Computational Analysis of External Biomedical Fixator and Orthotropic Bone

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Abstract

Orthopaedic Fixator assemblies are used to hold broken bones together. Fixators are classified into two types depending upon their placement in the human body external fixator and internal fixators. When the fixators are designed, a great deal of focus and research goes into the study of forces acting on different points of the structure of the component, resulting in a modification in design. The traditional method of conducting such a study is to study the stiffness of fixators and then design the sub-components. However, for designing the fixators, stresses on the bone, the gaps between the fractured bone, bone stiffness and its properties are not widely taken into account. The results of this computational analysis of external fixators indicate that the rigidity of the Sarafix fixator is greater than the rigidity of the unilateral fixator.

Keywords: *Orthopaedic Fixators; Finite element analysis; Biomechanics; Biomedical; bone fracture;*

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1 Introduction

Fixators are prosthetic hardware used in the medical field to hold broken bones together. In internal fixation, pins, plates, and screws are used to keep the structure together. While in external fixation, the structure is held together with the help of plates on the outside. External fixation is a clinical treatment of the bone wherein rods are screwed into the bone and exit the body attached to stabilise the fixator structure outside the body. External fixation is an alternative to internal fixation, where the components used to provide stability are positioned entirely within the patient's body. Fixator provides unobstructed access to the relevant skeletal and soft tissue structures for its initial assessment and secondary interventions to restore bone continuity and an available soft tissue cover. Choosing which external fixator to use to treat bone injuries depends on the clinical situation and medical experts. Understanding the biomechanical behaviour of the external fixator concerning the bone structure during treatment is necessary to prevent failure of the fixator. The concept of computational analysis of the fixators concerning the Bone Structure and its properties is examined.

2 Materials and Methods

There are several studies in which one or the other way deals with the material characterisation of bones and tissues, mechanical forces, their orientation, magnitude and directions of acting on a particular type of bone and reports the analysis outcomes. The stiffness analysis is performed using FEA, and experimental testing can be carried out under three types of loads: axial compression, four-point bending and torsion (Mešić Elmedin, 2015). This study reports the findings of an experiment carried out on cylindrical wooden bars with known physical properties.

In the design of External Fixators used in Traumatology and Orthopaedics, (Karel Frydrýšeka, 2012) discuss the Delta fixator, which can be used in the treatment of open and unstable (i.e. complicated) fractures of limbs and pelvis. Further, the study explains that the stability of the fixators is directly proportional to the fixator components.

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A study (N. Giotakis, 2017) investigates the stability of unilateral external fixation in the tibia (unilateral fixator) involving three variables which directly influence the contribution to the stability of the external fixator. The study emphasises the bone-pin interface, the components of the fixator and the fixator configuration.

Thermal Osteonecrosis Caused by Bone Drilling in Orthopedic Surgery (Alexander Muacevic, 2019) reports that thermal osteonecrosis is the phenomenon a result of excessively high tissue temperatures during bone drilling. The research investigation reveals that the parameters of osteonecrosis are affected by drill design, drill diameter, drill wear and tear, drill speed and bone thickness.

Composite External Fixators: Design with Subsequent FEM Analysis Optimization (Ring Fixator) is demonstrated by (Filip Tomanec, 2019), wherein the finite element analysis of the composite fixator is simulated by applying a certain load and evaluating the deformation. In this report, composite materials DT806, are used for the fixator which is in the form of a ring Fixator.

It is quite possible to design, analyze and test an external fixation device manufactured from composite and polymeric materials as a Pro Spon UNI-FIX unilateral fixator (Z. Padoveca, 2017). This is because there is a disadvantage of metal materials in their high absorption of X-rays. Further, metals or metal impurities fixators cannot be used in MRI scans. The study reports that analysis of fixators made from Polymeric materials, considering the Boundary Condition, results in the estimation of equivalent stress, stiffness and behaviour of the fixator under load.

In a study by (Joan O'Connor, 2015) it is confirmed that there is a strong possibility of growth and Re-absorption in biological tissue. The research paper provides insight into the dimension of Bone.

The present study refers to the bone mechanical properties in Healthy and Diseased States given by (Elise F. Morgan, 2018). This is because discussion related to cortical bone, trabecular bone and multiple aspects of material behaviour such as elasticity, Yield, fracture, Density, and Porosity are widely explored. The paper consists of the Orthotropic Properties of Cortical Bone and its strength.

The uncertainties related to Knee joint forces: prediction, measurement, and significance of various forces along with their value acting on a knee while doing a certain type of activities are formulated (Darryl D. D'Lima, 2013).

