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Structural Topology Optimisation Of Femoral Bone Implant Plate For Biomedical Application

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Abstract

The design of commercially available fixation plates and the materials used for their fabrication lead to the plates being stiffer than bone. Consequently, commercial plates are prone to induce bone stress shielding. Topology optimization is a process that reveals the most efficient design based on a set of constraints or characteristics, often by removing material from the design. Additive technology is the ideal technique to produce TO components. For metal fixation plates, the ideal additive manufacturing technologies are selective laser melting (SLM) and electron beam melting (EBM). In this study, a 4.5mm diameter 8 hole DCP femoral fixation plate made of Ti–6Al–4V alloy is re-designed using topology optimization to reduce the risk of bone stress shielding. Fixation plate designs were optimized by maximizing stiffness while maintaining the structural integrity. The original plate model was obtained by reverse engineering technique. Altair Inspire topology optimization tool was used in this study for regenerating the optimized design.

Keywords : Topology optimization, stress shielding, DCP femoral fixation plate, SLM, Ti–6Al–4V

1. Introduction :

Stress shielding is an important phenomenon that must be considered during design optimisation of fracture fixation plates to minimise the risk of bone resorption and plate failure (Prasad et al. 2017). It is the result of the stiffness mismatch between the most commonly used metallic fracture fixation plates and bones (e.g. Young's modulus of Ti–6Al–4V is around 113 GPa and cortical bone is 15–25 GPa). This means that the load distribution in the bone-plate interface during healing will be uneven, mainly supported by the bone plate and screws. This will shield the bone from the stress stimulus required to provide adequate bone healing and eventually cause bone resorption and implant loosening, in a phenomenon known as "stress shielding" (Ridzwan et al. 2007; Prasad et al. 2017).

The use of topology optimisation is gaining significant attention due to the ability to automatically generate optimal redesigns for a given design, considering different loading conditions and volume reduction constraints. Several authors demonstrated the feasibility of topology optimisation for the redesign of orthopaedic medical implants to minimise stress shielding such as femur hip joints (Ridzwan et al. 2006; Fraldi et al. 2010; Saravana and George 2017), spine (Chuah et al. 2010) and pelvic prostheses (Iqbal et al. 2019). In these cases, results showed improved load transfer to the bone in the case of optimised implants. Similarly, Liu et al. (2017) used topology optimisation to design mandible fixation plates with adequate biomechanical performance. In order to ensure appropriate stresses imposed on the bone, fixation plates' stiffness should be optimised whilst maintaining plate stability during the healing process.

Additive technology is the ideal technique to produce these plates, not only due to the ability to produce very complex shapes, but also due to the fact that the use of additive manufacturing allows to reduce material waste, part fabrication without the use of complex tooling, being the ideal technology for mass personalisation. For metal fixation plates, the ideal additive manufacturing technologies are selective laser melting (SLM) and electron beam melting (EBM).

In this study, a 4.5mm diameter 8 hole plate was considered . The CAD model of the plate was obtained using reverse engineering techniques. Later, the model was imported in Altair Inspire topology optimization tool for analyzing the stresses acting on the plate under various loading conditions.

2. Materials and Method :

The Ti-6Al-4V alloy (by weights, Ti ~ 90%, Al ~ 6%, V ~ 4%, traces of Iron and Oxygen) is an alloy used in medicine, mostly for the manufacture of prostheses and implants, for example: fracture fixation plates, intermediate rods and nails, screws and medical threads. Titanium alloys have many advantages including titanium resistance is higher than stainless steel, the weight of titanium is lower than that of stainless steel, titanium has a high resistance to repeated loads, making it ideal for medical applications. Titanium and its alloys are the most common biomaterials due to biocompatibility, a problem that it solves because of properties very close to those of the bone: corrosion resistance, modulus of elasticity. In this study, plate is assumed to be made of Ti-6Al-4V alloy. The mechanical properties of this material are as follows:

Table1 : Mechanical Properties of Ti-6Al-4V alloy.

