Computer Aided Tissue Engineering for the Design and Evaluation of Lumbar-Spine Arthroplasty

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ABSTRACT

Degeneration of the intervertebral disc with age has been shown to be a significant source of pain and discomfort in the elderly, ultimately leading to a decreased functionality of the spine. Current treatments for disc degeneration focus on the fixation of the spinal unit by fusing the vertebra together, thus limiting and stabilizing the intervertebral motion, reducing the pain associated with the compression of the degenerated disc. Other treatments consist of entirely replacing the intervertebral disc, restoring function to the spine without reducing the range of motion. However, long term results of these treatments have been less than satisfactory, demanding a new approach to the treatment of degenerated intervertebral discs. The goal of this study was to develop a scaffold-like intervertebral disc with the mechanical characteristics required to function in the lumbar spine environment, thereby facilitating biological growth and eventual fixation of the disc within the spinal column.

Keywords: Lumbar Arthroplasty, Finite Element Analysis, Computer Aided Tissue Engineering.

1. INTRODUCTION

The medical treatment of degenerated intervertebral discs (IVD) within the spine is a clinical concern of rising interest in modern medicine. This has largely been the result of the enhanced technology used to treat both spine injury and disease. As a reflection of this enhanced ability to treat more diverse cases, recent studies have shown that on average, 450,000 spine fusion procedures are performed annually in the United States, of which 250,000 are for the lumbar region alone [9],[11]. These rates of spinal fusion illustrate not only how many procedures have been performed on an annual basis, but also the documented need to address the treatment of various spine disorders, particularly in reference to the lumbar spine. One such disorder of the spine, and one of the more commonly encountered ailments, has been the occurrence of disc degeneration disease (DDD). DDD is a disease of the spine that causes a thinning and hardening of the IVD as the nutritional mechanisms of the disc are deteriorated over time, eventually leading to the degeneration of the IVD [13]. To treat these clinical cases of DDD, there are relatively few procedures, aside from noninvasive therapy that can be used to alleviate the severe pain and discomfort of disc degeneration. As a result, surgical intervention is often the method of treatment used to treat DDD. Currently, the preferred methods of surgical treatment for DDD include partial discectomy, a removal of a region of the degenerated disc, spinal arthrodesis or fusion, a mechanical fixation of the spine preventing compression and irritation of the degenerated disc, and spine arthroplasty, a complete discectomy followed by replacement with a mechanical device in place of the degenerated disc. Although surgical arthrodesis of vertebra is currently the most commonly performed treatment for disc degeneration, it is widely considered to be a last resort, as long-term complications can often arise due to the nature of the procedure [4-5],[14].

More recent treatments, such as IVD arthroplasty, although still in their developmental phase, are now coming into more common use. Examples of current implants designed for spine arthroplasty applications include the ProDisc®, manufactured by Synthes Spine Solutions, the Maverick®, manufactured by Medtronic, and the Charité® artificial disc, manufactured by DePuy Spine, figure 1. As compared to the arthrodesis procedure these implants, as used for arthroplasty, have the benefit of maintaining the functional range of motion of the spine, unlike arthrodesis which immobilizes the spinal unit, effectively reducing the spine's range of motion [4-5]. The resulting benefit of these devices has been an increased rate of success over extended periods of time, avoiding many of the complications associated with arthrodesis. For example, the process of fusing two vertebra together effectively eliminates a vertebral joint,

reducing not only the rotational range of motion of the spinal unit, but also the ability of the spine to bend in the anterior, posterior, and lateral directions at the treated level. As a result of this reduced range of motion, increased stresses are induced at the adjacent levels of the spine as these surrounding joints attempt to compensate for the lack of mobility at the treated level. In many cases, it has been suggested that these heightened stresses bring about DDD in the adjacent levels much earlier than would otherwise occur, leading to further complications of the vertebral column [5]. In addition to this finding, other complications with mechanical arthrodesis have been found to include the inability to form solid fixation between implant and bone, device/screw loosening or failure, and in the worst of cases, the failure of the implant due to any of the above, followed by a migration of the implant within the body. Such occurrences pose dire risk to the patient due to the structure of the spine, and the proximity of the implant to the spinal cord and other vital structures [5-6]. Although IVD arthroplasty has the benefit of avoiding the complications associated with vertebral arthrodesis, it too is not without its own set of concerns. For example, the very design of the replacement disc and its metal-on-polymer bearing-surface design presents the risk for particulate debris to be generated by the implant. The generation of such debris has the potential for costly complications, as the interaction between this particulate debris and the spinal column poses severe consequences should the particulate material cause either tissue damage or necrosis of the spinal cord. The subsistence or migration of the implant has also been identified as a source of concern, not only because of the negative effects that unintended implant motion can have on the device, but also because the subsistence of the implant into the vertebral body can induce additional clinical complications of the spine and its architecture [4-5].