Methodology:

However, for designing the fixators, stresses on the bone, the gaps between the fractured bone, bone stiffness and its properties are not widely taken into account. And if there are any metallic parts or metal impurities in the bone or fixator, then it is not possible to perform MRI scans. Therefore, based on the dimension of the bone, it is decided to construct a 3-D cad model and by referring to the bone's various properties, this study examines bone and fixator interactions by considering suitable material models and loading conditions for the FEA model. Specifically, the estimation of deformation and stress distribution on fixator and bone considering the gap between the fractured bone, a factor of thermal necrosis and the stiffness.

The standard sequence is followed to obtain the finite element model, i.e., creating the geometrical models of different types of fixators as. The approximated geometric model of bone comprising both cancellous and cortical bone is shown in figure 1. Figure 2 shows how the assembly arrangement is made around the fractured bone on the external surface of the bone, for (a) Unilateral Type Fixator (b) Bilateral Type Fixator (Sarafix Fixator) and (c) Ring type Fixator. Then selecting elements followed by meshing, assigning material attributes, applying loading and boundary conditions and finally solving to obtain the results of physical parameters in post-processing. Table 1, presents the Mechanical Properties of the cortical and cancellous bone. The values of physical parameters to be observed are mainly the deformation and stress distribution on fixator and bone, considering the gap between the fractured bone, a factor of thermal necrosis and the stiffness.

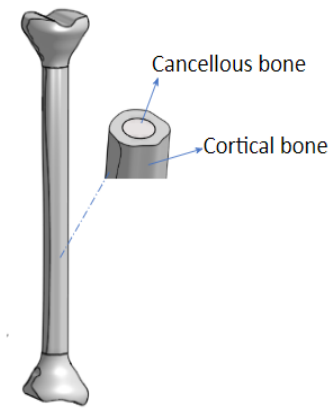

Figure 1: Cad model of the bone and description of its structure

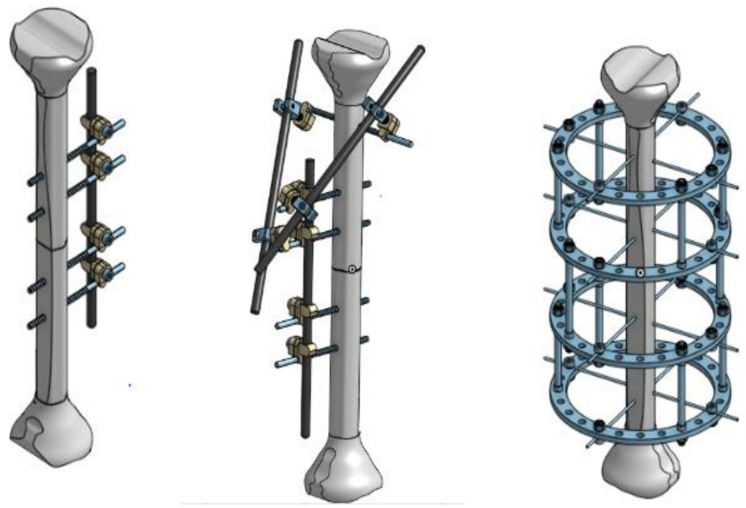

Figure 2: Geometric model of (a) Unilateral Type Fixator (b) Bilateral Type Fixator (Sarafix Fixator) (c) Ring type Fixator

Geometrical modelling and FEA of Bone: Femur Bone is 3D modelled in the Onshape software for modelling. Cortical bone is analysed with orthotropic properties, while cancellous bone and callous formation are analysed with isotropic material.

Table 1: Mechanical Properties of the cortical and cancellous bone

Mechanical Properties	**Values**
Cortical bone density	2 g/cm3
Young modulus along Circumference	10100 MPa
Young modulus along Diaphyseal axis	18160 MPa
Shear Modulus	3300 MPa
Poisson ratio	0.36
Tensile Yield Strength	71.56 MPa
Compressive yield strength	115.06 MPa
Compressive ultimate strength	150 MPa
Isotropic density of cancellous	1.874g/cm3
Poisson ratio	0.36
Young modulus of cancellous	10000MPa

The meshing of the Unilateral fixator, Bilateral fixator and ring type fixator is conducted in the Ansys software as shown in figure 3.

