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Cervical fusion cage computationally optimized with porous architected Titanium for minimized subsidence

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ABSTRACT

Anterior cervical discectomy with fusion is a common surgical treatment that can relieve patients suffering from cervical spondylosis. This surgery is most commonly performed with the use of a cervical cage. One serious complication of the fusion cages commercially available in the market is subsidence of the cage with loss of the normal alignment of the spine and recurrent pain. This work presents the proof-of-concept of a fusion cage made of a graded porous titanium with microarchitecture minimizing the risk of subsidence associated with fully-solid implants. The optimized properties of the porous implant are obtained through a scheme combining multiscale mechanics and density-based topology optimization. Asymptotic homogenization is used to capture the effective properties of the porous material, which uses a tetrahedron based cell as building block. The stress levels and normal strains obtained under various loading conditions on the C7 superior surface of the vertebrae are used as indicators of subsidence. The results suggest a reduced risk of subsidence for the optimized implant versus the fully-solid implant. Under the most severe condition of combined loading, a collective improvement of the average von Mises stress up to 14% can be observed on the posterior, left, and right lateral regions of the C7 superior surface. Similarly, for the average normal strain, the optimized cage exhibits a more favourable distribution with a top gain of 21.7% at given locations.

1. Introduction

Age-related degeneration of the cervical spine is the most common cause of neural disorder and has been reported that disc degeneration is common in over 50% of middle-aged individuals (Chong et al., 2015; Irvine et al., 1995). Although most patients are asymptomatic, disc herniation, osteophyte formation and hypertrophied ligaments can compress the cervical spinal cord and nerve roots resulting in cervical pain, radiculopathy, or myelopathy (Chau and Mobbs, 2009). If the physiotherapy or medications fail to relieve these symptoms, surgery is usually recommended. Among several surgical treatments, an anterior cervical discectomy with fusion (ACDF) is widely used to remove the herniated or degenerated disc in the neck (Fountas et al., 2007). ACDF has been shown clinically successful in more than 90% of patients, by alleviating their pain and allowing them to return to work (Bertagnoli et al., 2005). Historically, ACDF was accomplished by removing the compressing structures (Smith and Robinson, 1958) and wedging a bone block, harvested from the iliac crest of the patient (autograft), between the vertebral bodies. Although autologous bone graft is considered to be the gold standard in achieving fusion, the associated morbidity in harvesting the graft has motivated the search for alternative implants and materials. Since the fusion cage technology was proposed by Bagby in 1988, stand-alone cage designs, with or without additional fixation, have become the standard of ACDF. Cages avoid the morbidity associated with harvesting autogenous bone graft, and have been demonstrated success in achieving primary stability and long-term fusion (Chong et al., 2015, 2016). Although excellent results have been reported with cages, subsidence of the cage has been reported as a complication in 3–10%, of the cases (Anderson and Rouleau, 2004). Subsidence occurs when the implant protrudes through the adjacent vertebral body. Many reasons can lead to subsidence, such as inadequate determination of preoperative bone quality, and improper prosthesis design, which affects end plate preparation and load distribution (Whitecloud et al., 1994).

Ideally, interbody cage implants should have materials with improved biomechanical properties, be biocompatible and promote osseointegration (McConnell et al., 2003). Different materials have been used to manufacture cervical cages, including three main materials: 1) Titanium (Ti) and its alloys, 2) Polyetheretherketone (PEEK), and 3) Carbon fiber-PEEK. Ti and PEEK are preferred in current designs, since synovitis and lymphatic spread of fiber debris has been associated with radiolucent carbon fiber–PEEK cages, although all three materials have

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their advantages and disadvantages (Bartels et al., 2006; Ryu et al., 2006; Gercek et al., 2003; Parsons et al., 1985). Titanium and its alloys are biocompatible materials with high stiffness, corrosion resistance, and low density (Rao et al., 2014). Ti cages have demonstrated their ability to support osseointegration (Svehla et al., 2000). However, the mismatch in elastic modulus of the Ti material with the adjacent bone results in stress shielding (Kurtz and Devine, 2007). The PEEK cages can provide the advantages of radiolucency and lower subsidence rates than Ti cages (Park et al., 2013). Their elastic modulus is close to that of the bone, hence avoiding the stress shielding associated with Ti cages (Kurtz and Devine, 2007; Chou et al., 2008; Niu et al., 2010; Liao et al., 2008; Cabraja et al., 2012). However, PEEK cages without additional instrumentation or bone grafting, have been found to have a prolonged time to fusion and the fusion is usually incomplete (Cabraja et al., 2012; Kotsias et al., 2017).

