MECHANICAL PERFORMANCE OF CONVENTIONAL THREADED CAGE DESIGNS AND INTERBODY FUSION CAGES DESIGNED BY INTEGRATED GLOBAL AND LOCAL TOPOLOGY OPTIMIZATION

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INTRODUCTION

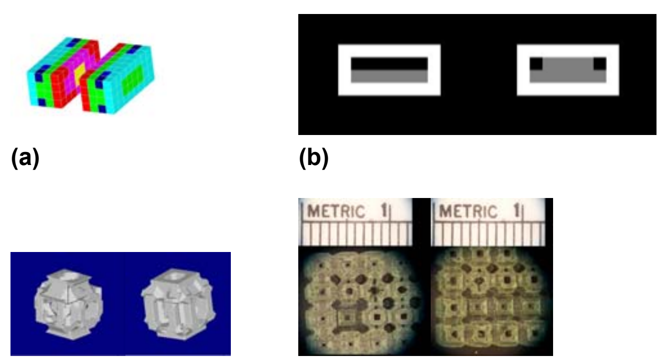
Conventional designs of spinal interbody fusion cages have mainly focused on providing immediate strength to maintain disc height and shielding the bone grafts within the cage. Therefore, the geometrical features of these conventional designs show little distinction from each other and most of them fall into a category of a pipe shape with thick shells as outer walls as well as a hollow interior space that brackets the fill of grafting materials. Further division is defined by the threaded and non-threaded anchorage mechanism that cage devices rely on to form rigid bonds with vertebral bodies. Threaded designs may be utilized along the entire outer surface of cylindrical cages, whereas they are distributed only on two collateral sides perpendicular to the insertion plane in wedge or rectangular blocks and are later wedged into the endplates of the vertebral bodies. These hollow pipe designs guarantee sufficient reconstruction stiffness in arthrodesis and play a substantial role in stability for motion segments postoperatively. Nonetheless, the rigid shells may shield an implanted graft or ingrown bone tissue from sufficient mechanical stimulus, (known as "stress-shielding") thus increasing the risk for decreased mineralization and bone resorption.

A new design approach for lumbar spine interbody fusion cage has been developed by using topology optimization algorithms to define the structural layout and inner microstructures. This approach addressed the conflicting design issues of having sufficient stability while at the same time having enough porosity to deliver biofactors like cells, genes, and proteins and impart sufficient mechanical strain to maintain developing tissue. The interior architecture consists of microstructures with reserved channel spaces for potential cell-based therapies and drug delivery. The interconnected struts of the microstructures formed a network of stress transmission so that the strain energy from applied loads can be not only absorbed by appositional bone ingrowth between the interface of the device and vertebrae but also by regenerate bone tissues inside the new cage design. The present study simulated performance of both conventional and the newly designed cages under various loading conditions of compression, torsion, lateral bending and flexion-extension using voxel-based finite element methods.

MATERIALS AND METHODS

New Cage Design of Integrated Topology Opotimization

The integrated global and microstructure topology optimization approach is used to design a spinal cage that meets design requirements of immediate stability following implantation, sufficient compliance to avoid stress shielding, and high porosity for biofactor delivery [1]. The global topology optimization algorithm is used to generate global density distribution under physiologic loading, which is shown in Figure 1a. Immediate stability is addressed by constraining the total displacement at the vertebral surface to be less than a desired target. Total porosity for biofactor delivery and sufficient compliance is input as a constraint for the global optimization. The result is a global volume fraction distribution, ensuring sufficient porosity for biofactor delivery and avoidance of stress shielding.



(a) (b) (c) (d)

Figure 1. New cage design processes

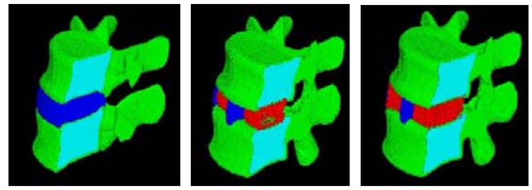
The layout density threshold was processed to segment the entire interconnected architecture into three separate material phases of a low porosity solid (45%~55%), a high porosity solid (20%~35%), and a completely void region (0% material), as shown in Figure 1b. Note that the global material layout only provides porosity and does not define the topology of the porous microstructure. To further define the microstructure, a local microstructural topology optimization method was used to generate periodic microstructures for the high percentage and low percentage solid regions that achieved Hashin-Shtrikman stiffness bounds for porous isotropic materials (Fig. 1c). The entire cage design could then be generated by repeating the periodic microstructures within the global density layout. The density of the global layout served as a flag to assign the microstructural topology. The design approach allows the prototype design customized for each patient with different loading conditions. It also allows the use of common solid free-form fabrication techniques to manufacture the designed cage from commonly used biomaterials including but not limited to titanium, hydroxyapatite, tricalcium phosphate, polylactic acid, polyglycolic acid, and poly(propylene fumarate). Figure 1d shows the microstructural features in the wax mold that was fabricated by 3-D jet printing. The internal architecture presented a spatial arrangement of the microstructures assigned by the global layout.