S.No	Property	Value
1	Youngs Modulus	113.8 GPa
2	Poissons Ratio	0.342
3	Tensile strength, Ultimate	950 MPa
4	Tensile strength, Yield	880 MPa

Selective laser melting (SLM) exploits the powerful capabilities of medical imaging (MI) such as X-rays, magnetic resonance imaging, and computed tomography scans to produce implants that complement or replicate the anatomy of the host tissues. One of the main advantages of SLM technology is its ability to process a wide range of metals including biomedical grade stainless steel (SS), cobalt–chromium (Co–Cr), titanium (Ti), and their alloys. For this reason, SLM has emerged as a promising technique for the fabrication of variety of medical devices. The complex anatomies of human knee, hip, skull, dental, and craniofacial tissues require a precise design and high dimensional accuracy during their fabrication to match and fit the target implantation sites.

3. Results and Discussion :

Following loading conditions were imposed on the plate for analysis:

1. Pressure of 400N (average patient weight of 800N is shared by both the femur bones) is applied on the top surface of the plate (horizontal axis of the bone)
2. Moment of 20 Nm were applied along the horizontal axis of the bone, simulating the moment load happening on the tibia during the swing phase (i.e. 10% of the body weight) in patients walking with crutches (Ramakrishna et al. 2004) .
3. Load of 400N is applied at the places where the screws are fixed to the bone in Z direction as a part of screw pre load values. (Talip Celik , 2020)

The screws are assumed to be fixed to plate and bone as shown in the figure1. The illustration of loading conditions in shown in figure 2.

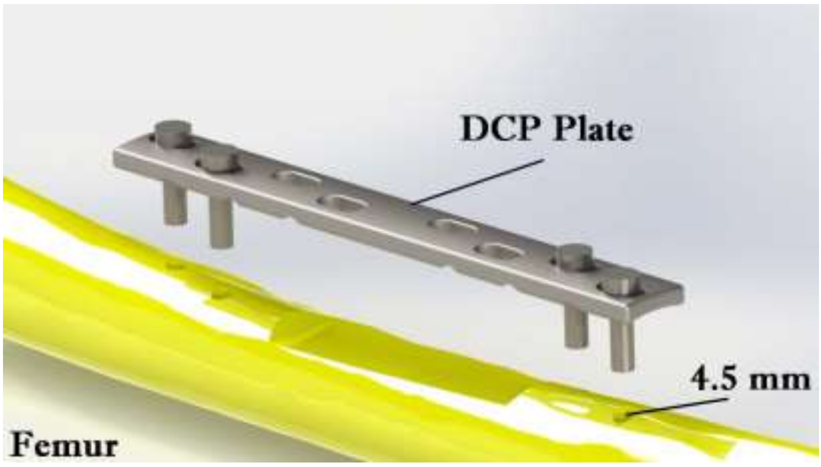

Fig1 : Assembly of Femur bone, DCP plate and cortical screws

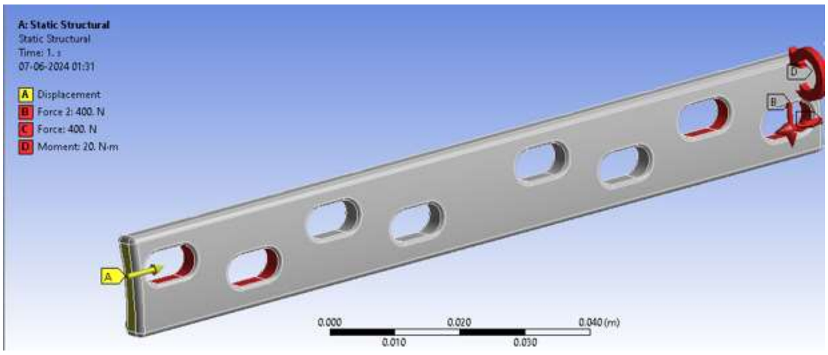

Fig2: loading and boundary conditions involved in the analysis

The results in comparision with Topology optimized plate and Original design, a table has been made as shown in Table2. The results are also shown from figure 3 to Figure 7.

