Optimization of a novel external fixator for orthopaedic applications

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Abstract. The use of external fixation devices is a very common method for the treatment of bone fractures. However, these fixators present some limitations in terms of mobility, significant risk of infection, and induce pain and discomfort. Moreover, they are also not fully customized to suit individual patients. To avoid these limitations, this paper presents a novel patient-specific external fixator developed using reverse engineering, finite element analysis and additive manufacturing. The fixator was designed based on a set of computer tomography (CT) scan images of a patient and optimized considering different thickness values and materials. New lightweight designs were produced through a manual process (regular distribution of circular and hexagonal voids) and topology optimization. Different polymeric materials (Polylactic acid (PLA); Acrylonitrile butadiene styrene (ABS) and Polyamide (PA)) were also considered for the fabrication of these designs. It was found that although both PLA and ABS allow to meet the design requirements, and that the best mechanical properties were obtained with fixators made of PLA. Results also showed that the best results in terms of mechanical performance and weight reduction was obtained with topology optimization.

1 Introduction

Locomotion problems and bone disorders are often caused by car accidents, falls, wars and natural disasters. These injuries represent a major health issue as their treatments are complex and expensive affecting the public health system and are usually treated using an external fixation method [1]. External fixation is a biomechanical method widely used for the treatment of bone fractures and soft tissue pathologies, playing a major role in preventing amputation [2,3]. It is often implemented through the use of bone fixing elements (i.e. pins, wires) in case of complex fractures or without these elements in case of simple fractures [4]. Currently, there are several commercially available external fixators that can be used for the treatment of a certain fractures. However, these fixators present several limitations as they correspond to a painful treatment process, presenting also other disadvantages such as skin irritation, discomfort, heavy weight, risk of infection and long

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treatment time [5-7]. The design of these devices presents a major challenge and it is considered one of the major causes for device failure. This occurs when the fixators are designed based on a standardized model to suit a wide range of patients' anatomy. Therefore, these orthotic devices need to be customized and personalized taking into account the individual patient's anatomy employing digital and advanced technologies (i.e. computed tomography, CAD modelling and additive manufacturing) in order to allow the design and fabrication of a more efficient and functional orthopaedic device [8,9]. Additive manufacturing (AM) gives designers and engineers the flexibility to design a lightweight but mechanically strong patient-specific device, which precisely fits the anatomy of the patient, increasing patient's comfort as well as device functionality [9-11].

This paper presents preliminary results related to the design of a novel patient-specific device for lower limb injuries to be produced using additive manufacturing.

2 Methodology

The production flow of customized external fixation devices comprises several steps as shown in Figure 1. The process starts with data acquisition using a scanning system (e.g. CT, MRI or laser scanning). The scanned data is post-processed in order to generate a model of the affected part of the patient. This model is then used as a reference to design and 3D model of the external fixator which perfectly fits to the patient. The CAD model is then assessed through finite element analysis to determine its mechanical performance. Finally, suitable models are produced using additive manufacturing.
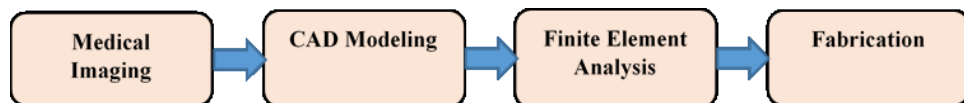

Fig. 1. Workflow process for fabricating personalized orthopaedic devices from patient-specific data.

2.1 Image acquisition and processing

A CT scan of a patient was used to obtain the anatomic details of the lower limb. The scanned data was exported in a common medical file format known as digital imaging and communications in medicine (DICOM). The DICOM file is imported into the three dimensional (3D) Slicer Software (www.slicer.org) to perform the anonymization process, enabling to convert the DICOM format into a nearly raw raster data (NRRD) format, removing sensitive patient's information. This file is then processed using the Embodi 3D cloud service (www.embodi3d.com), converting it into the 3D STL model of the lower limb. Finally, the STL model is imported into the Autodesk Meshmixer Software (Autodesk, Inc., San Rafael, CA, USA) for segmentation of the region of interest, correcting also potential errors. The process of transforming the DICOM file into an STL model of the patient's leg is shown in Figure 2.
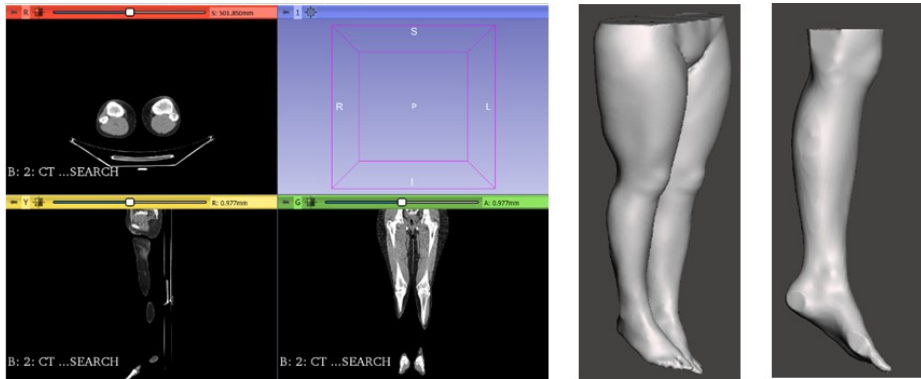
Fig. 2. Post-processing of CT scan data to obtain the STL model of the patient's lower limb.

