARAMETER ANALYSIS

The combinations of three levels of design parameters of bone plate are considered as per L9 table of Taghuchi method of optimization. The finite elemental analysis of bone plate is carried out for all these cases. The results for contact pressure are analyzed in every case and one set of design parameters is opted depending on the maximum value of average contact pressure. The average contact pressure in each case is plotted as column graph in Figure 4.14. The maximum average contact pressure is achieved in case 9 i.e G9R1M1. So, the design parameters corresponds to case 9 are selected to perform further analysisThe generated contact pressure at the interface of bone and bone plate is validated with the results obtained by C Ko et.al[8] . Contact pressure generated in the present work and the results obtained by C Ko et.al are compared as a column chart as shown in Figure 4.15.

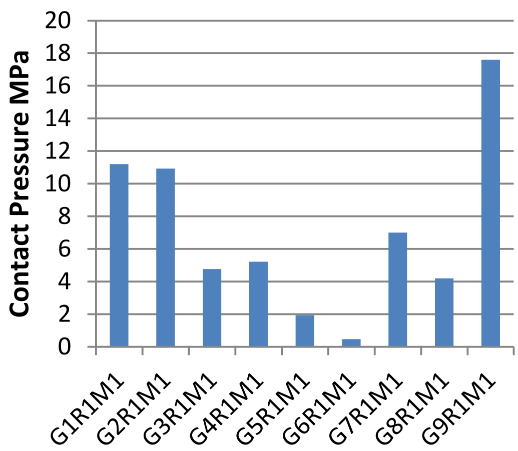


Figure 3 Column chart of contact pressure for all nine cases.

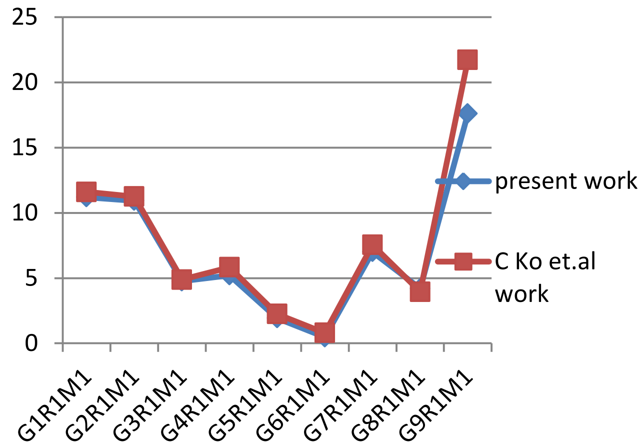


Figure 4 Validation of present work with C ko et.al work.

The loading is done as discussed previously with and addition load step for axial pull loading at the nodal component BL. The bone plate and femur CAD model assembly is able to sustain 600 N of axial pull with very less axial displacement i.e 0.582 mm. The contour for axial displacement under the axial pulling load is shown in Figure 5. Axial displacement is 0.5826 under axial pull of 600 N which is very less. So, the assembly of bone and bone plate is able to sustain axial pull. Hence, Contact pressure is within the yield limit of human femur bone and also has enough magnitude for stable bone plate and femur CAD model assembly.

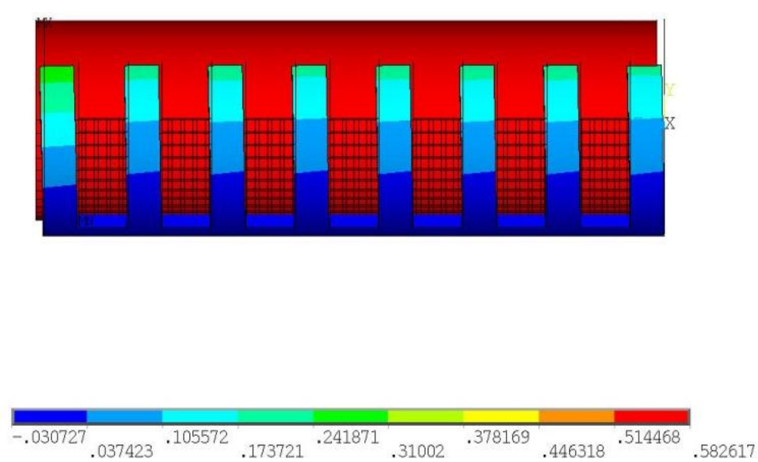


Figure 5 Contour of axial displacement under the axial pulling load of 600 N.

