Lumbar interbody fusion: a parametric investigation of a novel cage design with and without posterior instrumentation

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Abstract

Introduction A finite element model of the L4-L5 human segment was employed to carry out a parametric biomechanical investigation of lumbar interbody fusion with a novel “sandwich” cage having an inner stiff core and two softer layers in the areas close to the endplates, with and without posterior fixation.

Methods Considered cage designs included: (a) cage in a homogeneous material with variable elastic modulus (19–2,000 MPa), (b) “sandwich” cage having an inner core ($E = 2,000$ MPa) and softer layers ($E = 19$ MPa) with variable thickness (1–2.5 mm). The latter cage was also considered in combination with posterior rods made with a material having variable elastic modulus (19–210,000 MPa). All the models were loaded with 500 N compression and moments of 7.5 Nm in flexion, extension, lateral bending and axial rotation.

Results The homogeneous cage stabilized the segment in flexion, lateral bending and axial rotation; in extension there was a destabilization up to 60% and remarkable cage movement (1 mm). The “sandwich” cage limited this phenomenon (cage movement <0.6 mm), effectively stabilized the segment in the other directions and lowered the maximal contact pressure on the endplates, reducing the risk of subsidence. Posterior fixation reduced spinal flexibility and cage movement.

Conclusions The soft layers of the “sandwich” cage had the potential to limit the risk of cage subsidence and to

preserve a significant loading of the structure even in combination with flexible posterior instrumentation, which may have a beneficial effect in promoting bony fusion.

Keywords Interbody fusion · Cage · Spine stabilization · Flexible rods · Sandwich cage

Introduction

Interbody fusion cages are commonly used to treat spinal degeneration and instability, to achieve bony fusion while restoring the intervertebral and foraminal height. Currently, many interbody cage models are available on the market, and can be categorized based on the surgical approach, which can be anterior (anterior lumbar interbody fusion, ALIF), posterior (PLIF), transforaminal (TLIF) and less commonly, extraforaminal (ELIF) [3]. Cages can be made from titanium alloys, or from polymers, typically polyether etherketone (PEEK), non-reinforced or carbon fiber-reinforced. Polymers allow a better assessment of fusion on X-rays or CT scans [23, 28] and higher loading of the bone graft, thus promoting bony fusion [33].

Cages were implanted initially stand-alone in combination with bone grafts [2], with generally satisfying clinical success [24] and high fusion rate, generally over 90% (reviewed in [3]). Although device failures were not reported, interbody cages may subside into the vertebral bodies (14% subsidence rate in a literature study [7]), thus losing the intervertebral height restoration achieved post-operatively [35]. The clinical outcome of interbody fusion was generally good, but less satisfying results were also reported. Agazzi et al. [1] obtained good or excellent results using the Prolo scale only in 39% of the patient population at an average follow-up of 28 months.

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The worst clinical results were obtained for multisegmental implantation, with fusion rates of 71% [24].

To achieve a higher stabilization degree and to relieve the load supported by the cage, thus reducing the risk of subsidence and collapse of the intervertebral space, interbody cages are frequently supplemented with posterior instrumentation. Posterior fixation was proven to effectively enhance stability (reviewed in [27]) [14, 17], but does not significantly increase the compressive strength of the construct [16].

To limit the risk of cage subsidence and to promote bony fusion, DSM Biomedical BV (Heerlen, The Netherlands) developed a “sandwich” design for cages, which consists of an inner polymeric, stiff core covered with two layers made in a softer material in the areas in contact with the endplates. The soft layers are expected to create a more uniform pressure distribution at the cage-endplate interface and adapt to the geometrical irregularities of the bony endplate after the surgical preparation, thus maximizing the contact area and reducing the risk of subsidence.

Despite the promising rationale of such a design, its biomechanical effectiveness needs to be proven. Some design variables, such as the thickness of the soft layers and the stiffness of the cage, may be expected to have a critical influence on the clinical success rate of the device. Therefore, the aim of the present study is to conduct an explorative parametric finite element (FE) investigation about the novel cage, with and without supplementation with posterior fixation, to test the effect of the design on biomechanical aspects such as the residual spinal flexibility, the force transmitted through the cage, the contact pressure at the cage-endplate interface, the cage movement and the force in the facet joints. The design variables included in the parametric investigation were the cage stiffness, the thickness of the soft layers and the material properties of the rods in the case of supplementary posterior fixation.

