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Application of Finite Element Method in Enhancing Performance of 2.4/2.7 mm Wise Lock X Plate: Case Study

Sahil Garg[1*], Mohit Kumar[2] and Gaurav Luthra[2]

[1]*Assistant Professor, School of Mechanical Engineering, Lovely Professional University*
[2]*Research Engineer, Auxein Medical Private Limited, Sonipat, Haryana-India-131001*
[2]*Technical Director, Auxein Medical Private Limited, Sonipat, Haryana-India-131001*
sahil.24834@lpu.co.in

Abstract

This case study provides a glimpse into the application of finite element analysis (FEA) in the bio-medical industry. The work presented has been carried out on one of the products manufactured by Auxein Medical Private Limited, Sonipat, Haryana-India. The product selected for study is 2.4/2.7 mm Wise Lock X Plate. The product is designed and tested in FE environment for its robustness and longevity. Two types of tests are demonstrated in this work namely Analysis of Stress and Displacement under normal loads and Fatigue Analysis. The components are tested under normal(loading conditions according to literature) and worst case scenario conditions(Five times normal load).

Keywords: *Implants; FEM; stress Analysis; Surgery; Bone*

1. Introduction

Metatarsal bone in the foot along with the hallux is responsible for almost 65% of total load on the five toes[1]. The hallux valgus deformation is related to Metatarus primus varus which calls for the recognition of corrective surgical procedure for misalignment of Metatarsal bone. Many procedures and their respective success rates are represented in the works of Scott *et al.*[2]. Schuh et al.[3] in their works provided the biomechanical analysis of ostetomy procedures on Metatarsal one(MT 1). The progression in technology invited researchers to use Finite element method (FEM) in the field of biomechanics along with variety of engineering problems[4–6]. The complex field of bio-medical engineering utilized the applications of FEM for modeling dental implants and bone implants[7–9].

The work presented discusses the applicability of FEM in complete analysis of implants manufactured in an industry. The novelty of work lies in design of implant based on the requirements and physical attributes of Indian patients. This work provides analysis of one product of Auxein Medical Private Limited, Sonipat, Haryana-India namely 2.4/2.7 mm Wise Lock X Plate . The future scope of computational methods lies with the use of Meshfree Methods(MMs) in biomechanics. MMs provide a myriad of applications[10]. More work on implants analysis e.g. fracture analysis using MMs is currently under progress in our labs as well.

2. Literature Survey on 2.4/2.7 mm Wise Lock X Plate

The purpose of this FEA study is to check the safety performance of 2.4/2.7 mm Wise Lock X Plate made of Titanium by calculating the deformation & stresses on the plate. So the focus of the literature research is to

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evaluate the various types of FEA techniques and experimental techniques that researchers have utilized for their studies to evaluate the safety of the 2.4/2.7 mm Wise Lock X Plate .

Table 1: Brief Literature on 2.4/2.7 mm Wise Lock X Plate

S.No.	Literature Title	Type of Study	Reason for Selection/ Rejection
1.	Ferguson *et al.*[11]	FEA study	In this paper a model with a standard metal fixation plate was generated for comparison purposes. The FE model was used to study the performance of biodegradable polymer inserts in the plate system. The flexible plate reduced stress-shielding effects at the fracture site when subjected to an axial load.
2.	Atik *et al.*[12]	FEA study	The aim of this study was to evaluate the mechanical behaviour of different rigid fixation methods in mandibular angle fractures.
3.	Saidpour[13]	FEA study	A three-dimensional, quarter-symmetric FE model was generated for the plate system. The stress state in the underlying bone was examined for several loading conditions.
4.	Chang *et al.*[14]	Prospective Study	The work was directed to assess the effectiveness of AO minifragment implants and 1.25-mm Kirschner wires using fragment-specific fracture fixation and double-column plating for displaced or unstable distal radial fractures.
5.	Sugiura and Ando[15]	FEA study	The work illuminated on study of stress propagation and dynamic stress concentration phenomena in case of rectangular plates conjugated with a disc having hole and fabricated of different materials, by utilizing the strain gauge method, the dynamic photo-elastic method.
6.	Kamath *et al.*[16]	Clinical Study	In this study advantages and disadvantages of various approaches, anaesthesia, technique and mode of fixation have been discussed.
7.	Qian *et al.* [17]	FEA study	The objective of this study is to provide a novel computational representation for development of a generalized model of dynamic behaviour and the internal loading conditions under the influence of locomotion in case of human foot.

