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## Development of a spinal fusion cage by multiscale modelling: application to the human cervical spine

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### Abstract

This work presents a design approach to obtain a cage to enhance the fusion between adjacent vertebrae of the cervical spine. This approach makes use of a multiscale model for topology optimization of structures to define the cage microstructure. The cage is designed in order to respond to the structural requisites for load bearing as well as to the requirements of osteoconductivity to promote the bone formation within the fusion domain. The design domain is the intervertebral space that will be filled with the bone substitute (scaffold) which is considered a periodic porous structure characterized by a representative unit-cell. The topology of the unit-cell is defined in order to obtain the optimal equivalent properties for stiffness and permeability, which are computed using an asymptotic homogenization method. So, the optimization goal is to obtain the stiffest cage structure for the local strain/stress field through the solution of a global finite element model of a human cervical spine. A constraint on the cage microstructure permeability is assumed to obtain interconnected porosity necessary to bone cell migration and nutrient supply. The final cage design presents interconnectivity in all spatial directions and the elastic properties meet the stiffness requirements. This design approach has revealed to be very useful to design site-specific scaffolds for bone regeneration, in particular for interbody fusion, since each cage is defined for a specific mechanical environment obtained by the mechanical analysis of the whole organ.

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## 1. Introduction

Bone tissue engineering for spine arthrodesis has a great potential to be used in clinical practice in alternative to conventional bone grafts such as the autographs and cadaveric allografts. Although spinal fusion is commonly attempted, non-union is reported to occur which makes spinal fusion a preferential application for testing artificial bone substitutes. Moreover, the development of new devices for arthrodesis is a way to overcome the complications of conventional therapies involving grafting [1].

Tissue engineering for spine fusion relies on the development of a scaffold (working as a spinal cage) that must achieve multiple design criteria due to conflicting mechanical and biological functions [2]. In fact the cage must be designed to respond to structural requisites for load bearing as well as to the requirements of osteoconductivity in order to promote the bone formation within the fusion domain. Thus, it requires a design methodology that allow us to control the scaffold microstructure and respective properties. Topology Optimization applied to scaffold design has been showing to be able to respond to this challenge [3-5] supported by the development of additive manufacturing techniques that allow to manufacture complex three-dimensional shapes [6-8]. Additionally, for a better simulation of the boundary conditions on bone scaffolds, multiscale approaches have been pointed as a possible strategy [9, 10].

In the present work, the objective is to develop a cage for the cervical spine fusion using the bone remodeling model based on multi-scale topology optimization recently developed by Coelho et al. [11-13]. The scaffold here is assumed as a periodic cellular porous structure characterized by a representative unit-cell. The topology of the unit-cell is defined in order to obtain the optimal equivalent properties for stiffness and permeability, which are computed using an asymptotic homogenization method [14]. So, the optimization goal is to obtain the stiffest structure for the local strain field with a constraint on the microstructure permeability to obtain interconnected porosity. The local strain field is obtained through the solution of a global finite element model of a human cervical spine [15].

In order to get a better approximation of the actual boundary conditions on the scaffold site, an accurate finite element model of the healthy human cervical spine from C2 to T1 was developed, including the bone structures, discs and ligaments. After validation of this model, the multiscale model was applied considering the removal of the disc between C5-C6 and defining a cage design domain at this intervertebral disc space. The cage was optimized for multiloading conditions corresponding to the basic motions of the cervical spine: flexion, extension, lateral bending and axial rotation. The obtained cage presents interconnectivity in all spatial directions and elastic properties that fulfill the requirements.

## 2. Methods

### 2.1. Cervical Spine Model

In this work, a detailed geometrical and finite element model from C2 to T1 vertebrae was developed from CT medical images from a 34 year-old male subject without any local degeneration. These medical images were used as an input to a geometric modelling pipeline developed to create our model. Several image and geometric processing tools make part of the pipeline: for image segmentation, the freeware software ITK-SNAP [16] was used; Solidworks [17] was the software used for surface mesh adjustment and solid model generation; the finite element modelling and analysis was performed in ABAQUS standard [18]. The modelling pipeline used for the development of the geometrical and finite element model of the cervical spine is described in Fernandes et al. [19] and similarly applied by Espinha et al. [20]. Bone structures were distinguished in cortical and trabecular regions and for intervertebral discs the annulus fibrosus and nucleus pulposus regions were identified. These last were defined based on quantitative data of the disc and nucleus' cross sectional areas presented by Yoganandan et al. [21]. Both structures were defined with material properties from the literature assuming a linear elastic behaviour (see Table 1) [22]. Tetrahedral elements were used for all of these structures.

Five major cervical spine ligaments were inserted in the model: anterior longitudinal ligament (ALL), posterior longitudinal ligament (PLL), flavum ligament (FL), interspinous ligament (ISL) and capsular ligament (CL). The ligaments are discretized using 3D truss elements with the insertion regions defined based on the adaptation of the anatomical insertion points to the mathematical biomechanical models [21-23]. Therefore, anterior and posterior longitudinal ligaments (ALL and PLL) were defined from the midheight of the inferior vertebral body to the midheight

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