3.4 EFFECTIVNESS OF SMA BONE PLATE

Appropriate mechanical stimulus such as stress or strain or micro-movement at the fracture site stimulates growth of curing tissue (callus). Based on BHN theory, strain ranging from 2 % to 10 % is suggested as the most appropriate condition for healing bone. Hence, percentage of body weight which the femur should undergo to provide strain within 2% to 10 % at fracture site is investigated for all the fracture healing stages. The finite element model of bone plate and femur CAD model with the boundary condition is shown in Figure 6.

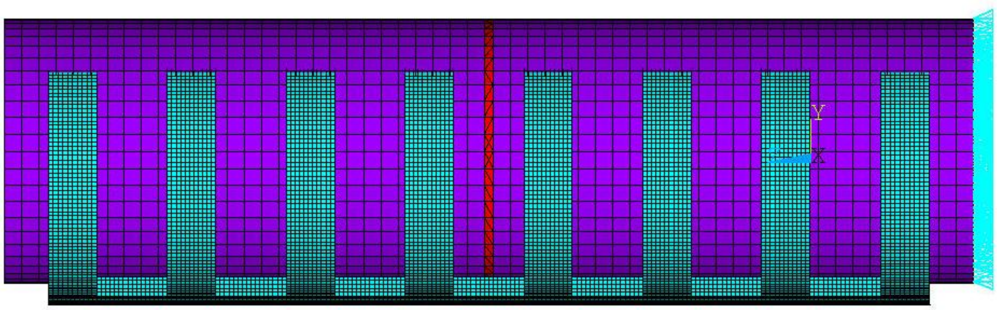
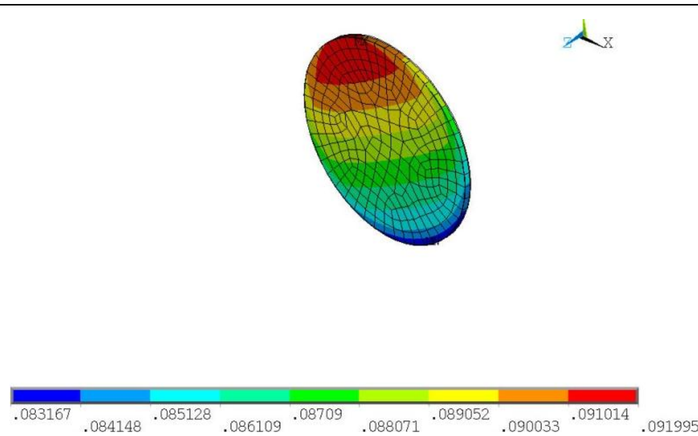
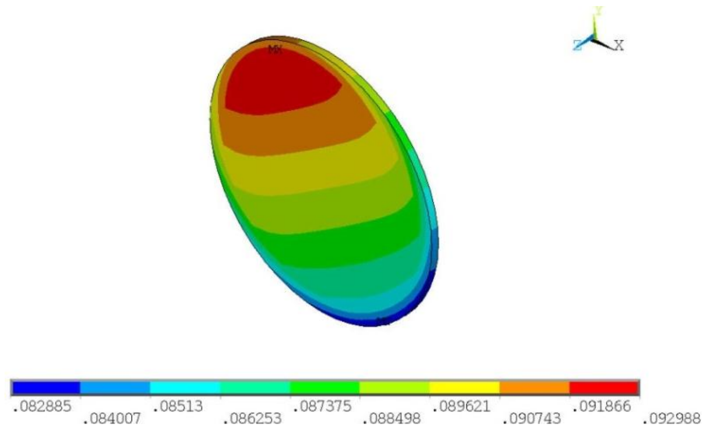
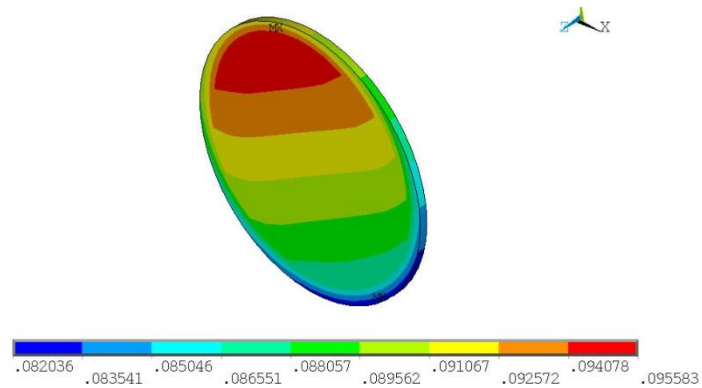
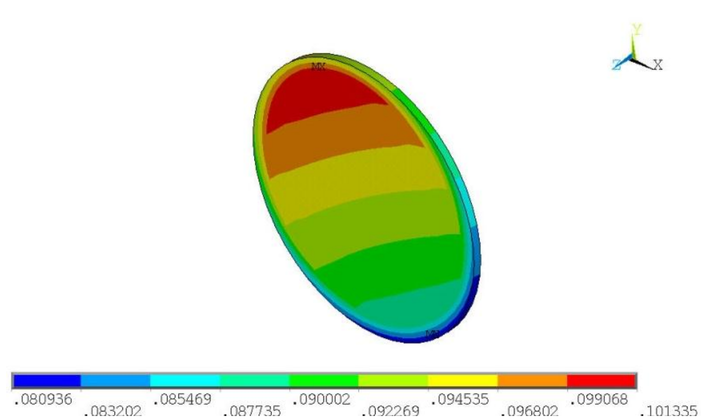
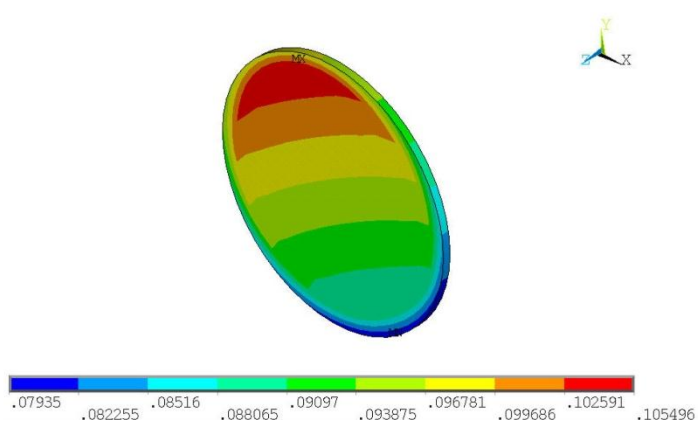
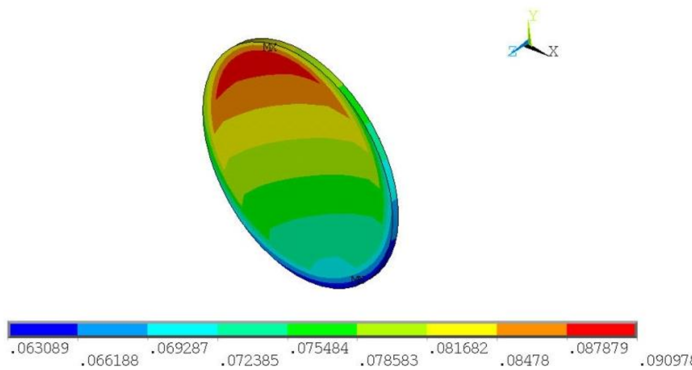