Fig. 1. Above are three spine arthroplasty implant designs currently used in limited clinical applications. (Left) ProDisc II®, Synthes Spine Solutions; (Center) Maverick®, Medtronic; (Right) Charité® Artificial Disc, DePuy Spine.

As a result of the conditions and complications surrounding the use of implants used for both arthrodesis and arthroplasty, and the justified need for the development of new treatment alternatives for spine ailments, the goal of this study was split into three components. The first component of the project was to combine the concepts of the arthrodesis and arthroplasty technologies into a single new device, taking advantage of the benefits of each device while eliminating their respective complications. The second component of this new implant design revolved around the notion of building a scaffold-like implant, such that cell-seeding and tissue-engineering methods could be used in conjunction with the implant for biological development both in-vitro and in-vivo. The third and most important part of the study was to design the implant such that its mechanical properties were similar to that of vertebral bone, rather than alloyed metal. As a result, the fulfillment of these objectives will provide a methodology that when combined with the use of patient specific CT scans, will allow for a truly patient-specific design to be generated. This aspect of the design would drastically enhance the ability of the IVD implant to perform in long term applications, as compared to the standardized implant designs of the currently used surgical spine treatments, thereby avoiding the potential secondary complications resulting from extended periods of implantation. The hypothesis behind these concepts is that an engineered implant could be developed to replace the degenerated disc using these principals of biomimetic design and computer aided tissue engineering, yet possess the mechanical characteristics of vertebral bone, and have the ability to support biological growth. Such an implant could provide a mechanism for the biological fusion of vertebral bodies, rather than mechanical fusion, and support the loading of the spine without being susceptible to the implant subsistence observed with metallic implants, a result of the more appropriate material properties and patient specific design of the implant.

2. MODEL DEVELOPMENT

To begin the development of the IVD replacement, a finite element analysis (FEA) model was developed from Human CT scans for the establishment of the effective material properties of the vertebral body. By generating these effective

mechanical properties, it would be possible to match the mechanical properties of the IVD replacement to those of the vertebra, generating a structure of more appropriate composition for interaction with the vertebral structures.

2.1 CAT Scan Analysis

To generate the model, a series of lumbar spine CT scans of a human patient were obtained for analysis. Using Materialise Mimics software, each of the CT files were assembled allowing for the reconstruction of the biological structures within the body. The first step consisted of isolating the bony architecture from the surrounding tissues to define the surfaces of the L4 and L5 vertebra. Once isolated, the bony structures were separated from the adjacent tissues and regenerated as a three-dimensional reconstruction of the two vertebral bodies. Following reconstruction, the vertebra were then segmented, removing the posterior elements in conjunction with protocol observed in the literature, reducing the computational power necessary to evaluate the complex three-dimensional structures [3],[10]. Following three dimensional reconstruction of the two vertebral bodies, the vertebra were transferred into the Geomagic software environment as STL files to remove unnecessary surface detail.

2.2 Component Editing

In the Geomagic workspace, the first step involved smoothing the surface of the vertebra, removing many of the surface details not regarded as vital to the mechanical behavior of the structure. After processing and smoothing the vertebra, a thin slice of bone was then removed from the vertebral endplates of each vertebra, as performed in real-life arthroplasty procedures [1]. This process, corresponding to the removal of the surface articular cartilage and remaining IVD tissues, was performed to create a smooth endplate surface for optimal contact between the vertebra and IVD during the later FEA simulations.

During this process, the material architecture of the vertebra and the fact that human vertebra are not homogenous in nature, but rather a mixture of both trabecular and cortical bone, was taken into consideration. As described in the literature, a vertebra contains two sections. The first is a trabecular interior structure with a porous lamellar composition comprising nearly the entire vertebra, while the second is a dense cortical bone shell surrounding the outer surface of the trabecular interior, measuring approximately 0.35 mm in thickness [5]. To take each of these components of the structure into account in the construction of the model, a shell was generated, using the Geomagic software, from the vertebral structure measuring 0.35 mm in thickness as reported in the literature. In addition, an interior section was created, matching the surface contour of the shell, entirely filling the interior space created by the shell component.