2.2 Modelling and simulation

The novel external fixator (Figure 3) was modelled based on the STL model of the patient's leg using Solidworks Software (Dassault Systems, Massachusetts, USA). The fixator was designed through the creation of multiple planes along the patient's leg and spline curves to accurately represent the irregular geometry of the limb. These splines were connected together by the loft command to obtain a smooth surface. The solid model was then obtained through the offset of the generated surface and then thicken the offset surface in the outward direction. Finally, the model was divided into three regions (top, middle and bottom) allowing to remove material from the middle region and to keep both the top and bottom regions as solid regions in order to maintain the integrity of the fixator.
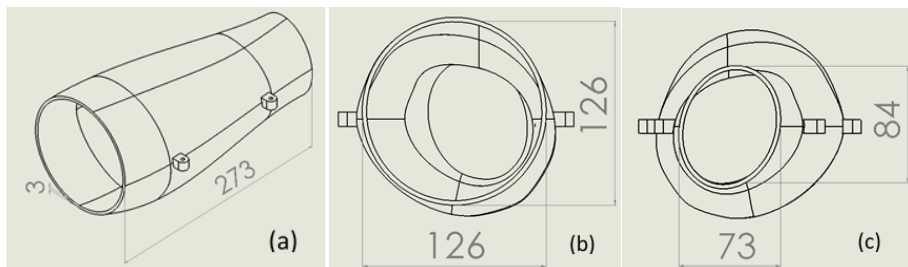

Fig. 3. The dimensions of the fixator (a) isometric view, (b) top view, (c) bottom view.

The solid model of the fixator was optimized in terms of thickness, materials and cut out configurations. Different thickness values (3, 4, 5, 6 mm), commonly used to design orthopaedic devices [12-14], and three materials (PLA, ABS, PA), commonly used for additive manufacturing, were considered. Besides the solid model, different cut out configurations (circular, hexagonal and topological models) (Figure 4) were also designed and evaluated. In the case of circular and hexagonal hollow-patterned models, the material removal was achieved by distributing the holes uniformly on the structure, without considering stress distribution. On the other hand, in the case of topology optimization, the stress distribution is considered, and the material removal is achieved by removing materials in low stress regions, resulting in an initial topology model with rough and sharp element edges. The model is then imported into the CAD software to perform the interpretation step, thereby obtaining a smooth and refined geometry of the topology optimized model. An arbitrary value of 15% of mass reduction was imposed to all designs.
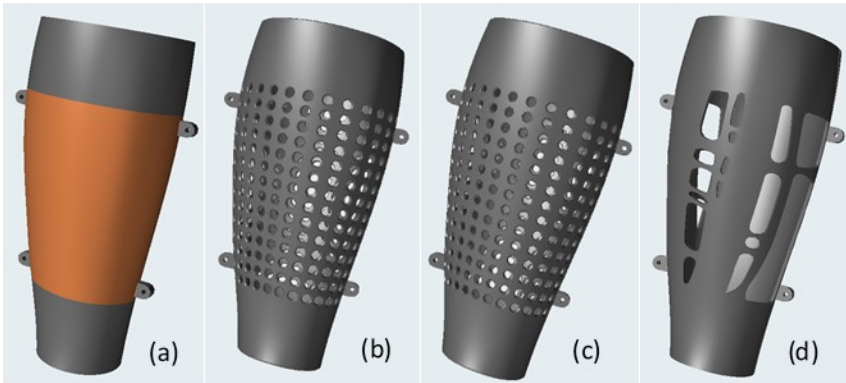
Fig. 4. (a) solid design, (b) circular design, (c) hexagonal design, (d) topology design.

The mechanical behaviour of all designs was investigated using the Ansys Workbench Software (Ansys, Inc., Pennsylvania, USA). A mesh of tetrahedral elements with a 1 mm element size was used. A static compressive load of 700 N that represents the average weight of an adult human (70 kg) was applied on the top face of the model, while the bottom face of the fixator was completely fixed. Three different materials were also considered (Table 1). The purpose of this analysis was to determine the Von Mises stresses and maximum displacements in the fixators according to the applied loading conditions. Each design should meet specific criteria and if one criterion has not met the design will be considered as not a suitable design. These criteria are: i) the maximum stress should be less than the yield strength of the material and, ii) the maximum displacement should be less than the allowable displacement (2 mm) [15].

