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Design and experimental evaluation of super alloy bone plates for transverse fractured tibia bone using Inter-fragmentary strain theory

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Abstract

Fractured tibia bone healing is primarily influenced by themechanical and biological environment at the fracture site. Inter-fragmentary strain and Von-Misses stress developed at the callus formation play a crucial role in the timely healing of the bone which isaffected by design and material of the bone fixation plate.This paper presents an investigation on the design of tibia bone plates made of titanium alloy (C, 0.10 %; N, 0.03 %; O2, 0.25 %; H2, 0.015 %; Fe, 0.30 %; and Ti, 99.03 %.)to improve bone remodeling and efficient fracture healing. A time-dependent analysis up to 16 weeks in the interval of 4 weeks is carried out to analyze the healing process of a fractured bone under various loading conditions. The healing of the bone is analyzed using Finite Element Analysis (FEA) to determine the Inter-fragmentary strain (IFS) between 2%-10% to get optimal healing results which depend on different parameters of the bone plates like the plate thickness, working length, thegap between the bone and bone plate. Moreover, these parameters are varied with an objective to minimise the stress on the bone as it hinders the blood supply into the bone. Results indicatethe behaviour of the Inter-fragmentary strain and Von-Mises stress on the bone and bone plate throughout the healing period with varying loading conditions.

Keywords: Tibia Bone; Inter-fragmentary Strain Theory; Finite Element Analysis; Bone Plates; Titanium Alloy.

1. INTRODUCTION

Fracture in tibia bone occurs in many ways depending on the external load acting on the bone during impact. Different types of tibia bone fractures such as stable fracture, transverse fracture,oblique fracture, spiral fracture, comminuted fracture, and open fracture and their characteristics depend on the external load acting on the bone during impact [6].Three major phasesof fracture healing are reactive, reparative, and remodelling phase[10]. Bone plates stabilise fractures while allowing for adequate compressive force on the fracture ends and decrease the fracture gap by the formation of endosteal callus [21]. Mechanical loading environment is known to have an influence on bone’s mass, structure, the control of interfragmentary movement and implant failure [19].As the callus formation rate is directly proportional to the compressive force between the fracture ends, shielding due to bone plates, delays callus formation, which retards the bone healing rate [2][8].From a biomechanical point of view, fracture fixation must possess sufficient stability, to reduce interfragmentary movement occurring due to external loading and muscle activity to such an extent that it promotes timely and fruitful fracture healing. In general, parameters which influence fixator stiffness are its material properties, geometry of the fixator , fixator position relative to bending direction (plate fixator), number and position of screws, screw type, arrangement of screws, the offset distance from the underside of the fixator to the bone surface (internal plate fixator) [25].The success of any internal fixation depends on the ability to maintain interfragmentary compression. Locked implants like the locking compression plate maintain the interfragmentary compression preliminarily applied by a reduction clamp [14].

Over the years there has been a significant change in the design of bone plates where callus formation, blood supply and stress shielding explains the causes of poor bone healing due to the design of the bone plate.As conventional non-lock plating disrupts the periosteal blood supply and to improve plate fixation even in poor bone stock, the concept of locked plating was developed where the screws are directly fixed to the plate, acting as an internal fixator. Therefore, direct plate to bone contact is no longer required. However, hardware failures such as plate breakage still occur. Required stability and flexibility are measured by the stiffness of the whole bone-plate construct and the movement between the bone fragments at the site of the fracture. Some of the key factors that affect the stiffness and fracture movement are the thickness and material properties of the plate, along with the design, positioning and number of the screws[8].

Hence, this study considers various factors affecting the bone healing process like thickness, working length and gap between the plate and the bone. While designing a bone plate, one should understand the effect of the material surface of the bone plate. From the definition of biocompatibility [3], we can conclude that while choosing proper materials for bone plates one should analyse the corrosion resistance and tissue reaction to the material. Based on corrosion resistance and tissue reactions for various elements and practical alloys, titanium and Ti-alloys categorised as vital and therefore biocompatible and on the contrary that some metallic elements like Cu are categorised as toxic[22].Another aspect deduced from the definition of biocompatibility is the influence of the surface characteristics on bone integration. The previous study sorted that pure Titanium plates with rough surfaces have the best bio-adhesion [4].

In this paper, we focus on the transverse bone fracture in a tibia bone and the design of bone plateplays a crucial role in developing effective, safe and reliable implant especially to reduce problems due to stress shielding, delay of bone healing and formation of weaker bone. In this current study, we analysed the effect of thickness, working length, and the gap distance on healing characteristics of the bone based on two theories namely IFS theory where it suggests that IFS in the fracture gap ranging from 2% to 10% is beneficial for proper callus formation and timely bone healing. The other theory involved isthe design of flexible plating where the plates allow transfer of loads to the bone during initial stages of healing process ensuring a reduction in stress shielding of bones.One should consider the fact that too much flexibility also causes adverse effects due toincreasing in micro movements of the fracture gap, rupturing the tissue around the bone. Therefore, in this study,we primarily focus on designing bone plate for optimal flexibility and obtaining a reduction in stress shielding effect during the initial period of recovery. By maintaining the required fracture gap with proper IFS at the callus formation, considering the effect of thickness of the plate and working length using FEA to find the behaviour of these plate under the given load conditions and during different stages of healing.

2. MATERIALS AND METHODS

2.1Material Selection

Material choices for implementable biomedical products are limited owing to the requirements of biocompatibility, corrosion/fatigue resistance and the difficulties in obtaining regulation clearances. In recent years, Pt alloys are replaced by new titanium alloys owing to the latter's more economical production and better properties [18].There has been a significant increase in the use of titanium and its alloys as biomaterials stem due to their lower modulus, superior biocompatibility, and better corrosion resistance when compared to more conventional stainless and cobalt-based alloys [12]. As a hard tissue replacement, the low elastic modulus of titanium and its alloys is viewed as a biomechanical advantage because the smaller elastic modulus can result in smaller stress shielding. Hence, for the present study, pure Titanium (Grade-2) has been chosen as the test material. The chemical composition of work material taken for experimentation work as follows: C, 0.10 %; N, 0.03 %; O_2, 0.25 %; H_2, 0.015 %; Fe, 0.30 %; and Ti, 99.03 %.