2.3 Establishing Material Properties

After the two components of each vertebra were generated, a set of material properties had to be established prior to being imported into Abaqus to establish the initial FEA model. To determine the material properties, a literature review of prior finite element models and biomechanical testing of the lumbar vertebral structures was carried out. Despite the wide range of values found throughout the literature, a set of material properties was established based on the frequency of their occurrence in published material. Once established, these material properties were applied to the shell and interior components, and can be seen below in table 1.

Property	Modulus (MPa)	Poisson's Ratio
Cortical Bone	12,000	0.3
Cancellous bone	100	0.2
Effective	395.837	0.206

Tab. 1. Material properties as derived from the literature and the effective material property equations, equations (1) and (2). Values for Modulus are representative of Young's Modulus (E) [5],[8],[12].

Following the application of material properties to the vertebral components, the vertebra components were imported into Abaqus as IGES files, and a set of surface interactions and boundary conditions were established within a preliminary FEA model containing only a single vertebra. These boundary conditions included the application of a purely axial force of approximately 7.1 kN, ramped linearly over time [3], applied to the superior surface of the vertebra; a set of tie-interactions, such that when loaded, the shell and interior would contact each other and act as a single unit; and boundary conditions fixing the base of the vertebra in place. As in the case of a real-time mechanical test, an FEA simulation was run in which the vertebra was compressed under axial load, producing a stress-strain

graph. After running the simulation, the stress and strain data were used to calculate the modulus of the vertebral components. These modulus values were then used in equations (1) and (2) to calculate the effective mechanical properties of the vertebra. The purpose of this was to generate a set of material properties that would reflect the properties of the bulk vertebra structure. Once determined, these properties would then be used in the development of the IVD, thereby reducing the risk of implant subsistence by matching the material properties of the IVD with those of the composite vertebra structure [12].

To calculate the effective mechanical properties of the vertebral body, a set of equations were derived to take into account not only the material properties of each section, but also the proportion of volume that each section contributed to the overall vertebra volume. Using Geomagic, the volume of each portion of vertebra was calculated and used in conjunction with the material properties of the literature, table 1, to calculate the effective mechanical properties of the vertebra structure. The equations used to calculate the effective Young's Modulus and Poisson's ratio are as follows, equations (1) and (2).

$$E_{Effective} = \left[\left(\%V_{Shell}\right)\left(E_{Shell}\right) + \left(\%V_{Interior}\right)\left(E_{Interior}\right)\right] \quad (1)$$

Eqn. 1. The equation above illustrates the calculation of the effective Young's Modulus based on the volumetric contribution of each component to the overall volume of the vertebra. $\%V_{Shell}$ and $\%V_{Interior}$ correspond to the percent volume of the shell and interior respectively. E_{Shell} and $E_{Interior}$ correspond to the Young's Modulus of the vertebra shell and interior respectively.

$$\nu_{Effective} = \left[\left(\%V_{Shell}\right)\left(\nu_{Shell}\right) + \left(\%V_{Interior}\right)\left(\nu_{Interior}\right)\right] \quad (2)$$

Eqn. 2. The equation above demonstrates the method used to calculate the effective Poisson's ratio of the vertebra, based on the Poisson's ratio of the shell, ν_{Shell}, and interior, $\nu_{Interior}$ obtained from the literature.

After determining the mechanical characteristics of the two types of bone, and the effective vertebra mechanical properties to be applied to the designed IVD, the information generated in the analysis of the preliminary model was used to generate the specifications of the replacement IVD.

3. BASIS OF IVD DESIGN

The structure of lumbar vertebral bone is unlike anything found throughout the body, or even throughout the spinal column. The variation of the bone structure within the spine is largely the result of differing forces experienced by different regions of the spine, and the way in which loading patterns of bone tend to dictate its interior architecture. Due to the variation of forces, and according to Wolf's Law, bone remodels itself over a period of time, adapting to its mechanical environment through the process of biological remodeling [7]. For example, in the cervical region, the spine tends to experience lateral or rotational loads with a great deal of bending associated with the motions. However, in the lumbar region there are minimal rotational and bending forces, but rather a great deal of the force is in the form of axial loads resulting from the weight of the torso above. As a result, not only are the vertebra shaped differently within the different regions of the spine, but their bone composition varies as well, as the lamella of the cervical region are found to be more plate-like, and those of the lumbar region tend to be more rod-like [2],[7]. Consequently, the bone found in the cervical region tends to have a greater bone volume, approximately 20-25%, due to the greater variation of forces and micro-structural organization, as compared to the bone of the lumbar spine, where there are fewer forces acting on the vertebra, and the bone volume is found to be approximately 10% [2]. This difference in bone structure translates into an inability to use the same implant design for both cervical and lumbar regions, as the structural makeup and behavior of these regions are exceedingly dissimilar. Therefore, since the region of interest in this study was the lumbar spine, the core design criteria were based on accommodating the axial loads of the spine rather than the rotational forces.