Table2 : Comparision of results

S.No	Result	Original Design	TO Plate
1	Equivalent elastic strain	0.024148	0.0042844
2	Equivalent Vonmises stress	178.26MPa	237.67 MPa
3	Total Deformation	0.00531mm	0.00783mm

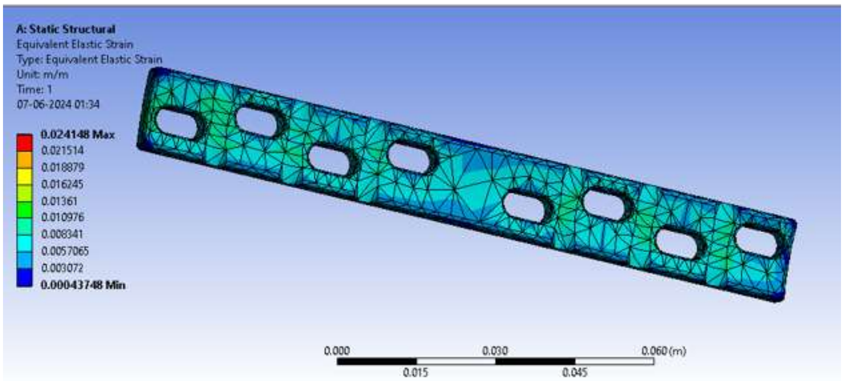

Fig3 : Equivalent Elastic strain of original design

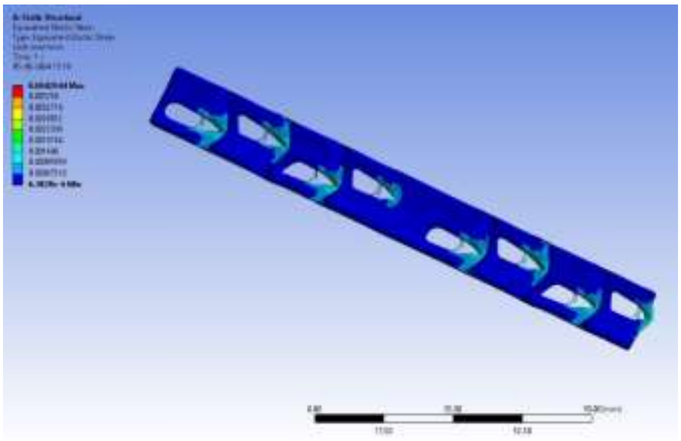

Fig4: Equivalent Elastic strain of TO model

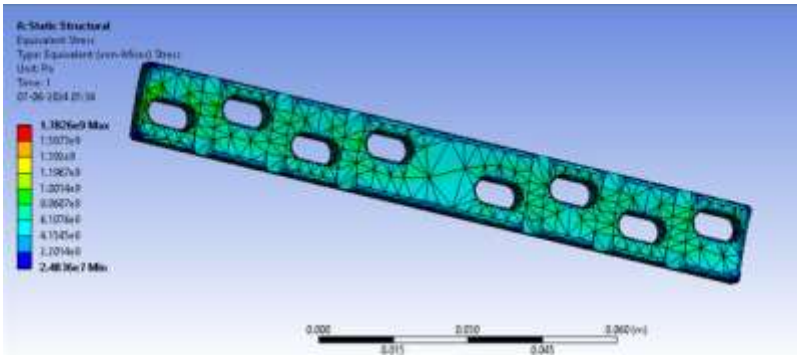

Fig5 : Equivalent Vonmises stress of Original model

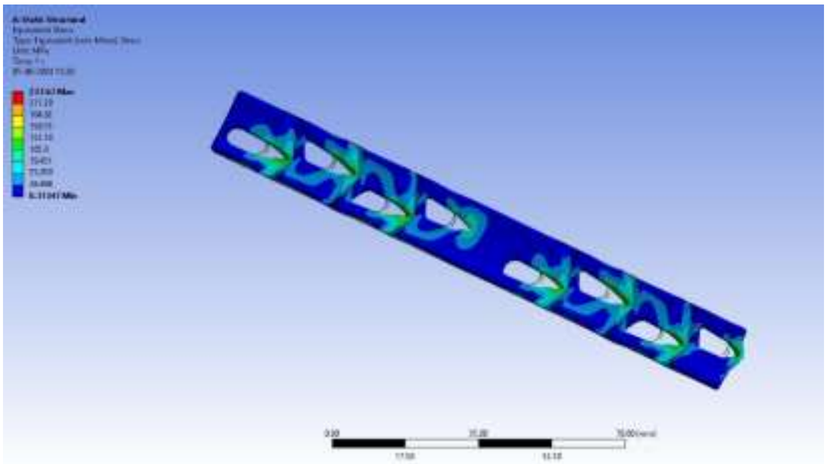

Fig6 : Equivalent Vonmises stress of TO model

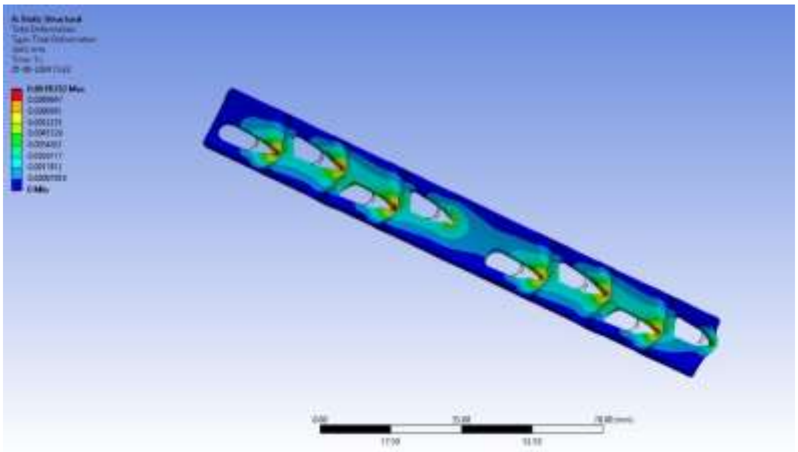

Fig7: Total Deformation of TO model

Based on the finite element analyses performed on the femoral plate, the overloaded areas were identified and the geometry is changed to improve the requirements that an implanted medical device must meet. The implant redesigning has many advantages. One of them is that working time decreases due to decreased processing volume. The complexity of geometry is not a disadvantage because the SLM process can perform any kind of geometry. The stresses in the bone increase when topology-optimised plates are used. The most substantial increase in stresses at the fracture plane was observed for the combined loading conditions. In comparison with the initial designs, the maximum stresses at the fracture plane increased by 33% for the eight-hole plate in the combined case with a 30% of volume reduction. The stress distribution shows that less stiff plates produce higher compressive stresses (in the plate-bone interface due to the bending load) at the fracture plane. Based on the results, the proposed redesigned plate considering the combined loading and boundary conditions is shown in figure8. The comparison of physical properties of the initial design and TO model plate is tabulated in the table3.