2.2 Designing of bone plate

2.2.1 Geometric Modelling

A Solid Works model developed for both the fractured bone and locking compression plate. A generic plate available in the market and based on vivo studies on different manufactures of bone plates, synthes bone plates are taken as reference due to their smaller length and higher load bearing capacity and modifications are made to obtain the desired results [16].

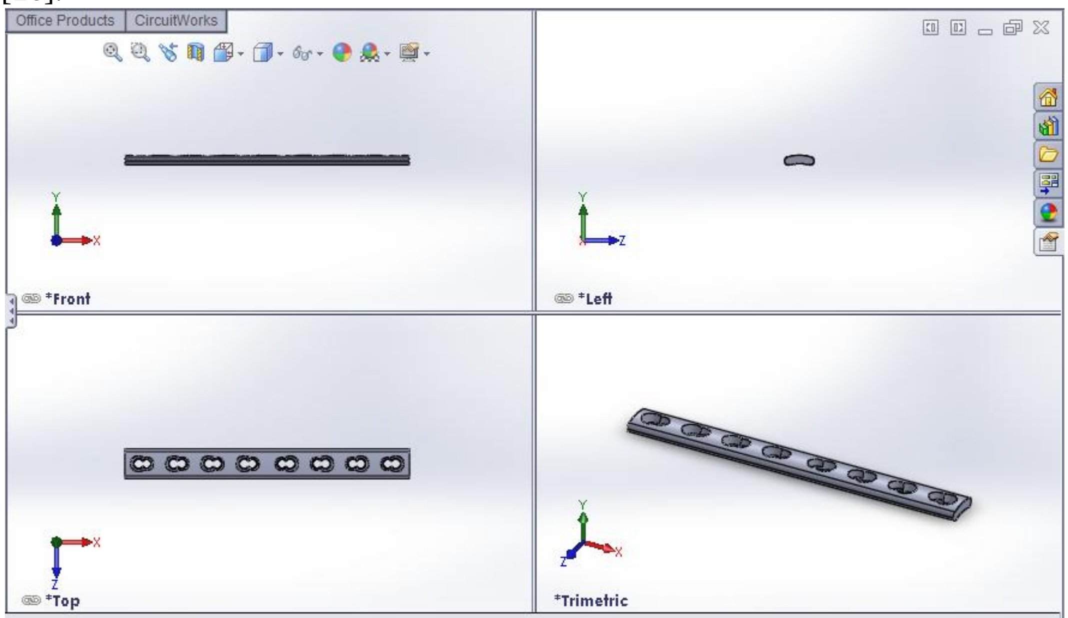

Figure 1a: Geometric Model of Locking Compression Bone Plate

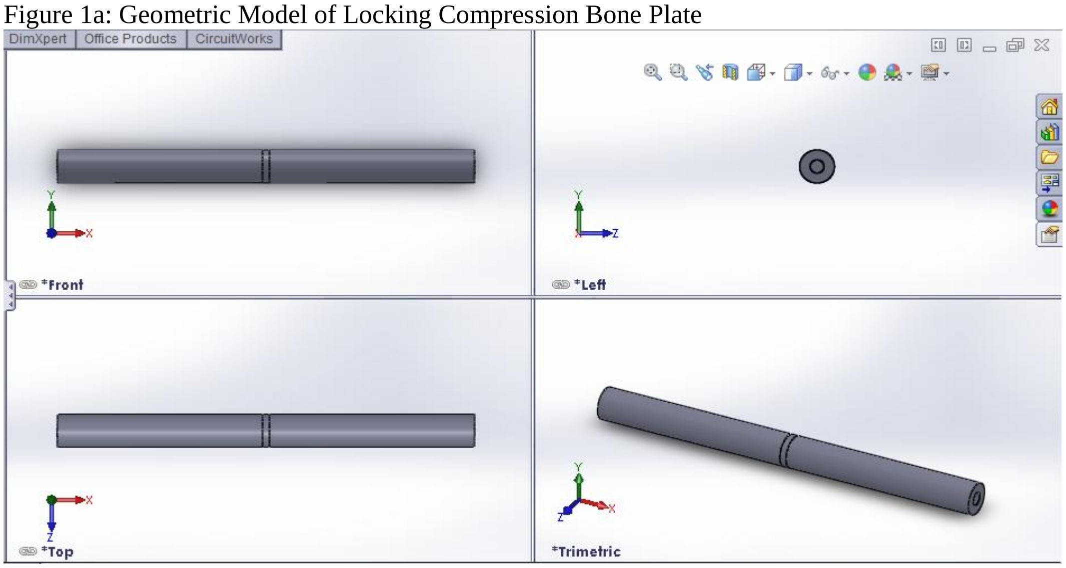

Figure 1b: Geometric Model of Tibia Bone

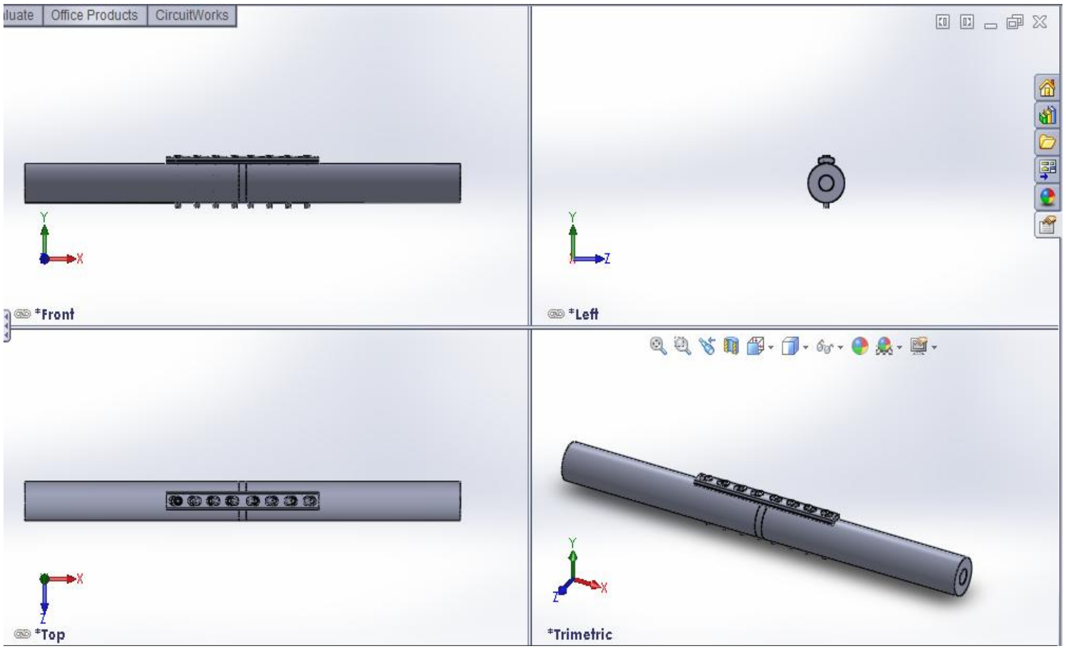

Figure 1c: Assembly of Bone and the Bone Plate

Figure 1a, 1b, 1c shows different geometric models created in this study using SOLIDWORKS software. Tibia bone has an irregular cross-section consisting of a foam-like trabecular bone and cortical bone. To visualise a tibia bone, a cortical bone simplified as a cylinder and the trabecular bone modelled as a circular rod within the cortical bone cylinder [13]. The tibia model has a fracture gap of 5 mm which is filled by the curing tissue (callus) as healing progress; thus, the callus moduli vary throughout the healing period. The bone plate considered in this study has a slender shape with eight screw holes and a curved cross-section.

Different thickness of bone plate starting from 3mm to 4.5mm with an increment of 0.5 mm is used to analyse the effect of thickness of bone plate on IFS and stress-shielding. Table 1a, 1b, 1c and 1d mentions the dimensions utilised in this study for various parts such as trabecular bone, cortical bone, locking compression plate, and locking screw respectively.

Table 1a: Dimensions of Cortical Bone

Shape	Hollow cylinder
Length	300 mm
Outer Diameter	25 mm
Inner Diameter	10 mm
Fracture Gap	5 mm

Table 1b: Dimensions of Trabecular Bone

Shape	Solid cylinder
Length	300 mm
Diameter	10 mm
Fracture Gap	5 mm

Table 1c: Dimensions of Locking Compression Plate

Length	105 mm

Width	11 mm
Thickness	3,3.5,4,4.5 mm
Number of holes	8
Gap between holes	13 mm

Table 1d: Dimensions of Locking Screw

Pitch Diameter	3.5 mm
Pitch Distance	0.8 mm
Pitch angle	60
Head Diameter	5 mm
Height	26 mm

2.2.2 Analysis Condition

The bone with a transverse fracture (5 mm gap) simplified by a hybrid cylinder composed of cortical and trabecular bones[13]. Small sized fractures gaps are filled with the help of bone plates and fractured bone without any bio material [17]. The central callus is most sensitive to the external mechanical stimulus during the healing period [5]. Therefore, our primary focus in this study is to model the central callusfor analysing the IFS acting on it. The isotropic material properties of bones [26], [28] and titanium bone plates listed in Table 2. Although the properties of bone have anisotropic behaviour, yet for this study they are assumed to have isotropic properties along all directions.

Table 2: Elastic properties of Bone

Material	**Young's Modulus (Mpa)**	**Poisson's ratio**
Titanium (Grade 2)	105	0.37
Cortical Bone	15	0.3
Trabecular Bone	1.1	0.225

Calluses generated at the fracture site have different healing rates and properties according to the IFS developed at the site[20].Callus modulus measured at regular, 4-weeklyintervals after surgeryis chosen as thecriterion for timely healing of the bone [9]. Immediately after surgery, only soft granulation tissues (E = 0.02 MPa) are considered to be generated at the fracture site [15]. The callus properties according to the healing period listed in Table 3 [13]. The friction coefficient of 0.4 was taken for all the contact surfaces involved, based on clinical research [7].

