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Biomechanical analysis of a novel external fixator with finite element method

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Abstract: External fixation is a common technique for the treatment and stabilization of bone fractures using pins or wires. Different designs were considered, but all of them present limitations such as high weight (they are based on heavy frame), not comfortable to use and not customized to individual patients. Therefore, this paper proposes a novel lightweight customized external fixator, overcoming some of the identified limitations. It also investigates the mechanical characteristics of the newly developed fixator considering different stages of healing using finite element method. Results show that the fixator has sufficient stiffness to withstand the forces a patient is subjected to during the healing process.

I. Introduction

The use of external fixation devices is one of the most common methods to stabilize and hold the fractured bone segments in the proper position during the healing process. They often consist of percutaneous pins or wires that are inserted into the bone and clamped onto the external frame [1]. However, they are usually associated to long applications time, painful processes, heavy frames and not customized to individual patients. Therefore, these devices should be designed taking into account the anatomic details of the patient through the use of digital and advanced technologies (i.e. computed tomography, CAD modeling and additive manufacturing) to perfectly fit individual patients, increasing patient's comfort and device functionality, thus improving the healing process. Moreover, the external fixator should also be designed with sufficient stiffness and strength to be able to carry most of the applied load until the bone heals. Figure 1 shows the different stages of bone healing and the role of the external fixator in removing the load from the fracture site and divert it to the other side of the bone. Initially, when the tissue at the fracture gap has a low modulus, the bone stresses pass mainly through the wires and fixator, bypassing the fracture site. As the broken bone starts to mature and has a high modulus, more stresses can be carried by the bone, contributing to the stability of the system. The aim of this paper is to evaluate the mechanical characteristics of a novel lightweight and customizable fixator using the finite element method, ensuring its capability to withstand the working loading conditions.

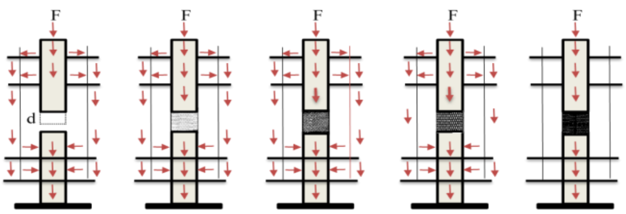

Figure 2: Load transmission along with the fracture site and fixator during healing.

II. Material and methods

The geometry and dimensions of the fixator were obtained from the anatomy of a patient using computer tomography (CT) data. A CT scan of the patient's lower limb was processed to segment the required area using both the 3D Slicer software (www.slicer.org) and 3D cloud service (www.embodi3d.com), generating a 3D model of the anatomic structure of the patient and the corresponding STL model. Then, the STL model was imported into the Solidworks software (Dassault Systems, Massachusetts, USA) to allow the design of the customized fixator. The fixator was designed through the definition of multiple planes and splines along the patient's leg representing the variation and irregular shape of the limb. Moreover, the fixator was divided into two parts to facilitate the assembly during its application on the patient. Four Screw seats were also designed in each part to allow the two parts to be fastened. The mechanical performance is simulated considering the assembled fixator with a simplified cortical bone model. The cortical bone was designed as a solid cylinder with two segments with a length of 165 mm each and a diameter of 30 mm and an interfragmentary gap of 2 mm to simulate the bone fracture. Eight K-wires of 1.8 mm diameter were also considered. Finally, all components were assembled into one single CAD model (Figure 2) with a bonded contact type. The CAD model of the fixator was then imported into the Ansys Workbench software (Ansys, Inc., Pennsylvania, USA) to evaluate the performance of the fixator.

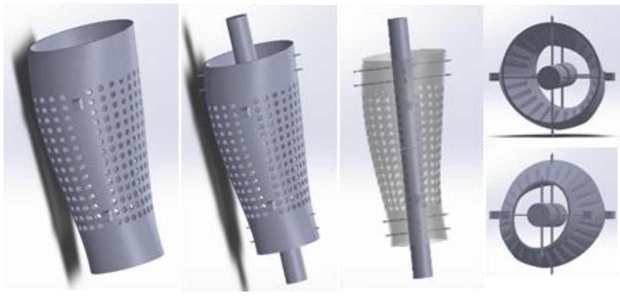

Figure 1: Different views of the design of the assembled external fixator.