Fig8 : Proposed model after Topology Optimization

Table3: Comparison of physical properties of Initial design and proposed re-designed model

S.No	Physical property	Initial design	Re-design
1	Volume	100% (0.0000107m^3)	70% (~0.000749m^3)
2	Mass	47.19gms	33gms

4. **Conclusion** :

The main objective was achieved with the modeling and the analysis with finite elements of a commercial model of the femoral plate, the design of a distal femoral plate with improved characteristics and the preparation for the manufacture of the plate designed. It was possible to model the distal femoral plate and to subject it to normal and unfavorable conditions. The weight of the new plate decreased by 30% by removing the material from the passive surface. The new distal femoral plate has a pleasant, organic and symmetrical appearance. The thickness of the plate decreased by ~ 40% and varies between 3.2-4.8 mm. Another advantage that comes with plate design is the distribution of equivalent stress. Due to the redesign and modification of the material, the implant has a higher resistance, and the stress graph indicates that the plate has a higher limit. Topology optimisation permits the design of less stiff and lightweight fixation plates, reducing the stress shielding effect, promoting load transfer to the bone and thus contributing to bone remodelling. However, further analysis is still required, considering for example a fracture gap and measuring the gap strains to correlate the resulted strains (i.e. relative or absolute stability) with the healing process (i.e. secondary or primary healing). Furthermore, screw threads were not considered in the simulation and their role on load transfer must be also considered.

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