Table 3: Time-dependent elastic properties of callus

S.no	**Duration**	**Young's Modulus (MPa)**	**Poisson's ratio**
1	0-4 weeks	0.02	0.3
2	4-8 weeks	0.19	0.3
3	8-12 weeks	28	0.3
4	12- 16 weeks	30	0.3

The second step of the analysis was a loading process under axial compression forces considering the patient's gait cycle where one end of the tibia was fixed in all directions, and an axial force applied to the other end of the tibia. In general, the patient's walking pattern is incomplete—using crutches, the injured leg does not make contact with the ground for a while after surgery. During this period, the injured leg is under a no-load condition; however, some forces are transferred to the tibia by muscles such as the gastrocnemius and soleus around the fracture site [11],[1].In a normal gait cycle, one leg steps on the ground which usually resists a maximum of about 300% of body weight [19].At the same time, the other leg is in a swing phase and does not contact the ground. In the swing phase, some forces are generated by the adjacent muscles, and these forces are known to be in the range of 0–10% of body weight [11]. From these clinical observations, a loading condition of 10% of body weight (700 N x 10%) of a 70kg person during the early period of healing (until eight weeks after surgery) was used in this study. As the healing time elapses, the bony union proceeds and the fracture is partly healed. By considering this healing process, it was assumed that 100% of the body weight was imposed on the tibia until 12 weeks due to the incomplete gait pattern. From 12-16 weeks, it was assumed that the body carries 150% of body weight (Table 4)[13]. These time-dependent loading conditions were applied in the finite element model to calculate the IFSs at the fracture site, and the stresses in the bone plate and bone.

Table 4: Time-dependent loading conditions for analysis

S.no	**Duration**	**Body mass (kg)**	**Loading condition**	**Load (N)**
1	0-4 weeks	70	10 % of Body weight	70
2	4-8 weeks	70	10 % of Body weight	70
3	8-12 weeks	70	100% of Body weight	700
4	12-16 weeks	70	150% of Body weight	1050

2.2.3 Finite Element Analysis (FEA)

FEAis used in the design and evaluation of internal fixation plates and screws to overcome the significant weaknesses of current fixation devices in regards to fatigue failure of the plate and stress-shielding of the bone. The 3D finite element model is analysed using ANSYS Workbench software (version- 15, ANSYS Inc., USA).

Inter-Fragmentary Strain (IFS) defined as the ratio of the fracture gap displacement after the body load applied and the original fracture gap length [27]. In the current study, the IFS theory was used to correlate the level of stimulus (strain) and the corresponding callusstatus. An appropriate mechanical stimulus such as relative micro-movement at the fracture site stimulates generation of callus [20]. IFSs ranging from 2% to 10% suggested as the most appropriate condition for healing bone fractures. Small strains (below2%) have the same effect as an indirect bone healing method. Further, excessive strains (over 30%) cause bone resorption. As the healing period elapses, the fracture gap is filled with curing tissues such as callus, and mechanical properties of the tissues improve. However, this improvement is entirely dependent on the level of mechanical stimulus at the fracture site.