Materials and methods

Spine model

A FE model of the L4-L5 human spine segment derived from a previously developed and validated model of the lumbar spine [31] was employed (Fig. 1a). The model included vertebral bodies, posterior structures, the intervertebral disc, and seven ligaments [anterior longitudinal (ALL), posterior longitudinal (PLL), flaval (FL), capsular (CL), interspinous (ISL), supraspinous (SSL) and intertransverse (ITL)]. Quadratic hexahedral elements were used to model all the solid structures. Membrane fiber-reinforced elements were employed for the representation

Fig. 1 FE model of the L4-L5 functional spine unit implanted with the ALIF cage (a). The dashed lines indicate the position of the posterior instrumentation. FE mesh of the “sandwich” cage, depicting the point where the movement was measured (b)

of ligaments and annular collagen fibers. Eight criss-cross fiber layers were defined in the radial direction and each layer contained tension-only fibers. The fiber angle varied from $\pm 24^\circ$ to the mid-plane of the disc ventrally to $\pm 46^\circ$ at the dorsal side, according to a previous study [15]. The non-linear elastic material properties and the cross-sectional areas of the disc collagen fibers and ligaments were the same used in previous elastostatic studies [29, 31]. Facet joints were modeled by using a frictionless surface-to-surface contact; a layer of solid elements having thickness 0.5 mm represented the facet cartilage. All solid materials were modeled as linear elastic isotropic.

Stabilization with a stand alone cage

The model was then modified to include a stand alone elliptical cage (Fig. 1b). The cage had major and minor diameters of 30 and 20 mm, anterior and posterior heights of 12 and 9 mm, respectively. Different cage models were considered, with variable material properties replicating those currently being available from DSM Biomedical BV:

- homogeneous cage made with an isotropic elastic material with elastic modulus ranging from 19 to 2000 MPa and Poisson ratio 0.4,
- “sandwich” cage consisting in an rigid inner core having elastic modulus of 2,000 MPa and softer layers having elastic modulus of 19 MPa, both with Poisson ratio of 0.4. The thickness of the soft layers was varied between 1 and 2.5 mm, in steps of 0.5 mm.

Table 1 shows an overview of the mechanical properties of the materials employed in the present study for the cages and the fixation rods. The model was modified mimicking an ALIF (anterior lumbar interbody fusion) surgery for the cage implantation [12]. The ALL was removed, the whole nucleus and the cartilaginous endplates. In the annulus

Table 1 Mechanical properties of the materials

Material	Elastic modulus (MPa)
PCU 80A	19
High molecular weight PE	2,000–2,500
PEEK	3,500–4,000
Titanium	110,000
Stainless steel	210,000

fibrosus, an opening having size of 44 mm × 12 mm was created in the anterior part. The lateral and posterior parts of the annulus, the PLL and the bony endplates were preserved, as usually done in ALIF procedures. Then, the cage was positioned in the area previously filled by the nucleus pulposus. Since the cage had the same height of the intervertebral space, no distraction due to cage insertion was modeled. Surface-to-surface contact having friction coefficient 0.5, similar to previous studies aimed to simulate the immediate post-operative time [4, 20, 33], was employed to model the cage-endplate interaction.

Stabilization with cage and posterior fixation

The model, including the “sandwich” cage with soft layers having a thickness of 1.5 mm was modified to consider posterior fixation with pedicular screws and rods. The screws were ideally modeled as a network of stiff beam elements, not allowing any relative displacement or rotation between the pedicles and the rod attachments [36]. The rods were modeled as beams having circular cross section with diameter 5.5 mm, and having screw insertion points at a distance of 8 mm from the pedicles. The elastic modulus of the rods was varied between 19 and 210,000 MPa; Poisson ratio was 0.4 in all cases. The rods were classified as “very flexible”, “flexible” and “rigid” following the conventions reported in Table 2.