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8.	William *et al.*[18]	Experimental study	Aim of this study was to find out the ground reaction forces experienced on the feet for a normative population in comparison to data from the subject with the flat feet.

2.1 Conclusion of literature research

Based on the literature research it is concluded that FEA techniques are the most efficient methods to reduce the design iterations of the implants. Various design and evaluation technique to check the safety performance of implants were found. It is also concluded that virtual surgical planning techniques are a power full tool for optimal placement of 2.4/2.7 mm Wise Lock X Plate, which is very important for the proper functioning of the bone-implant assembly post-surgery. Material of the implant, design of the implant according to Indian population, and safety performance of these implants is the key area of research nowadays.

3. Results and Discussions

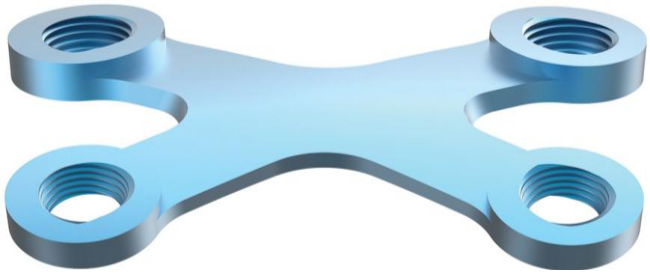
The static and dynamic analysis of implants shown in this section is carried out on product(implant) manufactured by Auxein Medical Private Limited, Sonipat, Haryana-India. One case of implant is studied namely 2.4/2.7 mm Wise Lock X Plate. The objectives of study are as follows:

1. To Analyze Stresses and Deformation on the Bone-Plate interface as per surgical planning using FEA Analysis.
2. Static and Dynamic testing of 2.4/2.7 mm Wise Lock X Plate.

The rationale behind the sample selection is to select extreme size of plate from the different lengths to have sufficient plate length available for analysis. ABAQUS 6.13 software is used for pre and post processing of the static testing and FE safe 6.4 software is used for the dynamic testing. The process of test follows Static FEA according to surgical approach. In Vitro static FEA testing set up was created by using assembly CAD Models of clavicle bone and 2.4/2.7 mm Wise Lock X Plate. Loading and Boundary conditions were applied in ABAQUS. Both normal and worst case compression loading were applied. Stress and deformation analysis locate the critical areas. Dynamic Testing using FEA is performed in the framework of FE-safe for fatigue analysis of finite element models. It is used alongside commercial FEA software, to estimate the location of fatigue cracks and the probability of survival at different service lives. For the static FEA, if the values of stresses are in safer limits as according to applicable standards to that material then the product is in safer limit. For the Dynamic FEA fatigue life up to 1000000 Cycles predicted using different loadings.

3.1 Case: The 2.4/2.7 mm Wise Lock X Plate

The Test sample/specimen for the case i.e. 2.4/2.7 mm Wise Lock X Plate is shown in Fig.1.



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Fig.1 The 2.4/2.7 mm Wise Lock X Plate

3.3.1 Stress and Deformation Analysis

The 3D model of Metatarsal bone is shown in Fig.2(a). Material properties were assigned in the ABAQUS software. Material properties according to ISO 5832-3 are used for plate and screws. **Table 2** of material properties are given below:

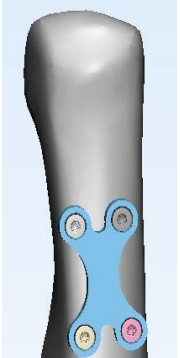
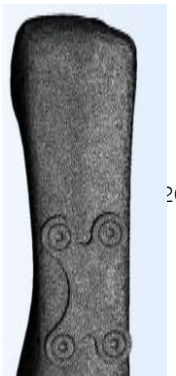
Table 2: Properties of Components of Model for Case 1

Component	Material Properties		
	Young's Modulus	Poisson Ratio	Density
Cortical bone	20 GPa	0.3	2000 Kg/m^3
Titanium	106 GPa	0.33	4700 Kg/m^3

The placement of the plate and the screws in the assembly were done as per the surgical planning as shown in Fig.2(b) The volume mesh assembly of the bone and plate is constructed using Tetrahedral C3D10M element. The total number of elements in the model are 413856 as shown in Fig.2(c) The loading and the boundary conditions were determined on literature works by several reference works[19,20] on loading of Metatarsal bone. The results are based on average human body weight equivalent to 125N. Results are presented as contour plots for plate only which can be seen in Fig.3(a-b).