The effects of following conditions were analysed:

(i) Bone plate thickness: Four plate sizes with varying thickness (3mm, 3.5mm, 4mm, and 4.5mm) are analysed with the time-dependent load condition to study its effect on IFS in the fracture gap.

(ii) Working length: The optimal plate is chosen according to plate thickness, and the effect of working length is analysed for proper IFS and better stress shielding effect. In this study, the first step ofthe analysis is carried out with all screws fixed to the bone and furtherremovingtwo innermost screws until better output characteristics obtained.

(iii) Effect of distance between plate and bone: Full contact or no gap between bone and the bone plate results in higher contact stress, and it also diminishes the flow of blood around the fracture gap. As the gap between the bone and plate increases, the rigidity as well as stiffness of the implant decrease. The optimal plate analysed for three gap profiles (0 mm gap, 0.5 mm gap, 1 mm gap).

3. RESULTS

3.1 Effect of bone plate thickness on fractured bone

The effects of plate thickness are analysed where deformation of the callus is studied using the FEA with an increment of 0.5mm starting from plate thickness of 3mm depicting total deformation during the initial recovery period of 4 weeks. Figure 2a, 2b,2c and 2ddepict the results of deformation in meters at the fractured gap which is filled with callus during the application of load and also show the deformationwith achange in thickness of the plate during the initial period of recovery (i.e., 0-4 weeks).

