Finite Element Analysis and Computer Aided Tissue Engineering Design of a Replacement Lumbar Intervertebral Disc

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***Abstract*—The treatment of disc degeneration disease of the spine has been a subject of particular interest in the medical community due to its effects on the lifestyle of afflicted patients. Current treatment modalities range from non-invasive treatment with physical therapy, to the invasive surgical repair of the degenerated disc(s). However, despite the existence of these treatment methods, each has its own set of drawbacks and limitations, most notably the use of surgical intervention. Examples of such limitations have included the mechanical failure of spinal implants, the destruction of the vertebral bone structure due to implant subsistence, graft site morbidity due to bone harvesting, and the promotion of disc degeneration at the surrounding spinal units. To overcome these limitations, a new implant design was conceived combining the concepts of arthrodesis, arthroplasty, and fusion via bone graft, allowing for the biological fusion of adjacent vertebra, in conjunction with the use of tissue engineering principals. In addition, this new approach to implant development, utilizing the practices of computer aided tissue engineering, permits the patient specific design of the implant, enhancing the ability to match implant design and architecture with patient anatomy. Resulting from these design criteria, the proposed novel design eliminates the drawbacks associated with the current vertebral implant designs, potentially extending both the lifespan and effectiveness of the implant, thereby improving the long term outcomes for the treatment of spinal disc degeneration.**

I. Introduction

Disc degeneration disease (DDD) is a condition of the spinal column in which the intervertebral disc looses its elastic properties, causing the morphology of the disc to become stiff and compressed. Although there is no single cause of DDD, it has commonly been thought to be the result of a combination of age, injury, and/or a degradation of the nutritional mechanisms of the vertebral endplates [1]. In addition to the severe morphological changes of DDD, there are also severe symptoms that can drastically influence the quality of life of an afflicted patient. The most common symptom is back pain, a result of the inelastic properties of the degenerated disc. However, more severe cases have been found to include the rupture of the IVD, and often osteophyte formation along the periphery of the vertebral endplates. Such symptoms can be extremely debilitating to an afflicted patient, limiting not only the range of motion of the affected spinal unit, but also the mobility of the patient due to the pain associated with a flexion or rotation of the degenerated disc [2]. As such, numerous surgical treatments have been developed to address the condition of disc degeneration in situations where non-invasive treatments, such as physical therapy, are ineffective. These surgical treatments include the mechanical fusion or arthrodesis of the spine, biological fusion as facilitated by the use of fusion cages, and replacement of the intervertebral disc, or disc arthroplasty. Despite the ability of these various procedures to treat disc degeneration, each has had limited rates of success due to the limitations of their design. These limitations include the mechanical failure of implant components, the inability to establish solid cage-graft fusion, implant subsistence, the generation of particulate debris, and in the worst scenarios, the migration of the implant due to any of the above limitations [3].

To avoid these limitations of current implant designs, a novel implant design was conceived combining the principals of the three previously mentioned treatments, in conjunction with the principals of tissue engineering. Such an approach allows for the effective treatment of disc degeneration by replacing the degenerated disc, yet generating effective biological fusion to adjacent vertebra with a patient specific design.

II. Model Development

A. Rational for Design

To meet the design criteria for this novel implant design, the replacement intervertebral disc was constructed in the form of a porous scaffold. Such a design allowed for a porous structure to be made that would support the growth of bone cells implanted into the disc structure. As a result, the use of osteoblast cells in the construction of the implant would promote the effective biological fusion of the disc to the surrounding bony endplates of the vertebra.

To generate the geometric parameters for the replacement IVD, Materialase MIMICS software was used to measure the intervertebral spacing and end-plate geometry of the patient's vertebra, as measured from patient specific CT scans. This allowed for an implant to be designed that would perfectly match the anatomical structure and geometry of the patient, ensuring the optimal biomechanical performance of the implant following implantation.