Table 1. Material properties

Property	Material		
	PLA	ABS	PA
Young's Modulus (GPa)	2.35	1.62	0.58
Poisson Ratio	0.39	0.39	0.35
Yield Strength (MPa)	49.5	39.0	27.8
Density (g/cm^3)	1.24	1.10	1.14

3 Results and discussion

3.1 Thickness selection

As the effect of thickness on the overall performance of the fixator is independent on the material, simulations were performed considering ABS and a solid fixator. Numerical results in terms of maximum displacement (mm), maximum stress (MPa), stiffness (N/mm), and specific stiffness/mass ratio (N/g.mm) are presented in Table 2. The results for maximum displacement and maximum stress are the two main criteria used for the thickness selection. As observed, all models show max stress below the yield strength of the material (σ_{ABS} = 39 MPa) and max displacement below the allowable displacement (2 mm). Therefore, all results obtained were acceptable by the criterion and the 3 mm thickness was selected for further optimization as it provides the least part mass among other models.

Table 2. Results for different thickness values

Thickness (mm)	Max. Stress (MPa)	Max. Displacement (mm)	Fcritical (N)	Safety Factor	Stiffness (N/mm)	Specific Stiffness (N/g.mm)
3	4.81	1.09	5664	8.1	642	2.0
4	3.06	0.59	8898	12.7	1173	2.8
5	2.79	0.38	9765	13.9	1829	3.4
6	2.47	0.27	11020	15	2586	4.0

3.2 Material selection

In this case a solid fixator with 3mm of thickness is considered, and the effect of three different materials (PLA, ABS and PA) on the mechanical performance of the fixator investigated. Obtained numerical results are presented in Table 3. The results of maximum displacement and maximum stress are the two main criteria used for material selection. As observed all fixators met the criteria except the PA fixator, which met the maximum stress criteria, but the maximum displacement (3.05 mm) clearly exceeds the allowable displacement (2 mm). Therefore, PA is considered inappropriate. The maximum displacement of both ABS and PLA fixators are 1.09 and 0.75 mm, respectively showing displacements smaller than the maximum allowable displacement. Therefore, these two materials are suitable for the fabrication of the external fixation device. However, although both materials exhibit similar stresses, PLA fixators present smaller displacement than ABS. Therefore, PLA was the selected material.

Table 3. Results for different materials.

Material	Max. Stress (MPa)	Max. Displacement (mm)	Fcritical (N)	Safety Factor	Stiffness (N/mm)	Specific Stiffness (N/g.mm)
ABS	4.81	1.09	5664	8.1	642	2.0
PLA	4.86	0.75	7115	10.1	931	2.6
PA	5.08	3.05	3829	5.5	221	0.7

3.3 Geometry optimization

Three cut out structures were investigated (circular, hexagonal, and topological models). The effect of each option was assessed using structural FEA and the results are presented in Table 4.

Results show that the obtained fixators' designs after manual material removal (circles and hexagons) present larger displacement and stress values compared to both solid and topology optimized models. This is due to the random material removal from the model without considering the maximum stress regions which can affect the strength of the fixator. However, in the case of topology optimization, the maximum stress value was reduced compared to the solid model and the maximum displacement is relatively larger than the solid model. Therefore, results indicate that the topology optimized model is the stiffest and strongest model, whereas the hexagonal model is the least stiff and weakest model. The improvement obtained from the topology optimized model is obvious as the mass reduction of 15% was successfully achieved without sacrificing its integrity and the maximum stress reduced by 20%. Besides, the stiffness was also maintained as it is within the range of ± 10% of the original model.

Table 4. Results for different cut out configurations.

Design	Max. Stress (MPa)	Max. Displacement (mm)	Fcritical (N)	Safety Factor	Stiffness (N/mm)	Specific Stiffness (N/g.mm)
Circle	8.19	0.95	4230	6.0	736	2.4
Hexagon	12.72	0.99	2722	3.9	701	2.3
Topology	3.86	0.80	8975	12.8	865	2.9

4 Conclusion

A novel custom-made external fixator for lower limb injuries based on a patient's CT scan data, is presented. The fixator was optimized in terms of thickness, material and geometry focusing on its suitability for additive manufacturing and weight reduction. Manual and topological optimization strategies were considered for weight reduction and 15% of weight reduction was successfully achieved. This reduction also allows to reduce costs and fabrication time. The fixator was evaluated using finite element analysis under a static compressive load. Results show that the topology optimized model presents better mechanical performance.

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