3.1 Determining Disc Geometry

In order to accommodate the large axial loads of the lumbar spine, an implant design was established according to the natural geometry of the spine. The first step was to measure the intervertebral gap at both the anterior and posterior of the spinal unit to establish the initial shape of the implant. After determining the separation between the articulating surfaces of the vertebra, the endplate geometry was characterized from direct measurement of the human vertebral CT images, figure 2.

Based on these measurements, an implant was generated in conjunction with guidelines established from previous work, indicating that the implant geometry should be as large as possible, covering as much of the vertebral endplate as possible without overlapping the edges of the vertebral body [2],[5],[12]. This concept was based on the idea that as the footprint of the implant decreases in area, the forces transmitted by the implant begin to increase, a scenario that can quickly lead to stress concentrations and the subsistence of the implant. It was also noted in the literature that the center of the vertebral endplate is much weaker in axial compression than the periphery, meaning that a smaller sized implant would not only transmit more force, but the vertebral bone would not have the structural strength to accommodate the loads [5].

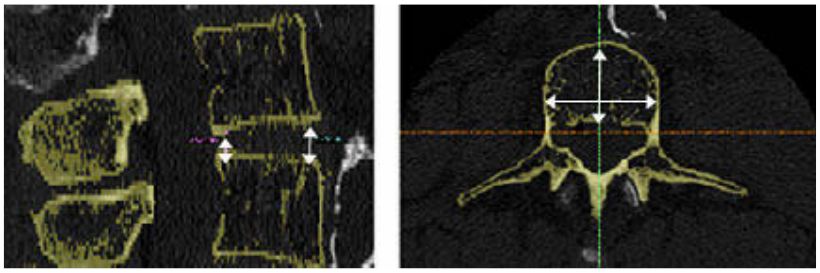

Fig. 2. (Left) Lateral image of the CT scan illustrating anterior and posterior measurements. (Right) Axial CT image showing measurements of vertebral endplate dimensions. Measurements are indicated by white arrows.

For that reason, the final implant design was one that occupied the maximum amount of room between the two vertebra, based on the neutral position of the CT scan, and a footprint that would maximize the coverage of the vertebral endplate, figure 2. Such a design would effectively distribute the axial loads of the lumbar spine over the entire vertebral endplate. In conjunction with this design, the effective material properties, as noted in table 1, were applied to the implant, providing the ideal mechanical properties for the proper function of the implant, thereby avoiding the complications associated with mismatched moduli. The final scaffold implant design can be seen below, along with the solid analogue of the design that was used for FEA analysis, figure 3.

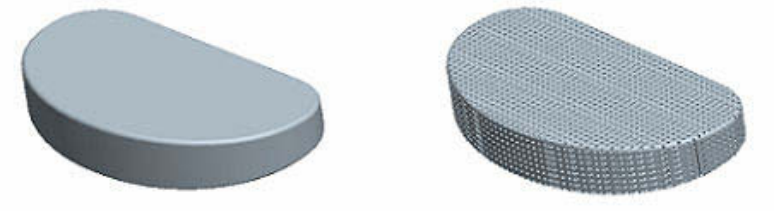

Fig. 3. (Left) Image of the FEA analogue of the designed IVD implant; (Right) Image of the final scaffold-like implant design.

3.2 Assembly of the FEA Model

Following the generation of the IVD implant, the vertebral components were again imported into Abaqus, along with the IVD implant, for the creation of the final FEA model. In this model, the two vertebra were aligned based on the initial alignment of the CT scans in MIMICS, preventing any artifacts from occurring due to misalignment of the vertebra. Once the vertebra components were assembled in the model, the material properties previously established, table 1, were applied to the respective components of the model, with the effective mechanical properties of the vertebra being applied to the IVD implant. The interaction between the trabecular interiors and cortical shells of the two vertebra were then established, defining the interaction as a set of ties between the outer surface of the trabecular interior, and the inner surface of the cortical shell. A set of ties was also established between the inferior surface of the IVD implant and superior surface of the lower vertebral shell, as well as for the superior surface of the IVD implant and the inferior surface of the upper vertebral shell. Such interactions produced the effect of bonding the IVD implant to the two vertebral bodies, simulating the biological fusion of the disc to the adjacent vertebra.