Maximum stress of 19.93 MPa was observed in the 2.4/2.7 mm Wise Lock X Plate under the specified loading and Boundary Conditions. The maximum stress in the result is less than the yield strength of Titanium as given in ISO 5832-3, henceforth is considered under the safer limits.

Under the applied load there was a maximum deformation of 0.00227 mm which is elastic in nature. For the Worst Case Scenario a five time loads i.e. 625N than the normal load was applied to the bone. Maximum Stress of 99.65MPa was observed and deformation was 0.0113mm shown in Fig.4(a-b) respectively under the same boundary conditions as used in the normal loading scenario. The maximum stress in the result is less than the yield strength of Titanium as given in ISO 5832-3.

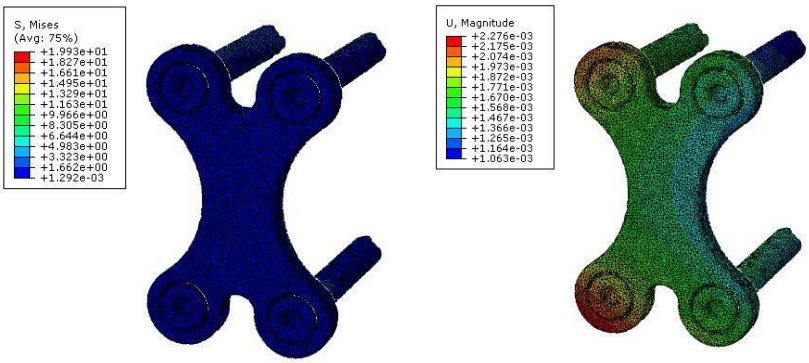




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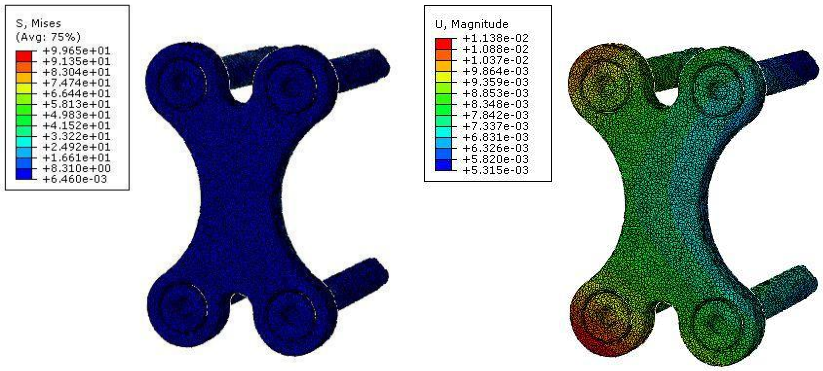
(a) **(b)** **(c)**

Fig.2 (a) 3D Model of Clavicle Bone (b) Bone and Plate Assembly (c) Meshed Bone and Plate Model



(a) **(b)**

Fig.3 (a) Stress Distribution Plate (b) Deformation



(a) **(b)**

Fig.4 Worst case Scenario (a) Stress Distribution Plate (b) Deformation

3.3.2 Dynamic Testing For Fatigue Test

To perform fatigue analysis FE-safe requires three inputs:

- The Stresses at every evaluation point in the FE model
- Loading details: Industrial standards can be used or manual input can be done

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- Materials Inputs: Properties defining fatigue strength are required..

For the purpose of analysis The surface finish defined is 1.6<Ra≤4μm and material is set to Titanium. Brown Miller Algorithm is used for the analysis. The test parameters are as follows:

- *Loading Waveform:* *Sinusoidal*
- *Frequency:* *5 Hz*
- *Default Endurance Limit:* *E7 cycles*

Table 3: Results of Fatigue Test for Case 1

S.No.	Min. Load (N)	Max. Load (N)	No. of Cycles	Result
1	100	1000	1000000	No Fracture
2	110	1100	1000000	No Fracture
3	120	1200	742728	Fracture
4	130	1300	278931	Fracture
5	140	1400	115982	Fracture

4. Conclusions

The work establishes the applicability of engineering based analysis in bio-medical sector by conjugating many spheres of science into one. The FEM analysis enables industry to save cost and provide insight into the points where the product can fail.

The conclusion based upon the results of various FEA results that "2.4/2.7 mm Wise Lock X Plate " has good strength and high load bearing capability. During realistic loading maximum stress on plate was 19.93 MPa, which is quite lower to the yield strength of the Titanium as given in ISO 5832-3. The focus of this study was to evaluate the safety performance of the implant using FEA. These results show the mechanical strength of the implant is good because all the stresses and deformations are within the safety limits.

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