Loads and data analysis

All simulations were performed with ABAQUS 6.9 (SIMULIA, Providence, RI, USA). All the described models were subjected to moments of 7.5 Nm in the three main directions (flexion-extension, lateral bending, axial

rotation) [37] combined with a compressive preload of 500 N [11]. Due to the symmetry of the considered anatomy and instrumentation, tests in lateral bending and axial rotation were performed only in the right direction.

Data extracted from the simulations included the ranges of motion (ROMs) in the three anatomical directions, the axial force transmitted through the cage and through the facet joints, the contact pressures at the cage-endplate interface, the relative cage movement between the cage and the L5 endplate measured in the most anterior cage point (Fig. 1b). For the models including posterior fixation, the forces and moments acting in the rods were also predicted.

Results

The stand-alone homogeneous cage proved to be able to effectively stabilize the segment in flexion, lateral bending and axial rotation (Fig. 2a), except for very soft cages (<100 MPa). The cage stabilization potential increased for increasing elastic moduli; however, for stiffer cages (>1 GPa), no marked differences in the ROMs were observed. Cage movement predicted at the cage-endplate interface was below 0.2 mm in all cases. The total axial force transmitted by the cage was not markedly dependent on the elastic modulus of the cage, and ranged between 270 N for axial rotation to 380 N for flexion. In extension, the cage implantation induced a destabilization of the segment, with ROM increased by 60% and a movement at the cage-endplate interface of 1 mm, for the whole range of material properties considered.

Increasing the cage stiffness induced a decrease of the force through the facet joints in lateral bending and axial rotation (Fig. 2b). In flexion, despite the high relative increase of the facet force, the absolute force values were below 10 N in all cases. In extension, an increase of the facet force (+25%), independently on the elastic modulus of the cage, was observed. The maximal contact pressure at the interface between the cage and the endplates (Fig. 2c), which can be regarded as an indicator for the risk of subsidence, was found to increase with increasing the elastic modulus of the cage, in all loading conditions. The highest pressure values were predicted for flexion, and were located on the anterior margin of the cage.

Considering the “sandwich” cage, the soft layer played a role in determining the residual mobility of the segment (Fig. 3a). Thicker layers induced significantly higher ROMs, in all loading conditions. It should be noted that, in extension, the soft layer prevented the destabilization predicted with homogeneous cages. Facet forces were less sensitive to the thickness of the layer (Fig. 3b). In flexion, despite very high ratios between the predicted facet forces and those obtained with the intact segment, the absolute

Table 2 Classification of the rod stiffness based on the mechanical properties of the considered rod materials

	Elastic modulus (MPa)	Axial stiffness (N/mm)
Very flexible	19–320	12–200
Flexible	320–10,000	200–6,300
Rigid	10,000–210,000	6,300–132,000

Fig. 2 ROMs (a) and forces in the most loaded facet joint (b) relative to the values calculated with the model of the intact segment, and maximal contact pressure (c) predicted for the cage made with a single material with varying elastic modulus

force values were low (<7 N). Movement at the interface between the cage and the endplates were not clearly dependent on the thickness of the soft layer, and was in all cases below 0.6 mm (Fig. 3c). The total axial force transmitted through the cage was also not influenced by the layer thickness, and was again maximal in flexion (380 N). The maximal contact pressure at the cage-endplate interface was not sensitive to the thickness of the soft layer, and

Fig. 3 ROMs (a) and forces in the most loaded facet joint (b) relative to the values calculated with the model of the intact segment, and movement (c) predicted for the “sandwich” cage with varying thickness of the soft layers

was remarkably lower if compared to the correspondent values predicted for homogeneous cages, except for the very flexible ones. Contact pressure values ranged from 4.5 MPa in axial rotation to 14 MPa in flexion.