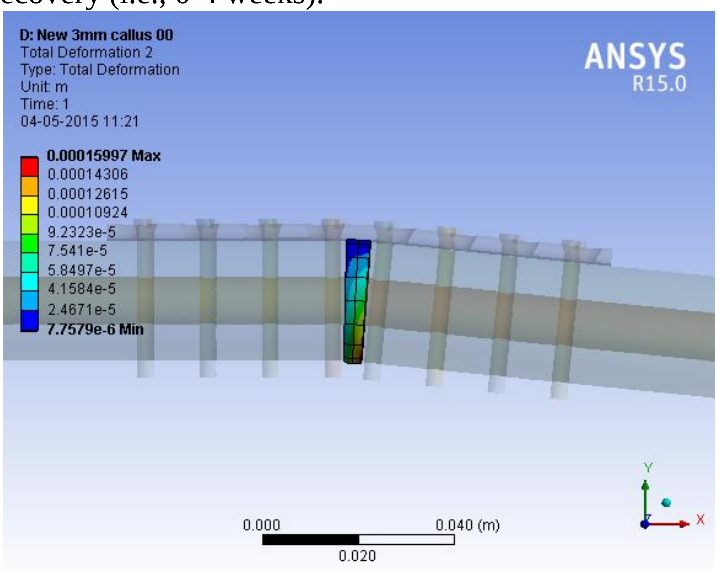

Figure 2a: Deformation at callus for a 3 mm thick bone plate during 0-4 weeks

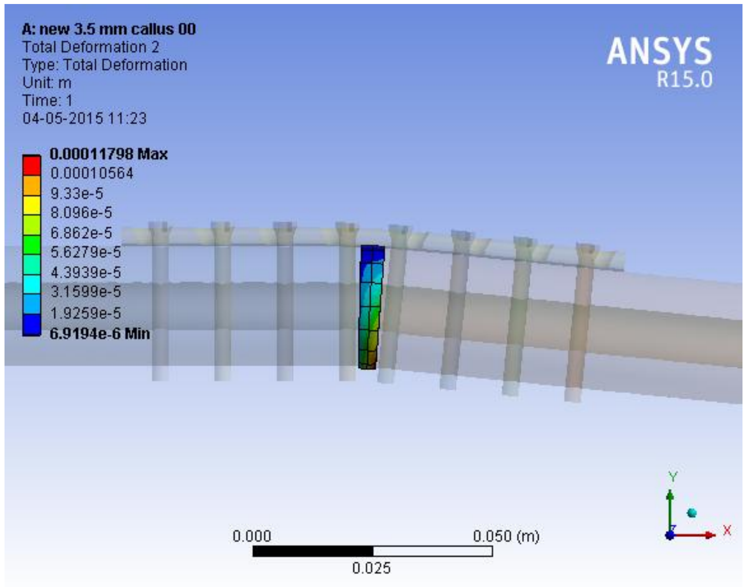

Figure 2b: Deformation at callus for a 3.5 mm thick bone plate during 0-4 week

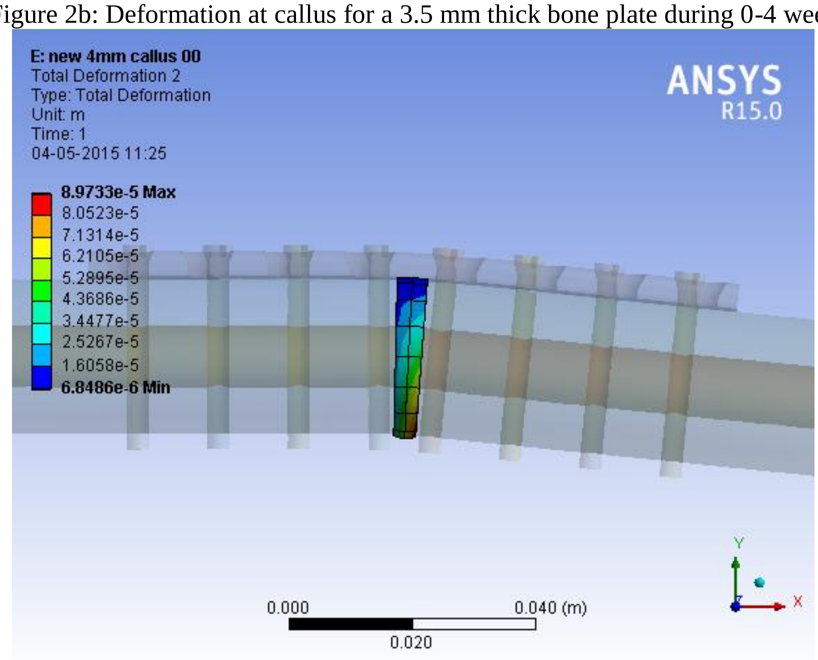

Figure 2c: Deformation at callus for a 4 mm thick bone plate during 0-4 weeks

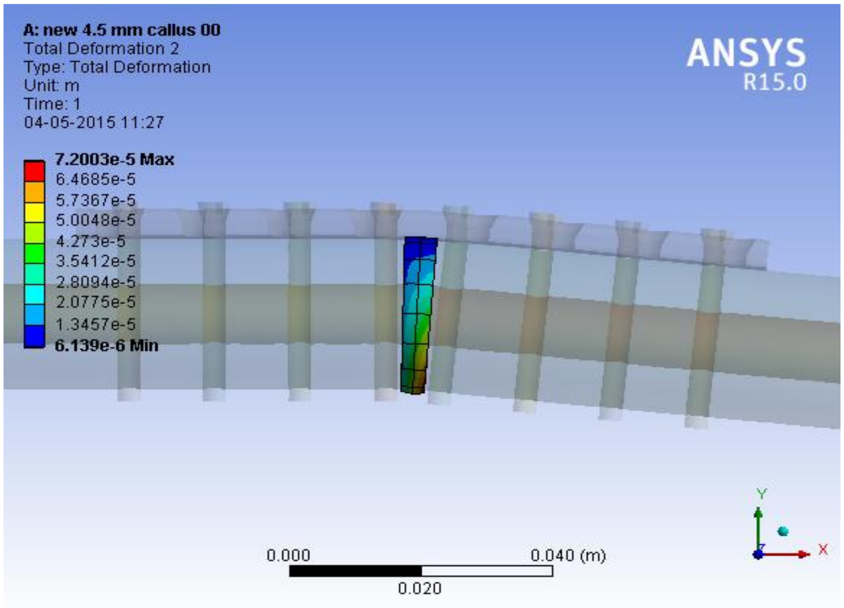

Figure 2d: Deformation at callus for a 4.5 mm thick bone plate during 0-4 weeks

Table 5a, 5b, 5c, 5d depicts the results of IFS and Von-Mises stress acting on the bone and bone plate were obtained by varying the thickness of the plate keeping other parameters constant in the analysis. Deformation in the callus and Max IFS are found with different thickness.

Table 5a: Results for IFS and Von-Misses stress during 0-4 weeks with variable thickness

S.no.	**Plate Thickness (mm)**	**Deformation in callus (m)**	**Max. IFS (%)**	**Max. Stress on Plate (Pa)**	**Max stress on bone (Pa)**
1	3	1.60E-04	3.1994	8.89E+07	1.47E+07
2	3.5	1.18E-04	2.3596	6.37E+07	1.37E+07
3	4	8.97E-05	1.79466	5.13E+07	1.31E+07
4	4.5	7.20E-05	1.44006	3.89E+07	1.30E+07

Table 5b: Results for IFS and Von-Misses stress during 4-8 weeks with variable thickness

S.no.	**Plate Thickness (mm)**	**Deformation in callus (m)**	**Max. IFS (%)**	**Max. Stress on Plate (Pa)**	**Max stress on bone (Pa)**
1	3	1.56E-04	3.1284	8.70E+07	1.47E+07
2	3.5	1.16E-04	2.3212	6.27E+07	1.37E+07
3	4	8.86E-05	1.77264	5.07E+07	1.31E+07
4	4.5	7.13E-05	1.42606	3.86E+07	1.30E+07

Table 5c: Results for IFS and Von-Misses stress during 8-12 weeks with variable thickness

S.no.	**Plate Thickness (mm)**	**Deformation in callus (m)**	**Max. IFS (%)**	**Max. Stress on Plate (Pa)**	**Max stress on bone (Pa)**
1	3	3.21E-04	6.4198	1.64E+08	1.62E+07
2	3.5	3.04E-04	6.0848	1.49E+08	1.65E+07

3	4	2.86E-04	5.7124	1.48E+08	1.70E+07
4	4.5	2.66E-04	5.3214	1.33E+08	1.79E+07

Table 5d: Results for IFS and Von-Misses stress during 12-16 weeks with variable thickness

S.no.	Plate Thickness (mm)	Deformation in callus (m)	Max. IFS (%)	Max. Stress on Plate (Pa)	Max stress on bone (Pa)
1	3	4.98E-04	9.95	2.16E+08	1.82E+07
2	3.5	4.20E-04	8.3982	1.96E+08	2.01E+07
3	4	3.97E-04	7.9498	1.95E+08	2.20E+07
4	4.5	3.73E-04	7.4694	1.77E+08	2.33E+07

Fig 3a, 3b shows the maximum stress acting on the bone and the bone plate during the entire healing period by varying the thickness keeping other parameters constant.

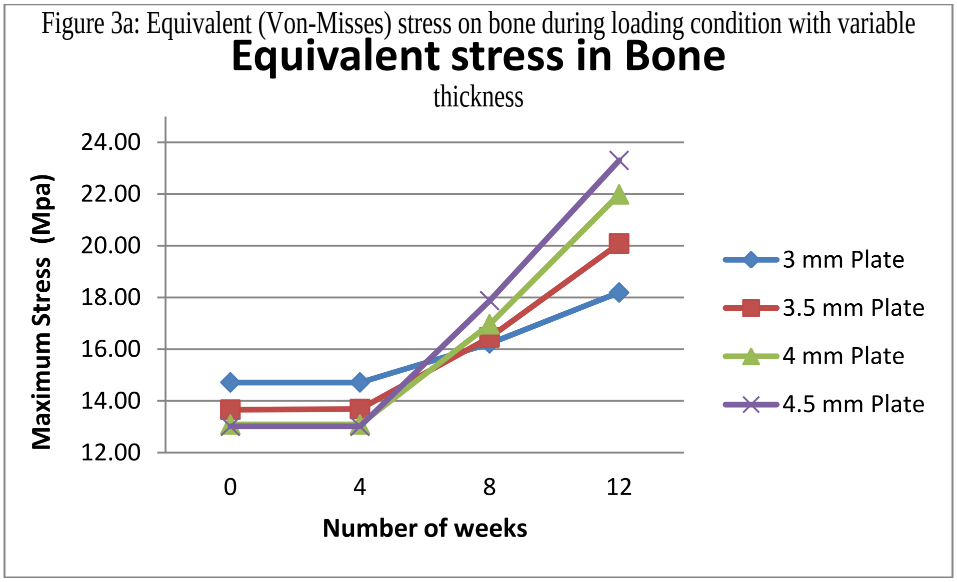

Figure 3a: Equivalent (Von-Misses) stress on bone during loading condition with variable thickness