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For all components, the material behavior was assumed homogenous, linear, elastic and isotropic. Bone was simulated considering a Young's modulus of 22 GPa and Poisson's ratio of 0.35. Wires were assumed to be made of stainless steel (Young's modulus of 200 GPa and Poisson's ration of 0.3) [2] and the external fixator in polylactic acid (PLA) (Young's modulus of 2.35 GPa and Poisson's ratio of 0.39) [3]. A static compressive load of 70 N that corresponds to 10% of the average body weight (70 kg) was applied to the proximal tibia, while the distal tibia was rigidly fixed in all directions. According to a previously performed convergence analysis, a mesh of 166,652 tetrahedral elements with an element size of 3 mm was used.

III. Results and discussion

Figure 3 shows the contour plot of the maximum von Mises stress for the external fixation. As observed, the von Mises stress values on both the bone and main part of the fixator are 70.25 and 23.48 MPa, respectively. The maximum stress on the assembled fixator (fixator, wires, bone) was 351.76 MPa and occurred on the wires, particularly at the interface of the wire-bone. This was also the main reason for surgeons not allow patients to experience full weight-bearing at the early stages of treatment. Nevertheless, when compared the obtained values with the yield strength of PLA, stainless steel and bone, no failure is observed.

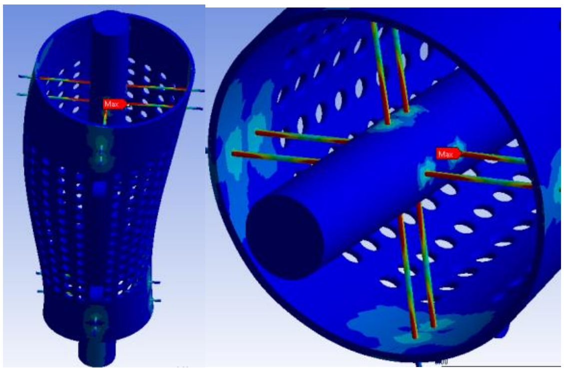

Figure 3: Stress contour plot of the fixator and wires.

The graph of load vs. displacement curve used to compute axial stiffness is shown in Figure 4 with a linear response. The axial stiffness of the circular fixator was found to be 88.1 N/mm, which falls within the range of (50-2500 N/mm), as reported in the previous literature [4].

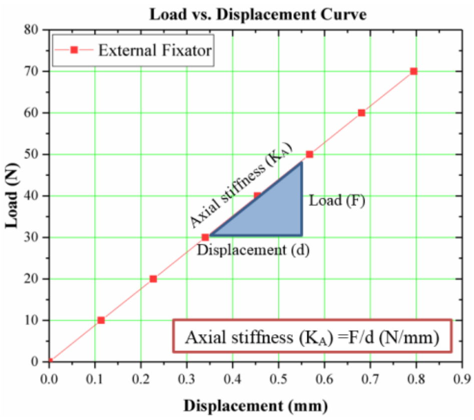

Figure 4: The load vs displacement curve.

Table 1 shows the transmitted stresses to the fracture site and wires during different stages of bone healing. At the beginning, when there is a gap, all stresses on the bone were transferred to the fixator through the wires, taking an active role in load carrying. After the initial inflammation stage, stresses at the fracture site increase during the other bone healing phases (primary soft callus formation, hard callus formation, callus remodeling and concurrent modeling), whereas stresses at the wires decrease due to a load transfer to bone.

Table 1: Maximum stress values at the fracture site and wires.

Healing rate	Maximum stress (MPa)	
	Fracture site	Wires
0 % healing (gap)	0	351.7
1 % healing	0.266	36.5
50 % healing	0.336	7.07
75 % healing	0.364	7.04
100 % healing	0.388	7.02

IV. Conclusions

In this study, a novel customized external fixator for fracture stabilization was developed and evaluated using the finite element method. This fixator shows the ability to transfer and withstand the applied load by patients during the healing process. It may provide a viable and attractive alternative to conventional fixators due to its lower weight and appearance, while not compromising its mechanical behavior. In the future, topology optimization will be used to design the fixator.

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Author's statement

Conflict of interest: No potential conflict of interest was reported by authors. Informed consent: Informed consent has been obtained from all individuals included in this study.

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