Once the interactions were defined, an axial load was generated and applied to a loading platen attached to the superior surface of the upper vertebra. This construct would replicate the action of the loading platen in a

biomechanical compression test, allowing for simulated uniaxial compression of the test sample. To ensure the accuracy of the replicated biomechanical compression test, the degrees of freedom of the loading platen were adjusted to prevent rotation about the X, Y, and Z axes, as well as motion in the horizontal plane. This process allowed for a pure axial load to be applied to the virtual test sample. The final step was to apply a boundary condition to the base of the spine, fixing the base of the spinal unit in place, while an additional interaction was defined between the two vertebral endplates should the disc fail and the two endplates come into contact with one another.

After the loading conditions were established, each component of the model was meshed, allowing Abaqus to generate structural data for each element of the model during the simulation. The mesh size for each of the various components was determined by the software algorithm and the surface detail of each component, while a tetrahedral shaped element was used to fill each of the structures. Allowing the program to determine the appropriate size mesh allowed for an adequately refined mesh to be generated without producing excessive amounts of information. The final meshed structure can be seen in figure 4, illustrating the complexity and number of elements required to mesh the entire structure. After meshing the components of the model, a non-linear geometric analysis was used to calculate the output variables and behavior of the model during the simulation.

Following the computational analysis of the model, the deformed states and corresponding stress distributions were observed, illustrating the dynamic behavior of the spinal unit during the loading of the spine. The visual results of the non-linear geometric analysis can be seen below, showing the stress distributions of the two vertebra and IVD during the simulation, figure 4.

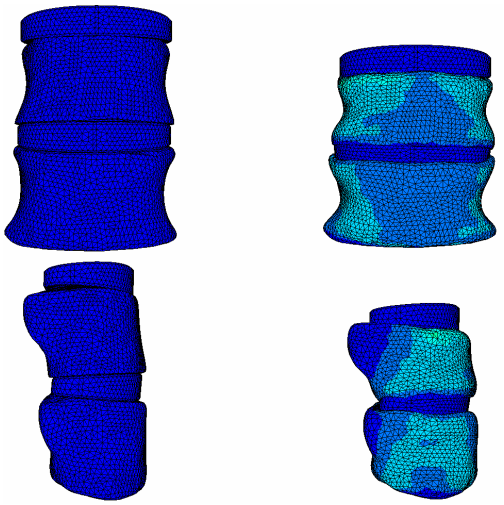

Fig. 4. (Left) Images of the meshed, undeformed vertebra from anterior and lateral views, (Right) Images of the compressed and distorted geometry of the vertebra just prior to failure. Colored regions indicate regions of high stress.

4. RESULTS

Based on the computational analysis of the two level vertebral model developed for this study, the results obtained illustrate a mechanical behavior that parallels the design objectives. Visual interpretation of the results from this model show a clear indication that implant subsistence was not an issue using the designed implant, even when the spinal unit was loaded to failure with compressive axial forces. Further evaluation demonstrated that the designed implant deformed during loading, accommodating the deformation of the vertebral bodies rather than succumbing to failure. As indicated by the literature, such occurrences are not commonly found with the use of traditional metallic implants, such as with the designs discussed in this paper. Visual interpretation alone suggests that the design of an implant with the effective mechanical properties of the vertebra provides the optimal mechanical characteristics for a vertebral implant, avoiding both implant subsistence and device failure, two of the major complications associated with current implant designs.

To further evaluate the results of this simulation, both the stiffness and offset yield-stress were calculated for the following components of the model: The endplate surfaces of the trabecular interiors, the endplate surfaces of the cortical shells, the entire trabecular interiors, the entire cortical shells, and the IVD implant. This was done to determine the behavior of the spinal unit numerically, allowing for evaluation of the mechanics and stress distributions observed from the compression of the vertebra, and the respective interactions between the vertebral bodies and the IVD implant. To perform this evaluation, the stress and strain data from each of the model components were first obtained. From this data, the apparent stiffness for each component of the model was calculated as the slope of the linear region of the stress-strain curve in accordance with standard practices. The offset-yield stress was defined as the point of intersection between the stress-strain curve and a line parallel to the linear region of the curve, corresponding to an offset strain of 0.2%. Using these values, the mechanical behaviors of the five model components were numerically characterized in the following graph, figure 5.