Figure 6. Finite element model of bone plate with femur bone having callus at fractures site.

The fraction of body weight is applied to the femur end at the different healing stages and value of loads that produce strain within 2 % to 10 % are shown below along with the contours of total mechanical strain at callus for different healing stages.

Healing Stage	**Total mechanical strain contours of callus**
Healing Stage 1 **Load- 50 N**	

Healing Stage 2 **Load- 100 N**	
Healing Stage 3 **Load- 200 N**	
Healing Stage 4 **Load- 400 N**	

Healing Stage 5 **Load- 500 N**	
Healing Stage 6 **Load- 600 N**	

After the implantation of bone plate at fracture site, these are the loads which can be applied at the fractured bone as a part of body weight at different healing stages of bone for the faster healing of callus.

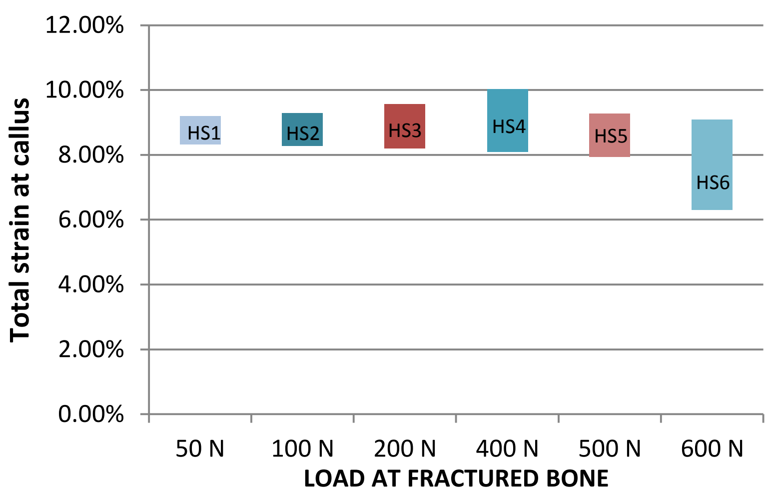


Figure 7 Floating column chart for load and total strain at callus in different healing stages.

4. RESULT AND DISCUSSION

The present work aims to examine major design factors of femur fracture fixation plate made of shape memory alloy. The design factors are optimized using Taguchi method and finite element analysis is carried out in two parts. Firstly, optimum design parameters are investigated considering contact pressure as objective function. Then bone plate with optimum design parameters is assembled with fractured bone to investigate the effectiveness of bone plate. To this end, finite element analysis is carried out and conclusions are as follows-

1. Among the three materials SMA1, SMA2 and SMA3, it is found that SMA1 bone plate generates maximum contact pressure while SMA2 bone plate generates minimum contact pressure.
2. Average contact pressure is found maximum in case of G9R1M1 (inner diameter 27 mm, circumferential angle 270 deg and thickness 2.4 mm) while minimum in case of G6R1M1 (inner diameter 28 mm, circumferential angle 240 deg and thickness 2.4 mm).
3. Average contact pressure for bone plate with optimum design parameters is 17.59 MPa and 12.31MPa in case of CAD and CT scan model of femur bone respectively, which is much lower than yield value of femur bone but at the same time sufficient to sustain pulling force of 600 N.
4. For every healing stage, fraction of body weight which the fractured bone should undergo for the optimum fracture healing is investigated. For optimum fracture healing, it is found that patient with fractured bones and SMA bone plate should provide axial load to fractured femur but not more than 50 N, 100 N, 200 N, 400 N and 600 N during healing stage 1, 2, 3, 4, 5 and 6.

5. The required axial load for optimum fracture healing can be provided as the fraction of body weight by using cane or other support during walking. It is found that as the callus grew to healing stage 6, application of load equivalent to average weight of human leads to the strain required for optimum fracture healing.

REFERENCES

1. Muller, M.E., Allgower, M., Schneider, R. and Willengger, H., Manual of Internal Fixation, Techniques Recommended by the AO-ASIF Group, 3rd Edition, (1991), Springer-Verlag, New York.

2. Burstein AH, Currey J, Frankel VH, Heiple KG, Lunseth P, Vessely JC, Bone strength: the effect of screw holes, J bone joint surg/Am/1972;54-A:1143-56.

3. Akeson WH, Woo S, Rutherford L, Coutts RD, Gonslaves M, Amiel D. The effects of rigidity of internal fixation plates on long bone remodeling.Acta orthop Scand 1967;47:241-9

4. Pivonka,P., Komarova, S.V., 2010, Mathematical modeling in bone biology : from intracellular signaling to issue mechanics. Bone 47 (2), 181-189.

5. Pivonka,P.,Dunstan,C.R., 2012, Role of mathematical modeling in bone fracture healing, BonekEy rep1.

6. Claes, L., Recknagel, S., Ignatius, A., 2012. Fracture healing under healthy and inflammatory conditions. Nat. Rev. Rheumatol. 8 (3), 133-143.

7. Elliot, D.S., Newman, K.J.H., Forward, D.P., Hahn, D.M., Olliver, B., Kojima, K., Handley, R.,Rossiter, N.D.,Wixter, J.J., Smith, R,M., Moran, C.G., 2016. A unified theory of bone healing and nonunion. BHN Theory 98-B (7), 884-891.

8. C Ko, M Yang, T Byun, SW Lee. Design factors of femur fixation plate made of shape memory alloy based on taguchi method by finite element analysis. International Journal For Numerical Methods In Biomedical Engineering, 2018, 34(4-5),78-93.

9. Petrini L, Migiavacca,F. Computational studied of biomedical application of shape memory alloys. J.Metall. 2005, 23(4-5), 112-119.

10. Enhorn, T.A.,Gerrstenfeld, L.C., 2015. Fracture healing: mechanisms and interventions. Nat. Rev. Rheumatol. 11 (1), 45-54.