A number of studies using in vitro and numerical approaches have investigated the various reasons for cervical cage subsidence, with the modulus mismatch being one of the most prominent. Among the former group, Wilke et al., (2000a, 2000b) and Kettler et al. (2001) have examined the role of neck movements on the subsidence of a set of commercially available cages, i.e. the WING cage (Medinorm AG, Quierschied, Germany), the BAK/C cage (Sulzer SpineTech, USA), and the AcroMed cervical I/F cage (DePuy AcroMed International, UK). Their results show the significant role of postoperative neck movements, with the WING and the AcroMed cages having lower subsidence than the BAK/C cage. Another in vitro study by Furderer et al. Furderer et al. (2002) on bovine vertebrae has compared subsidence caused by a selected number of cage designs under prescribed loading conditions. Abrasion of the vertebral endplates has been recognized as one cause for increased subsidence. Among the second group of investigations using numerical techniques, Lin et al. (2004) have used a commercial software package to generate a lumbar interbody fusion cage with a porous architecture optimized for structural stability, reduced stress shielding, and biofactor delivery. Compared with conventional threaded cages, their design claims reduced stress shielding and lower stress at the cage-vertebra interface, thereby resulting in low subsidence. Another numerical study has compared the performance of selected cervical cages in the market, each with its own geometry and materials: Bryan (Medtronic Sofamor Danek, Minneapolis, MN), Prestige LP (Medtronic Sofamor Danek), and ProDisc-C (Synthes, Inc., West Chester, PA) (Lin et al., 2009). The results contribute to better understand the underlying mechanisms causing cage subsidence, which is evaluated numerically through stress predictions at the vertebrae-prosthesis interface. Among the designs, the Bryan disc featuring a very complaint core with no cage fixators shows the lowest stresses superior to C6, which results in a reduced risk of subsidence. Chiang et al. (2004) have also used finite element analysis to understand the role of loading, cage geometry and material, along with bone mineral density on the mechanism of subsidence of two prostheses: the SOLIS (Stryker Instruments, Kalamazoo, USA) and the BAK/C (Sulzer SpineTech, USA). The results show substantial subsidence under extension load, and suggest the cause for this problem to the mismatch of material properties between the cage and the adjacent cervical vertebrae.

This paper presents a proof-of-concept fusion cage that reduces the mismatch of elastic properties with the native bone, thereby reducing the risk of subsidence associated with fully-solid implants currently available in the market. Density-based topology optimization is used to tune the elastic properties of a porous microarchitected cage featuring tetrahedron based cell, here chosen for both its load bearing and bone ingrowth characteristics (Arabnejad et al., 2016). Asymptotic homogenization (Hassani, 1997; Hollister and Kikuchi, 1992) is used to capture the mechanical properties of the representative volume element (RVE), as a function of its relative density. The topology optimization problem is formulated for maximum implant compliance (strain energy) under a set of constraints, which include the overall porosity range of the cellular implant, bone ingrowth, stability, and additive manufacturing requirements. Five loading modes are considered as a combination of compression with either flexion, extension, right lateral bending, flexion combined with right lateral bending, or extension combined with right lateral bending moments, and the pertinent stress levels, as well as normal strains, are assessed on the C7 superior surface with values indicating the potential for subsidence reduction of the optimized porous cage versus its fully-solid counterpart. In Section 2, the article first presents the methodology to generate the computation model from the CT-scan data and the material properties assignment, and then describes the problem formulation for constrained topology optimization. In Section 3, the results, i.e. von Mises stress and normal strains distribution, are presented and a comparison of the optimized versus the fully-solid implant is given for the five load cases. A discussion follows in Section 3 framing the results within the broad clinical context and highlighting current limitations and future work.

2. Methodology

One of the main cause of subsidence is the mismatch of elastic properties between the implant and surrounding native bone (Crawford et al., 2003; Rho et al., 1995). This work proposes to tune the elasticity gradients of the former to achieve mechanical biocompatibility with the latter while guaranteeing the satisfaction of strength requirements. Topology optimization is used for the purpose and applied to a three-dimensional domain replicating the implant macrogeometry ($11 \times 14 \times 5$ mm, 7° Lordotic angle) of a commercially available cage (Trabecular Metal TM-S Cervical Fusion Device, Zimmer Spine, Minneapolis, MN, USA). Fig. 1 briefly depicts the scheme here presented, where the key steps rely on combining concepts of multiscale mechanics and density-based topology optimization, as briefly summarized below:

- *Acquisition of patient vertebral geometry and elastic tissue properties*. CT-scan data of a 59-year-old female are obtained from the database "visible human project" (VHP) provided by the US national library of medicine (NLM, Bethesda, Maryland, USA).
- *Reconstruction of functional spinal unit and assignment of material properties.* After segmentation of the CT slices at the C6-C7 levels, the three-dimensional geometry of the C6-C7 vertebrae is reconstructed and assembled along with the implant and bone graft. This operation allows to create a complete functional spinal unit (FSU), where bone material properties are assigned based on the Hounsfield Unit values (*HU*) of the voxels of the CT data (see Appendix B).
- *Unit cell geometry and mechanical properties of porous Titanium.* An open cell with tetrahedron based topology is chosen as building block of the cage porous architecture. The choice is motivated by the proven capabilities of this cell to provide both load bearing capability and bone ingrowth (Arabnejad et al., 2016). Asymptotic homogenization (Hassani, 1997; Hollister and Kikuchi, 1992; Arabnejad Khanoki and Pasini, 2013; Arabnejad and Pasini, 2013) is used to calculate the homogenized stiffness tensor and yield properties (Section 2.2. and Appendix D) of the unit cell, with characteristic length much smaller than the implant. The implant material properties are assigned to each tetrahedron unit cell as a function of its relative density. A uniform distribution of relative density is initially assigned.
- *Finite element model.* A 3D finite element analysis (FEA) is used for the FSU under prescribed loads and boundary conditions that replicate the normal physiological range of the cervical vertebrae. Five loading cases are considered as shown in Fig. 1(a), and for each of them the distribution of stress, strain, displacement, as well as strain energy is obtained over the whole spinal unit.
- *Elastic properties tuning.* To minimize implant subsidence into the vertebral endplate, the implant compliance, i.e. strain energy, is maximized (Fig. 1(b)) via topology optimization. The design