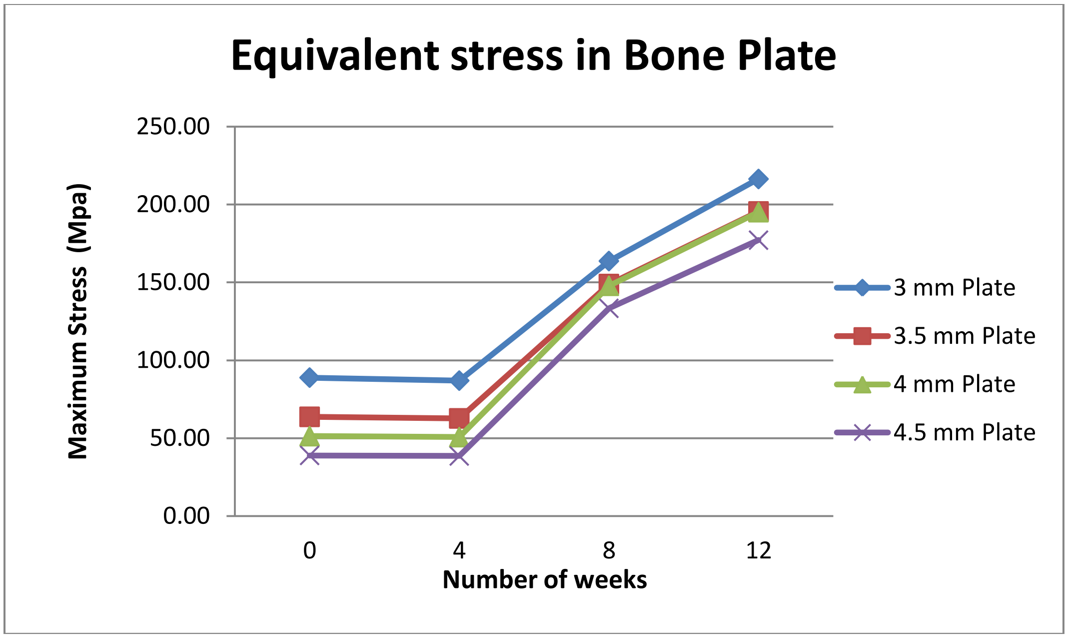

Figure 3b: Equivalent (Von-Misses) stress on bone plate during loading condition with variable thickness

3.2 Effect of working Length

To study the effect of working length, we considered aplate with thickness 3.5 mm as it provides optimum results regarding IFS and stress shielding. Working length is varied by removing innermost screws two at a time from the bone plate. Three working lengths (13 mm, 39 mm, and 65 mm)taken in this study. Fig. 4a, 4b, 4c shows the distribution of stress on the bone plate when different working lengths used.

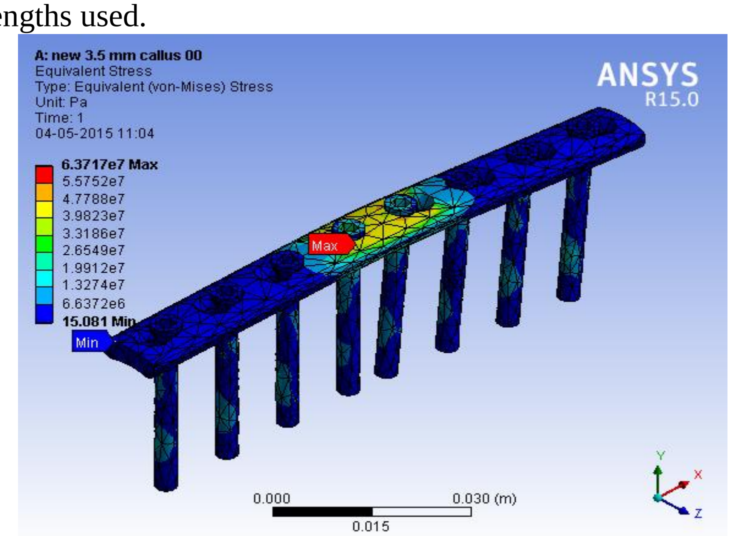

Figure 4a: Von-Misses stress on the bone plate when working length is 13mm

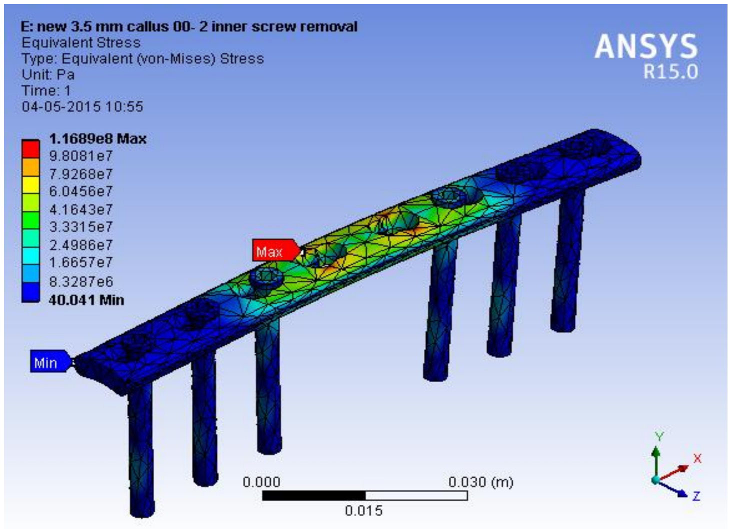

Figure 4b: Von-Misses stress on the bone plate when working length is 39mm

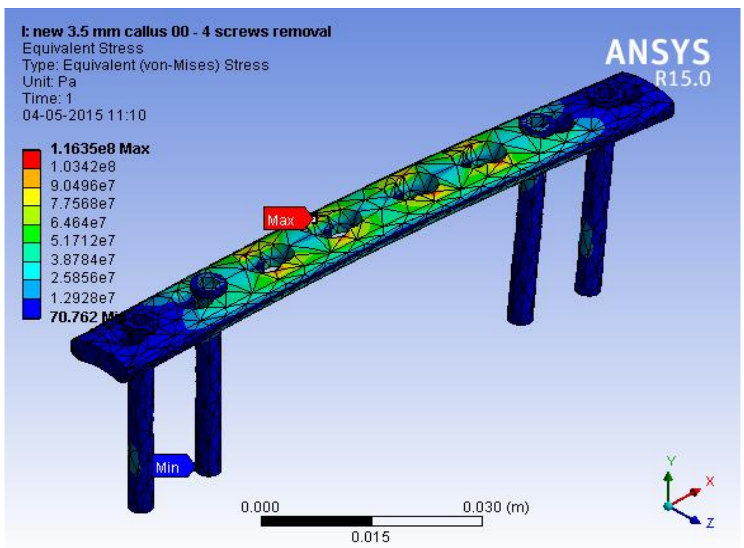

Figure 4c: Von-Misses stress on the bone plate when working length is 65 mm

Table 6a, 6b, 6c, 6d shows the results of IFS and von-mises stress acting on the bone and bone plate during 0-16 weeks varying the working length (13mm, 39mm and 65 mm). Deformation of callus is also found out to understand the behaviour of the callus under loading conditions with varying the working length.

