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Stand-alone lumbar cage subsidence: A biomechanical sensitivity study of cage design and placement.

Andrea Calvo-Echenique, José Cegoñino, Raúl Chueca, Amaya Pérez-del Palomar*

Group of Biomaterials Aragón Institute of Engineering Research (I3A) Department of Mechanical Engineering, University of Zaragoza, Spain

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ABSTRACT

Background and objective: Spinal degeneration and instability are commonly treated with interbody fusion cages either alone or supplemented with posterior instrumentation with the aim to immobilise the segment and restore intervertebral height. The purpose of this work is to establish a tool which may help to understand the effects of intervertebral cage design and placement on the biomechanical response of a patient-specific model to help reducing post-surgical complications such as subsidence and segment instability.
Methods: A 3D lumbar functional spinal unit (FSU) finite element model was created and a parametric model of an interbody cage was designed and introduced in the FSU. A Drucker–Prager Cap plasticity formulation was used to predict plastic strains and bone failure in the vertebrae. The effect of varying cage size, cross-sectional area, apparent stiffness and positioning was evaluated under 500 N preload followed by 7.5 Nm multidirectional rotation and the results were compared with the intact model.
Results: The most influential cage parameters on the FSU were size, curvature congruence with the endplates and cage placement. Segmental stiffness was higher when increasing the cross-sectional cage area in all loading directions and when the cage was anteriorly placed in all directions but extension. In general, the facet joint forces were reduced by increasing segmental stiffness. However, these forces were higher than in the intact model in most of the cases due to the displacement of the instantaneous centre of rotation. The highest plastic deformations took place at the caudal vertebra under flexion and increased for cages with greater stiffness. Thus, wider cages and a more anteriorly placement would increase the volume of failed bone and, therefore, the risk of subsidence.
Conclusions: Cage geometry plays a crucial role in the success of lumbar surgery. General considerations such as larger cages may be applied as a guideline, but parameters such as curvature or cage placement should be determined for each specific patient. This model provides a proof-of-concept of a tool for the preoperative evaluation of lumbar surgical outcomes.

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1. Introduction

Spinal degeneration and instability are commonly treated with interbody fusion cages either alone or supplemented with posterior instrumentation. The aim of this surgery is to stabilise the segment and restore intervertebral height. Lumbar cages are widely employed in combination with additional screw instrumentation to ensure segment immobilisation and avoid the risk of non-union. However, although widely accepted as a successful treatment, this additional fixation, apart from being more invasive, has been reported to present some complications such as screw loosening or implant failure. Besides, some biomechanical studies have suggested that lumbar intervertebral disc (IVD) cages are sufficiently stable to be used as stand-alone devices [1], provided that they are introduced using a minimally invasive technique that ensures preservation of important stabilising structures [2,3]. Large scale clinical studies have also demonstrated no differences in clinical outcomes between patients with stand-alone cages versus those with additional posterior fixation [4]. Although instability was initially defined as a loss of stiffness, and later as a reduction of the neutral zone [5], it is generally accepted that instability is associated with an abnormal load pattern which not necessarily would imply an increase in segmental movement as occurs during disc degeneration [6]. For that reason, and given that the fusion surgery aims to reduce the movement, throughout this paper the outcomes would be discuss in terms of segmental stiffness, directly related with the relative movement of the segment.

* Corresponding author at: Mechanical Engineering Department. Betancourt Building. School of Engineering and Architecture. University of Zaragoza, Zaragoza, Spain

E-mail address: amaya@unizar.es (A. Pérez-del Palomar).

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The use of stand-alone cages has shown to be very controversial presenting several problems chief of which is the risk of subsidence of the device into the bone owing to the high contact pressures on the bony endplates. For this reason, this study was focused on the investigation of possible factors which may contribute to reduce this risk in cages placed as a stand-alone construct. Although subsidence in early postoperative stage may increase the contact area, avoid the peak pressures caused by irregularities and prevent the progression of subsidence, high-grade subsidence can lead to a reduction in the intervertebral space height [7]. Thus, the use of an appropriate constitutive material of the vertebral bone incorporating a plasticity formulation would lead to a better prediction of the risk of subsidence in a stand-alone fashion. Previous studies have used Von Mises equivalent stress as the criterion for bone yielding [8,9]. However, considering that bone should be treated as a brittle material, the Von Mises criteria would not be suitable [10]. In this study, we used the modified Drucker–Prager Cap model, which takes the contribution of hydrostatic stress into consideration, as the yield criterion to model the inelastic behaviour at a continuum level.

On the other hand, cage characteristics such as shape, material and positioning are also expected to have a significant influence on surgery success. Previous studies have used finite element (FE) models to compare among commercial cages, but only some of them have discussed the influence of cage material [11] or shape [8,12] using parametric or optimisation methods. In their study, Hsu et al. [12] used a genetic algorithm to find the cage shape with an optimal subsidence resistance. However, they assumed flat endplates instead of real geometry which may lead to a more uniform pressure distribution and an underestimation of subsidence risk. Later on, a study comparing a standard cage with a custom-fit one showed that patient-specific cage geometry could reduce the stress concentration on the endplates [8]. However, these studies provided a limited prediction of subsidence as they used elastic material models.