Image-based Finite Element Analysis of Post- operation and arthrodesis

A human lumbar spine model of level L4-L5 vertebrae was established by the reconstruction of slices from original Computational Topography (CT) scans with proper surface modifications. Instead of traditional finite element methods to mesh components and define the element types, an image-based approach was used to deal with the enormously large-scale problem generated by merging two complex 3D geometries of the designed cages and vertebral bodies. In fact, the traditional meshing would be doom to fail in such cases if a more accurate of the analysis is required for the interaction between biological tissues and polygonal devices since the geometrical dataset and connecting relationship will definitely cost extraordinary burdens for the calculation. The concept of this approach is simply to construct the model into a three-dimensional voxel dataset and then convert the voxels to finite elements. Different values of grayscale correspond to different materials. After the assignment of the material properties to respective components and definition of the boundary conditions for cases of interest, the resulting large-scale model is solved using the large-scale iterative algorithms. All aspects of the voxel finite element modeling process, including pre/post processing and analysis were performed using the commercial voxel finite element package Voxelcon (Quint, Inc., Tokyo, Japan; Voxel Computing, Ann Arbor, MI). However, one limitation of the current version is that it allows only four different kinds of materials to be incorporated simultaneously in the same model. Therefore, in the present study we classified three prominent components of the spine segment for the spine model, cortical bone, cancellous bone, and disc. We used the same material properties for each individual as described by Kim [2]. The fourth material was assigned to be titanium that is used for both conventional and our new designs. Figure 2 demonstrates the three-dimensional images of the final model, preoperatively (Fig. 2a) and postoperatively with both designs (Fig. 2b and 2c), respectively. These voxel models contained 3,360,533 number of elements for the normal vertebral bodies, 3,044,317 elements for the vertebra with conventional cage and 3,082,622 elements for vertebra with the newly designed cage.

RESULT AND DISCUSSION

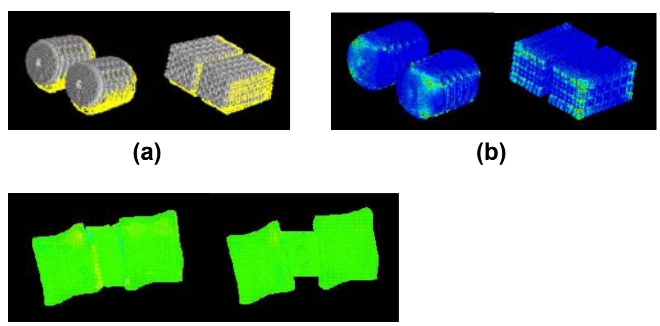
Relative slip distance at the interface between the vertebrae and implanted devices and the contact stress were obvious at the anterior edges both in conventional threaded cages and the new design. These results were consistent with previous study of the analysis of collateral threaded cage implantation in the L4-L5 spine model by Kim [2]. The maximal displacement (0.106 mm) shown in the new design case indicated a better stability to conventional cages (0.157 mm) (Fig. 3a).



(a) (b) (c)

Figure 2. Spine segment models. (a): preoperative, (b): postoperative with conventional cages, (c): postoperative with new designed cages

A more profound observation in the present study was to investigate the strain energy density absorbed by both appositional and localized new forming bone after the arthrodesis. The result image of the stress analysis revealed that there is no significant difference of Von-Mises equivalent stress for both designs that the range in the new design is from 85.5 MPa to 171.1 MPa, while it is 88.2~176.4 MPa in threaded cages (Fig. 3b). Interestingly, however, the shear stresses were significantly higher in regenerate tissue within the newly designed cage (4.76~12.72 MPa) than within the conventional designed cage (0~3.24 MPa). Moreover, this stress propagation can reach deeper layers of the bony bridge (Fig. 3c). The result may imply that the new designed cages by the integrated topology optimization would be able to provide higher stress to regenerate bone tissue while maintaining comparable stability. Further studies will investigate other biomaterials besides titanium and incorporate degradation effects on design.



(a) (b)

(c)

Figure 3. Mechanical analysis results, (a): displacement (b): V-M stress distribution, (c): shear stress distribution

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