Posterior fixation additional to the “sandwich” cage reduced the ROMs in all loading conditions (Fig. 4a). The stabilization even for very flexible rods (<320 MPa, 200 N/mm) was effective for flexion, extension and lateral bending, while in axial rotation stiffer rods were required to achieve the same ROM reduction. For stiff rods, e.g.,

Fig. 4 ROM relative to the values calculated with the model of the intact segment (a), movement (b), axial forces (c) and moments (d) acting in the posterior rods, predicted for the “sandwich” cage with 1.5 thick soft layers and posterior instrumentation with varying stiffness. For flexion and extension, forces and bending moments are equal in the rods and shown for a single rod. For lateral bending and axial rotation, forces and moments (bending and twisting for axial rotation) are shown separately for both rods

titanium and steel, the residual ROM was in any loading conditions less than 20% of the respective ROM predicted with the intact model. Movement at the cage-endplate interface (Fig. 4b) and facet forces between the cage and the endplates were drastically reduced if compared to the values predicted with the stand alone cages. The highest movement was recorded in axial rotation (up to 0.23 mm for very flexible rods made from PCU 80A), while for the other load cases calculated values were below 0.05 mm. For flexible rods (<10,000 MPa, 6,300 N/mm), the axial force transmitted through the cage was not remarkably reduced if compared to the cases without posterior instrumentation, thus enabling a considerable loading of the anterior column. Stiffer rods markedly reduced the load through the cage. For steel rods, the maximal force through the cage was predicted in flexion (250 N).

The axial forces acting in the fixation rods did not generally show a monotonic behavior (Fig. 4c). The bending moments were very low for flexible rods, and become significant for stiffer rods (Fig. 4d). In flexion, the tensile force in the rods increased with increasing the stiffness of the rods up to an elastic modulus of 5,000 MPa (3,150 N/mm). For stiffer rods, the axial force decreased, and the bending moment drastically increased. In extension, the compressive force in the rods markedly increased up to an elastic modulus of around 1,000 MPa (630 N/mm), and remained almost constant for stiffer rods. In lateral bending and axial rotation, being the loading

conditions asymmetrical, the left and the right rods behaved differently. In lateral bending, the tensioned rod (left) showed an increase of the axial force for flexible rods (<10,000 MPa, 6,300 N/mm), and a decrease for stiffer rods, as described for flexion. The compressed rod (right) showed a monotonic increase of the axial force. In both rods, the bending moments were very low if compared to the other loading conditions. In right axial rotation, the left rod sustained a small axial force, tensile for flexible rods and compressive for stiffer rods. The right rod supported a monotonically increasing compressive force. Bending moments were remarkable and had the same value in both rods. Twisting moments in the rods were not significant (150 Nmm for steel rods).

Discussion

The effect of stabilization with a novel interbody cage with varying structure and mechanical properties, implanted stand-alone or supplemented with posterior fixation, was investigated using FE models. The presence of soft layers on the interface with the endplates provided significant advantage with respect to the homogeneous cage. First, it allowed to significantly reduce the peak contact pressure between the cage and the bony structures, thus lessening the risk of cage subsidence. The destabilization in extension, which is presumably due to the surgical removal of

structures active in this loading condition, such as the ALL, the anterior part of the annulus and the nucleus, was not predicted when the soft layers were modeled. However, coherently with previous literature (reviewed in [27]), no one of the considered cage models was able to provide a significant stabilization in extension. Another theoretical advantage, which was, however, not considered in the present models regarding the fact that the deformability of the soft layers allows for a better fit to the irregularities of the prepared endplate, thus maximizing the contact area and stability, and reducing contact pressures. The same fit could be achieved by implanting a homogeneous soft cage, but at the expenses of a lower stabilization, higher facet forces and therefore a higher risk of unsuccessful fusion.

Posterior fixation enhanced the stabilization potential of the cage, even for rods having a low stiffness, prevented the destabilization in extension and reduced the movement of the cage. Although in patients showing spinal instability or spondylolisthesis posterior fixation is in any case required to restore the correct stiffness and alignment of the spine segment [5], from biomechanical point of view, posterior rods showed to be able to remarkably supplement ALIF, and may be recommended. However, more complex surgeries requiring both anterior and posterior access, risk of complications such as retrograde ejaculation, increased morbidity and costs, and the support by an approach surgeon are required [3]. Implantation of PLIF cages coupled with posterior fixation does not require anterior/posterior access and exploits most of the advantage of interbody and pedicular instrumentation [9], but provides a less comprehensive evacuation of the disc space, thus making a smaller endplate area available for bony fusion. TLIF was proven to be as safe and effective as PLIF [38], providing a greater room for interbody fusion [13], but requires the removal of a whole facet joint. Furthermore, in some deformity cases, a posterior approach alone may not be the best choice to recreate the correct spinal alignment and intervertebral space [5], and was related to a higher risk of major complications such as dural tears and device migration into the canal [26]. Therefore, the choice of the most appropriate treatment should be based on the clinical conditions of the specific patient, being all ALIF, PLIF and TLIF, with or without posterior fixation, possible candidate treatments having advantages and disadvantages.