Table 6a: Results for IFS and Von-Misses stress during 0-4 weeks with variable working length

S.no.	Working Length (mm)	Deformation in callus (m)	Max. IFS (%)	Max. Stress on Plate (Pa)	Max stress on bone (Pa)
1	13	1.18E-04	2.3596	6.37E+07	1.32E+07
2	39	3.40E-04	6.8038	1.17E+08	1.39E+07
3	65	5.91E-04	11.8216	1.16E+08	1.24E+07

Table 6b: Results for IFS and Von-Misses stress during 4-8 weeks with variable working length

S.no.	Working Length (mm)	Deformation in callus (m)	Max. IFS (%)	Max. Stress on Plate (Pa)	Max stress on bone (Pa)
1	13	1.16E-04	2.3212	6.27E+07	1.32E+07
2	39	3.20E-04	6.393	1.11E+08	1.38E+07
3	65	5.30E-04	10.6022	1.05E+08	1.24E+07

Table 6c: Results for IFS and Von-Misses stress during 8-12 weeks with variable working length

S.no.	Working Length (mm)	Deformation in callus (m)	Max. IFS (%)	Max. Stress on Plate (Pa)	Max stress on bone (Pa)
1	13	3.04E-04	6.0848	1.49E+08	1.65E+07
2	39	3.47E-04	6.944	1.09E+08	1.58E+07
3	65	3.58E-04	7.1608	6.73E+07	1.39E+07

Table 6d: Results for IFS and Von-Misses stress during 12-16 weeks with variable working length

S.no.	Working Length (mm)	Deformation in callus (m)	Max. IFS (%)	Max. Stress on Plate (Pa)	Max stress on bone (Pa)
1	13	4.20E-04	8.3982	1.96E+08	2.01E+07
2	39	4.74E-04	9.4866	1.42E+08	1.69E+07
3	65	4.87E-04	9.7432	8.70E+07	1.73E+07

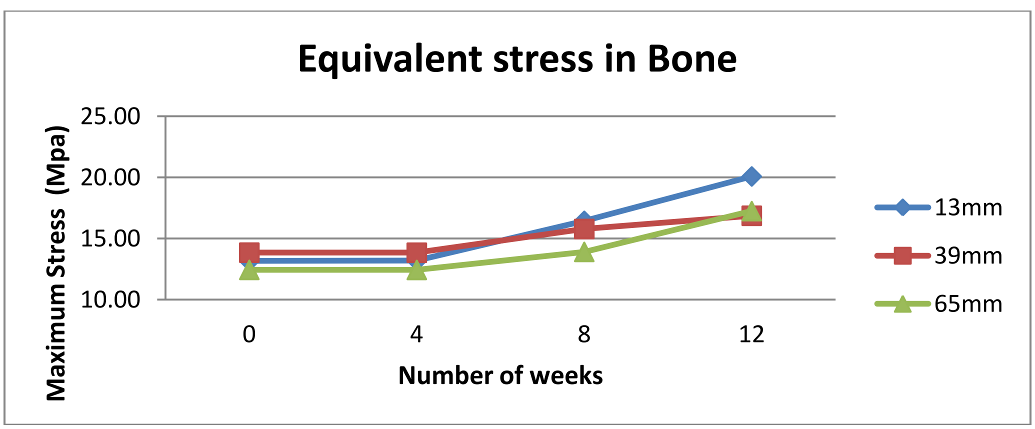

Figure 5a: Equivalent (Von-Misses) stress on bone during loading condition with variable working length

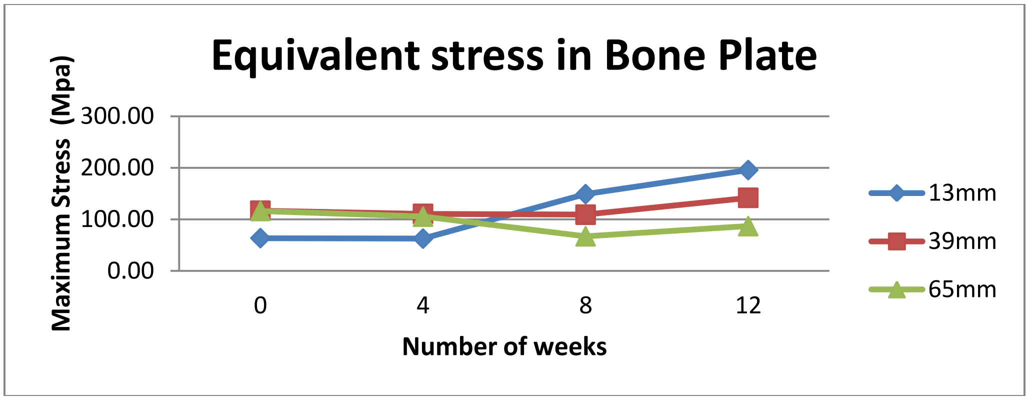

Figure 5b: Equivalent (Von-Misses) stress on bone plate during loading condition with variable working length

Fig 5a, 5b shows the maximum stress acting on the bone and the bone plate during the entire healing period by varying the working length (13mm, 39mm, 65mm) keeping other parameters constant.

3.3 Effect of Gap

The effect ofthe gap distance between bone and bone plate studied after choosing appropriate plate thickness (3.5 mm) and working length (65 mm) from the results above. Here, three configurations of gap distance are studied (no gap, 0.5 mm gap, 1 mm gap). Table 7a, 7b, 7c, 7d depicts the results of interfragmentary and Von Mises stress acting on the bone and bone plates during 0-12 weeks with variable gap distance.