In this study we aimed to prove a model which will serve as a tool for the preclinical evaluation of surgery outcomes that any interbody device or supplementary fixation may have in each specific patient. Particularly, in this work, the influence of different design parameters and positioning of a bean-shaped cage on segment stiffness and subsidence risk has been studied. The selection of a stand-alone device responds to the higher risk of subsidence reported for this technique but in no case it is aimed to show a comparison with additional instrumentation or to demonstrate a superiority of one technique over the other. To this end, we conducted a parametric FE analysis of a cage design of varying size, cross-sectional area and position, and evaluated it in a patient-specific functional spinal unit (FSU). The main contribution of this study is the evaluation of cage subsidence with an elasto-plastic material formulation with different behaviour for traction and compression for the bone. In addition, this formulation accounted not only for the stresses over the yield stress limit, but also considered the hardening of the material.

2. Materials and methods

A 3D FE model of a FSU was developed to evaluate the influence of cage design and positioning in the surgical outcome. Firstly, the intact segment was simulated and validated to set a control scenario. Then, the elements corresponding to the nucleus and inner annulus were removed to place a stand-alone cage. A total of 50 models were built (intact FSU + cage with neutral parameters + 8 variations of each parameter) as explained below.

2.1. FSU finite element model

A L4-L5 FSU was modelled including vertebral bodies, annulus fibrosus, nucleus pulposus, cartilaginous endplates, facet joints and the seven major ligaments. This model will be referred in the following as intact model. The vertebral bodies were segmented from a computed tomography of an asymptomatic 46-year-old male subject [13] and divided into a 0.5 mm thick cortical layer [14] meshed with one layer of hexahedral elements and the cancellous bone, meshed with tetrahedral elements of 2 mm mean size due to the geometrical irregularities. Bone was characterised as a transversal isotropic material with a Druker–Prager Cap plasticity formulation (see Online resource 1). Soft tissues were modelled according to anatomical characteristics: the annulus fibrosus and the endplates were meshed with linear hexahedral elements with mean mesh size of 1.5 mm. For the annulus fibrosus (AF) an anisotropic material with two families of fibres (±30°), using the Holzapfel strain energy function, was used [13]. While, the endplates were characterised as linear elastic material. The nucleus pulposus was meshed with hexahedral elements and characterised as a non-linear NeoHookean material. The spinal ligaments were modelled as uniaxial truss elements with strain-dependent behaviour under traction and without resistance to compression. Finally, the facet joints were modelled as 0.2 mm thickness cartilage with a frictionless surface-to-surface contact combined with a penalty algorithm for normal contact (200 N/m stiffness, initial gap of 0.4 mm) [15]. All mechanical properties are summarised in Table 1. To obtain the ideal size of the FE mesh (shown in Fig. 1), a process of mesh refinement was executed until verifying mesh convergence. The mesh refinement process was stopped when the difference between the results was 5% or lower. This analysis gave a global mesh size which is summarised in Table 2.

2.2. Cage design and parameterisation

The intact model described previously was modified to introduce the cage. Thus, the elements corresponding to the nucleus pulposus and inner annulus were removed to host the cage. After the insertion, the empty region left between the annulus and the cage was filled with tetrahedral elements simulating the granulation or inflammatory tissue (its mechanical properties are shown in Table 1). Furthermore, simulating a minimally invasive surgery, the ligaments were considered to remain intact.

A parametric model of a bean-shaped cage was created using Python scripting in ABAQUS 6.13 (SIMULIA, Providence, RI, USA) (Fig. 1a). The cross-sectional area of the cage was varied by modifying the axes distance (length), radius (width) and thickness (Fig. 1a) to investigate the influence of the apparent stiffness of the cage. On the other hand, the curvature of the cage ends, which will contact the top and bottom vertebral endplates, was varied from flat to high convexity to account for the effect of geometry congruence (Fig. 1b). This parameter was defined as the difference in percentage between the central and lateral cage height. An additional transversal hole was included varying its height because, despite it is very common in commercial cages to promote bone growth around the implant, it modifies the cage stiffness (Fig. 1b). Finally, the cage was placed at a central position and moved along the antero-posterior direction as shown in Fig. 1c. The election of the parameters to be varied responds to the clinically reported influence of cross-sectional area and cage positioning on surgery outcome [7,16–18]. The neutral parameter values were set in accordance to the standard shape of commercial implants. Then, one parameter was varied at a time while maintaining neutral values for all other parameters. The upper and lower limits and the neutral values for each parameter are summarised in Fig. 1a, b and c. Each parameter has been varied uniformly between minimum and

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