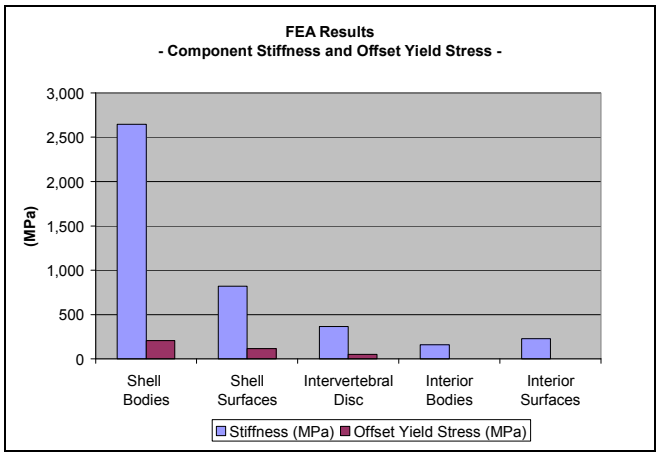

Fig. 5. The above graph illustrates the behavior of the vertebral model when subject to axial loading and a modulus-matched IVD implant. Shown are the apparent stiffness and offset yield-stress, calculated at 0.2% offset strain, of the various components. Units are measured in MPa.

As can be seen in the above graph, the apparent stiffness of the modulus-matched IVD, entitled "Intervertebral Disc" has an intermediate value of 364.47 MPa, as compared to the cortical shell bodies 2646.50 MPa, cortical shell endplate surfaces 821.43 MPa, trabecular interior bodies 160.69 MPa, and trabecular interior endplate surfaces 228.94 MPa. These results indicate that the behavior of the designed IVD is indeed in-line with both the objectives and the hypothesis of this study, as can be seen from figure 5, in which the IVD stiffness lies between the stiffness of the vertebral shells and interiors, rather than being much greater as the case would be with a metallic implant.

Also of interest in this study is the offset-yield stress and the way in which it characterizes the behavior of the modulus-matched IVD. Interestingly, it was found that neither the trabecular interiors, nor the endplate surfaces of the trabecular surfaces reached their yield point, whereas the shell components and the IVD implant did. This finding indicates that until the vertebra experiences a mechanical failure, the majority of the initial vertebra stiffness comes from the shell structures as compared to the interior structures. By comparing the offset yield-stress of the IVD implant with that of the shell, it can be seen that the yield-stress is less, 50.87 MPa, for the IVD implant, as compared to the entire shell and shell endplate surfaces, 205.13 MPa and 114.96 MPa respectively. This indicates that the IVD implant begins to yield before either the cortical shell or the trabecular interior, demonstrating that the modulus-matched IVD design is very suitable for the replacement of degenerated discs, as it yields before inducing damage to the surrounding vertebra or being subject to vertebral subsistence.

5. CONCLUSIONS

Overall, the development of a modulus-matched intervertebral disc implant to be used as a replacement for degenerated discs, as represented by this study, is both a valid and feasible option. Based on this simulated biomechanical analysis, a scaffold-like implant with the mechanical properties of human lumbar vertebra, as defined using the methods described above, would indeed be capable of functioning in the lumbar spine. This important

finding suggests that when such an implant is developed, in conjunction with biological materials, a highly functional implant will be generated that can not only accommodate the loads of the lumbar spine without resulting in subsistence into the adjacent vertebra, but would also be capable of biologically fusing the vertebra, stabilizing the spinal column and alleviating the symptoms of DDD. The ability of this method of design to be patient specific is also an advantage, as an IVD implant can be generated for a specific patient, with a specific spine ailment, based simply on the concept of image based modeling from non-invasive CT imaging. As a result, the treatment of spine ailments could become much more effective, addressing the specific problems of an individual, and without the extra cost or manpower associated with bringing a new implant design to market. This aspect of the image based modeling technique could potentially revolutionize the approach to surgical spine treatment, both technologically and economically, for all parties involved. In summary, although the availability of alternative treatment methods does not seem to be keeping up with the high incidence of the surgical treatment of DDD, the findings of this study show promise that alternatives for mechanical arthrodesis or arthroplasty do exist, and may soon become available for the treatment of disc degeneration disease in the near future.

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