Table 7a: Results for IFS and Von-Misses stress during 0-4 weeks with variable gap distance

S.no.	Gap (mm)	Deformation in callus (m)	Max. IFS (%)	Max. Stress on Plate (Pa)	Max stress on bone (Pa)
1	0	1.45E-04	2.9056	7.27E+07	1.20E+07
2	0.5	3.40E-04	6.8038	1.17E+08	1.39E+07
3	1	3.61E-04	7.2292	1.21E+08	1.34E+07

Table 7b: Results for IFS and Von-Misses stress during 4-8 weeks with variable gap distance

S.no.	Gap (mm)	Deformation in callus (m)	Max. IFS (%)	Max. Stress on Plate (Pa)	Max stress on bone (Pa)
1	0	1.42E-04	2.8478	7.12E+07	1.20E+07
2	0.5	3.20E-04	6.393	1.11E+08	1.38E+07
3	1	3.38E-04	6.7626	1.14E+08	1.34E+07

Table 7c: Results for IFS and Von-Misses stress during 8-12 weeks with variable gap distance

S.no.	Gap (mm)	Deformation in callus (m)	Max. IFS (%)	Max. Stress on Plate (Pa)	Max stress on bone (Pa)
1	0	3.16E-04	6.3118	1.40E+08	1.66E+07
2	0.5	3.47E-04	6.944	1.09E+08	1.58E+07
3	1	3.57E-04	7.1398	1.08E+08	1.53E+07

Table 7d: Results for IFS and Von-Misses stress during 12-16 weeks with variable gap distance

S.no.	Gap (mm)	Deformation in callus (m)	Max. IFS (%)	Max. Stress on Plate (Pa)	Max stress on bone (Pa)
1	0	4.34E-04	8.6866	1.85E+08	2.14E+07
2	0.5	4.74E-04	9.4866	1.42E+08	1.69E+07
3	1	5.20E-04	10.395	1.40E+08	1.63E+07

4. DISCUSSION

4.1 Effect of plate thickness

The effects of bone plate thickness on Inter-fragmentary Strain (IFS) in the fracture gap, and von-misses stress on the bone plate areanalysed by varying the thickness from 3 mm- 4.5 mm in increments of 0.5 mm.According to IFS theory from the above tables, it is inferred that plates witha thickness of 4 mm and 4.5 mm produce less than 2% IFS along the fracture gap during initial weeks of recovery (0-8 weeks). From these observations, we can conclude that as the plate thickness increases, the rigidity of implant increases and thereby reducing the flexibility of the bone plate which results in minor mechanical stimuli in the fracture gap. Hence, this condition is unfavourable for proper callus formation.

According to Table 5d, for the plate thickness of 3 mm, the IFS is found to be near 10% during 12-16 weeks. It indicates that smaller plate thickness have higher flexibility which is again an unfavourable condition for proper bone healing.Figure 3a and Figure 3bdepict the value of maximum stress experienced at bone and bone plate respectively. Figure 3a indicates that the maximum stress on the bone during initial stages of recovery developed when 3 mm plate used. As the thickness increases, thestressdrawn up on bone decreases resulting in higher stress shielding. These results comply with the previous studies [23] which show flexible plating reduces stress shielding effect on the bone. Both 3 mm plate and 3.5 mm plate provide better results regarding reduction in stress shielding effect but according to interfragmentary stress theory, the plate with thickness 3.5 mm is recommended as it also shows optimum behaviour (IFS between 2-10%) compared to the other plate thickness.

4.2 Effect of working length

It is evident from Table 6a and 6b, that when four screws removed (i.e., working length is 65mm), IFS exceeds 10% which isan unfavourable condition for bone healing. Fig. 5a and Fig.5b depict the value of maximum stress experienced atthe bone and the bone plate respectively when different working lengths used. Fig.5a shows that during the initial healing period, the bone plate of working length 39mm develops higher stress in the bone which helps in increasing the strength of the bone during the healing period. As the bone plates of working length 13 mm and 39 mm provide satisfactory results regarding IFS and as the bone plate with working length 39 mm has better stress shielding properties, it is recommended to choose the configuration of 3.5mm bone plate withthe removal of two innermost screws.

4.3 Effect of gap

It is evident from Table 7a that, during the later stage of healing, the IFS exceed 10% when the gap is 1 mm. Also, contact stress is developed when the gap eliminated, and it also hinders the blood supply to the bone. Hence, the difference of 0.5 mm between the bone and the bone plate is recommended for proper blood supply and optimal IFS. In addition, the validation of the results has been discussed with the statistical tests i.e. analysis of variance that is described as follows.

IFS versus Plate thickness

Analysis of Variance

Source	DF	SS	MS	F	P
Regression	1	1.7071	1.7071	57.81	0.017
Residual Error	2	0.0591	0.0295		
Total	3	1.7662			

Figure 6a: Regression analysis of IFS vs Plate Thickness

IFS versus Working length

Analysis of Variance

Source	DF	SS	MS	F	P
Regression	1	34.286	34.286	10928.43	0.006
Residual Error	1	0.003	0.003		
Total	2	34.289			

Figure 6b: Regression analysis of IFS vs working length

Using IFS as thedependent variable with different parameters on which the design of the plate was evaluated, regression analysis is performed to identify the significance of each factor in the design of the bone plate. From fig 6a, 6b we can observe that p-value in each case is less than 0.05 with a confidence level of more than 95%. From this, we can conclude that the results obtained from the simulation by varying the different parameters are statistically significant with the IFS where these parameters influence the growth of endosteal callus during healing.

5. CONCLUSION

The effects ofthe design of Bone Plate on healing efficiency are studied, and design modifications conducted for obtaining faster and efficient recovery of the fractured bone. The changes in design are performed by variable thickness, working length and gap distance between bone and the bone plate. The conclusions obtained are as follows:

1. Smaller thickness provides higher flexibility and helps in avoiding stress shielding effect. According to IFS theory, the plate thickness of 3.5 mm produced optimal results regarding better callus formation and less stress shielding effect.
2. The FEA of the geometric models reveals that 3.5 mm plate with working length 39 mm along with the gap distance of 0.5 mm proves to be the best configuration to provide faster and efficient bone recovery.

In future, effects ofthe bone plate on different types of bone fracture (transverse fracture, spiral fracture, anobliquefracture.) can be studied. The combined effects of all these parameters andoptimised results can be analysed through various optimisation techniques.

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