B. Establishing Mechanical Properties

One of the key characteristics of this implant is the modulus-

matched design, providing the implant with the mechanical characteristics and properties of the natural spine. By providing the implant with such properties, problems such as implant subsistence, a result of using an implant with a greater modulus than the surrounding bone, can be avoided. To determine the mechanical properties of the vertebra, a finite element analysis (FEA) was performed to analyze the behavior of the vertebra under simulated compression in terms of its cortical shell and trabecular interior structures. After obtaining the stress and strain behavior of each vertebral structure, the effective modulus and Poisson's Ratio were obtained by taking into account the volumetric contributions of each vertebral component in proportion to the volume of the whole vertebra, and the Young's Modulus obtained from each structure of the FEA vertebral model (see Table I).

C. Developing the Vertebral FEA Model

After developing the implant geometry and mechanical properties, the final vertebral model was created, again using the patient specific vertebral CT images. The final model consisted of a two level lumbar spine segment and the modulus-matched intervertebral disc specifically designed for the patient. Again, each vertebra was modeled as a trabecular interior, surrounded by a thin cortical shell 0.35 mm in thickness [3]. Using ABAQUS finite element software, each of the vertebral components were meshed and assigned a set of boundary conditions during the component assembly. The boundary conditions used consisted of ties between the vertebral shells and interiors, joining each surface node of the two structures together, as well as between the implant and the surrounding vertebral endplates. These ties served to bond the various structures together, allowing the model to behave as a single fused spinal unit. After the boundary conditions were defined, the base of the model was fixed in place and a uniaxial compressive force of approximately 7.1 kN was applied uniformly to the superior surface of the spinal segment (see Figure I).

III. Results

A. FEA Model Analysis

After performing the FEA analysis of the two-level vertebra implanted with the patient-specific modulus-matched implant, the behavior of the implant was characterized both visually and numerically. The first indication of the biomechanical performance of the implant was the fact that in the vertebral FEA, the modulus-matched implant deformed with the surrounding vertebra, rather than imbedding itself in the surrounding endplates. This result of the analysis indicated the ability of the implant to resist implant resorbtion, and deform to the same degree as the vertebra, rather than to crush the vertebra components during loading. Numerical analysis yielded the same findings, such that the implant stiffness, 364.47 MPa, measured from the FEA model was in between the stiffness of the trabecular interior, 160.69 MPa, and cortical shell, 2,646.50 MPa, reflecting the volumetric contributions of the respective components as per the design criteria. After examining the yield stress of the modulus-matched implant, it was found that the implant in fact reached its yield point, 50.87 MPa, a characteristic of this implant design not observed with any of the current implant technologies, verifying the ability of the implant to support the loading of the spine without inducing a failure of the surrounding bone structures.

TABLE I
MECHANICAL PROPERTIES OF VERTEBRA COMPONENTS [3-4]

	Young's Modulus	Poisson's Ratio
Cortical Shell	12,000 MPa	0.3
Trabecular Interior	100 MPa	0.2
Effective	396 MPa	0.206

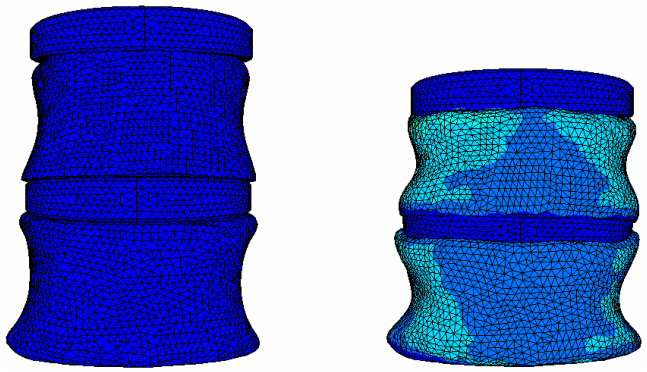

FIGURE I: FEA REPRESENTATION OF MESHED VERTEBRA

B. Conclusions

The findings of this study suggest that the ability to create a modulus-matched replacement disc for the lumbar spine can indeed be accomplished, satisfying the design criteria for improved performance over current designs. Not only do the design criteria for this implant avoid the limitations inherent to current treatment modalities, but the incorporation of cell seeding and tissue engineering with osteoblast cells will further enhance the ability of this implant to function in long term applications, providing enhanced biological fusion to the adjacent vertebra. In conclusion, the findings of this study demonstrate that alternatives for mechanical arthrodesis or arthroplasty can indeed be developed, allowing for improved mechanical and biological functionality to support long term implantation.

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