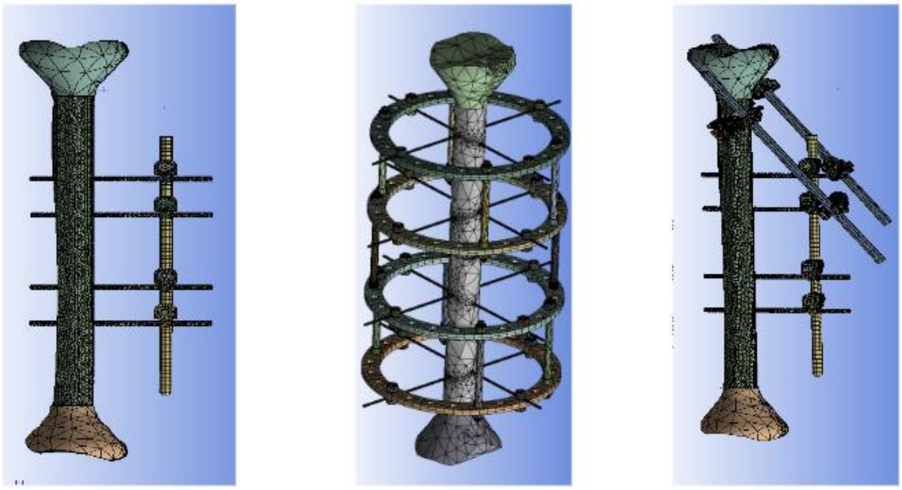

Figure 3: Meshing of (a) Unilateral Type Fixator (b) Bilateral Type Fixator (Sarafix Fixator) (c) Ring type Fixator

The boundary condition taken into consideration is the lower side of the bone is affixed as a base while a load of 500 N is applied on the tibia bone in the form of a step load of 100 N each in 5 steps, as shown in Figure 4. The simulation is carried out for the Sarafix fixator (1mm, 2mm callous formation) and Unilateral fixator (1mm, 2mm callous formation). The load applied as shown in figure 4, which acts on the bone fixator assembly is the self-weight of the human body around 3/4 of force in an upright standing condition. After the clinical trial of fixator fixation, the application of a 500 N load is enough to observe the stress on the fixator for the formation of callous.

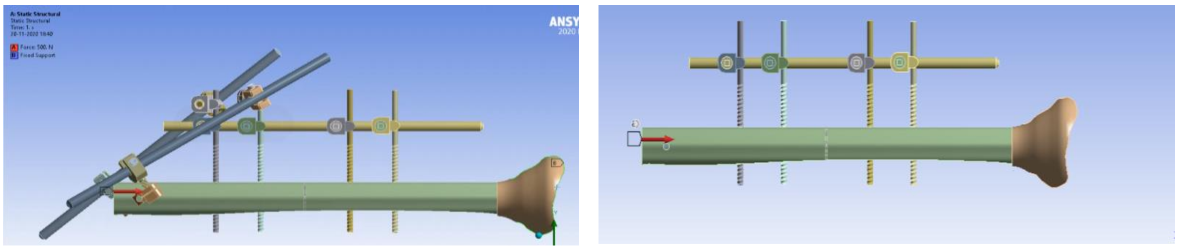

Figure 4: Direction of force applied on the (a) Sarafix fixators and (b)Unilateral Fixator

3 Results and Discussions

Results:

From the results of the Sarafix fixator having a gap of 1mm and 2 mm respectively, the stress distribution is in the range of 2.31 MPa for both case as shown in figure 5 and 6 . This signifies the stability of the fixator using both planes for the fixation.

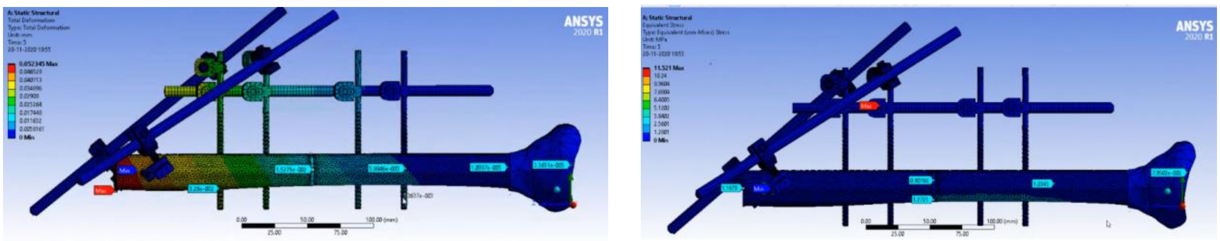

Figure 5: Stress and deformation of Sarafix Fixator having gap between fracture bone of 1 mm