Except for very flexible rods, the stabilization induced by posterior fixation coupled with an interbody cage was not strongly related with the elastic modulus of the rods, coherently with previous data [10, 30]. Therefore, if a classification system for the rods is based on the ROM reduction induced by the fixation, as done in the previous paper [30], flexible materials such as PEEK or dynamic systems as the Dynesys would be categorized as rigid. In this paper, the presented classification system (Table 2)

was aimed to be more closely related to the clinical aspects of spinal fixation than to the pure stabilization potential. Non-metallic rods, including PEEK, differ from titanium and steel rods in their ability of supporting lower loads, thus transferring higher loads to the anterior column and promoting bony growth [10], as confirmed by the present results. Furthermore, this type of rods may induce a lower stress on the screw-bone interface if compared to metallic rods, thus limiting the risk of screw loosening, despite there is no clinical evidence of this advantage yet [21].

Therefore, from a biomechanical point of view the implantation of an intersomatic cage coupled with flexible posterior fixation may be recommended. This material combination also provides better CT visualization and assessment of the fusion of polymeric implants, if compared to metallic rods [23].

Some limitations of the present study can be identified. An arbitrary friction coefficient of 0.5 was chosen; it could be expected that this assumption may have a relevant influence on some results, i.e., the movement. Therefore, the friction coefficient could be considered an additional degree of freedom in the design process, e.g., by modifying the surface rugosity of the soft layers, allowing to achieve movement values that would promote bony growth at best [34]. A parametric FE investigation of this parameter would be helpful in supporting the design.

Only one combination of cage geometry and spine anatomy was considered. The cage size was chosen in order to perfectly fit with the current size of the anatomic structures, which in turn could show a strong variability from patient to patient. Results are expected to vary for different spinal anatomic and mechanical conditions, especially including degenerative changes of the segment, as commonly found in segments requiring fixation and fusion. Changes in the endplate curvature may reduce the contact area between the cage and the endplates, therefore increasing the risk of subsidence. Different shapes of the cage contact area may also have an influence on the interaction between the cage and surrounding bone [6]. However, previous papers comparing different cage models mainly found only minor differences [16, 22, 25].

A major limitation concerns the constitutive modeling of the bony structures. Inelastic, damage and failure properties for the bone were not considered in the present study. High stress areas may be subjected to failure and therefore to high local strain which would induce a rearrangement of the contact surface between the cage and bone, therefore leading to a smoothening of the stress peaks and in general to different results. For an accurate prediction of the subsidence, taking into account such phenomena is definitely a requirement [8]. However, most FE models investigating intersomatic stabilization ignored this issue [4, 19, 20, 32, 33], while others considered in a simplified manner [18].

As a matter of fact, the inclusion of bone inelastic behavior in models at a continuum level still represents an open problem and a serious challenge in the creation of numerical models of spinal implants.

The behavior of the spine segment in the immediate post-operative period was simulated, neglecting any actual bony fusion. Fibrous or scan tissue is usually found in the first 3 weeks after the operation [39]; the introduction in the models of such tissues would reduce some negative effects of intersomatic fixation, such as excessive movement and destabilization in extension. Considering only the cage and the surrounding structures which are left intact during the surgery, however, allowed for the simulation of the worst case, the most unstable scenario, which provides more information for the evaluation of the mechanical performance of stabilization.

Conclusions

In general, results were found to be markedly dependent on the stiffness of the cage, the thickness of the soft layers when present, and on the elastic modulus of the fixation rods. Therefore, the wide range of variability of the predictions offers a potential for the optimization of the device, in order to achieve the desired performances. The soft layers showed to have the potential to limit the risk of cage subsidence and to preserve a significant loading of the structure even in combination with flexible posterior instrumentation, which may have a beneficial effect in promoting bony fusion.

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Conflict of interest None of the authors has any potential conflict of interest.

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