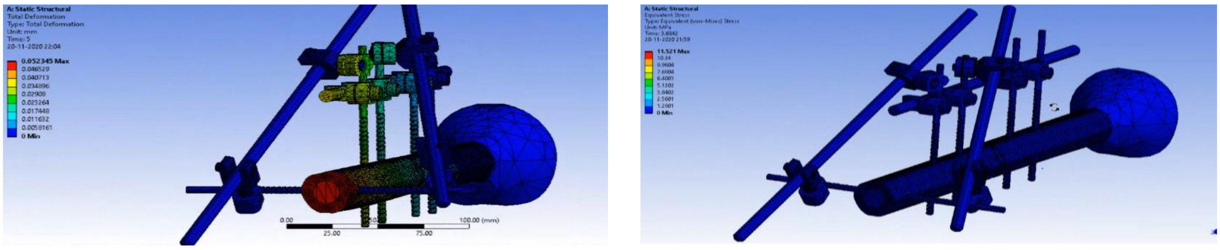

Figure 6: Stress and deformation of Sarafix Fixator having a gap between fracture bone of 2 mm

From the experimental results on Ansys Workbench 2020, the Stress acting on the unilateral fixator is 11.522 MPa as shown in figure 7, while the maximum deformation of the bone is 0.0523 mm. In the unilateral fixation techniques applying additional load distribute the stress unequally leading to the possibility of separation of the callous formation.

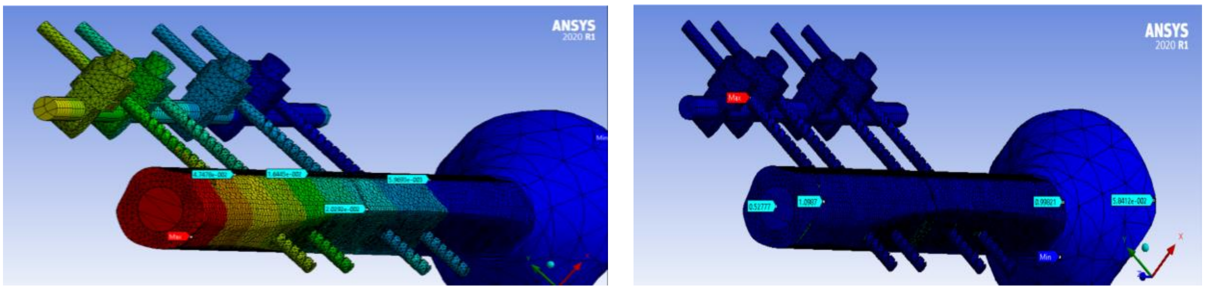

Figure 7: Stress and deformation of Sarafix Fixator having gap between fracture bone of 2 mm

Table 2: Stress and deformation acting on the fixator assembly

Description	Sarafix 1 mm gap		Sarafix 2 mm gap		Unilateral 1 mm gap	
Load	Stress on Fixator MPa	Deformation Mm	Stress on Fixator MPa	Deformation Mm	Stress on Fixator MPa	Deformation mm
100N	2.31	0.01	2.30	0.0104	2.9464	0.013
200N	4.61	0.02	4.7	0.021	5.89	0.026
300N	6.92	0.032	6.91	0.032	8.83	0.0381
400N	9.22	0.042	9.21	0.0418	11.78	0.0508
500N	11.52	0.053	11.53	0.0523	14.74	0.063

Consideration of the gap between the fracture bones plays an important role in the stress distribution of the fixator assemblies. Sarafix fixator has greater dimensional stability as compared to unilateral fixators by comparing the stress and deformation in Table 2. At the initial load, there is not much significant difference between the stress of Sarafix (bilateral) and unilateral fixator but as the load increases, the stability of unilateral fixators considerably decreases.

4 Conclusion

The following conclusion can be drawn from the simulation and the experimental results obtained from the analysis of the fixator assemblies.

Using the FEM model of Sarafix and unilateral fixator for bone fracture gap of 1 mm and 2 mm stress distribution and the displacement of the fixators are studied. The resulting stress distribution and deformation contours are useful in understanding the biomechanical behaviour of the external fixator with respect to the bone structure after the clinical treatment to prevent failure of the fixator. Based on the given arrangement of fixator and bone assembly, the stress distribution and the displacement are presented. Sarafix fixator rigidity is observed to be greater than the rigidity of the unilateral fixator. Application of the FEA models assist in evaluating the need for conventional clinical experimental testing of fixators.

In the current study, the computational analysis of the fixators with respect to the orthotropic material properties of bone structures is examined. Stresses acting on the bone fixator assembly in static conditions are evaluated for Sarafix and unilateral fixator which indicates there is still further scope in the analysis of the ring fixator assembly under similar boundary conditions and considering the nonlinear properties of tissues.

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