Optimum Topology Design of an Interbody Fusion Implant for Lumbar Spine Fixation

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Abstract

The goal of this research is to obtain the optimal topology of a new interbody fusion implant for use in lumbar spine fixation. A new minimally invasive surgical technique for interbody fusion is currently in development. The procedure makes use of an interbody fusion implant that is inserted between the vertebral bodies to be fused. The interbody fusion implant is packed with bone graft material to facilitate the fusion of the two vertebral bodies. The implant must be capable of supporting the mechanical loads of the lumbar spine while solid fusion of the vertebral bodies occurs. The implant restrains the bone graft material and maintains proper intervertebral spacing during fusion. Finite element analysis and topology optimization software are used to drive the topology design of the implant. The topology optimization process seeks to minimize strain energy subject to mass fraction constraints for different loading conditions: compression, flexion/extension, and lateral bending. The resulting topologies for each loading condition are superimposed to generate a composite optimum topology. This composite optimum topology is then converted to a candidate implant geometry that is suitable for manufacturing.

1 Introduction

Lower back pain is one of the most common and significant musculoskeletal problems in the world. It has been estimated that 80% of the Americans will experience lower back pain in their lifetime. Currently there are 600,000 surgeries performed per year in USA, with a 50% of failure rate. This high failure rate has motivated the development of new surgical procedures that are less invasive and more suc-
cessfull. One of the leading causes of lower back pain is related to disc disorders. Spinal discs are located between each vertebra in the spine and are designed to act as shock absorbers within the spine. In some cases, with time, they deteriorate and lose their shock absorbing abilities causing pain in the spine and/or vertebra. This gradual process is known as degenerative disc disease (DDD), and is one of the main causes of lower back pain and spinal disorders. Figure 1 depicts other forms of discs disorders that can occur in the spine.

![Disc disorders](image)

**Figure 1: Disc disorders**

For many disc disorders it is difficult to treat them through non-surgical methods. The most common surgical practice to alleviate the pain associated with these disorders is lumbar fusion. The history of spinal fusion begins in New York with the work of Fred Albee [1] and Russell Hibbs [2], each published in 1911. Previous surgery procedures using similar techniques are related by Wiltse [3]. The object of this technique is to eliminate the relative movement across a motion segment of the spine, or a series of motion segments, that have degenerated to the point of causing pain. The goal is to relieve pain, restore nerve function, and stop or prevent abnormal motion in the spine.

Lumbar spinal fusion involves the use of bone graft material and fixation instrumentation to prevent motion in the painful vertebral segment. The bone graft grows between the two vertebral elements and fuses the motion segment. Spine surgery instrumentation like plates, rods and cages are used to provide fixation as part of the fusion surgery process. There are several types of spinal fusion surgery options described in literature [4]. The most common practices include: posterolateral gutter fusion, posterior lumbar interbody fusion (PLIF), anterior lumbar
interbody fusion (ALIF), and anterior/posterior spinal fusion. The research presented in this investigation relates to a new surgical procedure for lumbar spine fixation that is currently in development. The new minimally invasive surgical procedure involves the use of a novel interbody fusion implant. The function of this implant is to house the bone graft material while insuring structural stability (i.e., minimum strain energy) of the motion segment, while the bone graft heals. The healing process can take several months.

Our goal in this work is to obtain the optimal structural topology (i.e., geometry) of the interbody fusion implant. One wants to maximize the volume available for bone graft material within the implant, while supporting the structural loads imposed on the system. GENESIS, a finite element-based optimization software, is used to drive the optimum topology design. Increasingly, topology optimization is being used to find preliminary, sometimes completely innovative, structural configurations that meets specific conditions (i.e. objective function and constraints). The automotive industry regularly uses topology optimization software tools for the design of innovative structures.

2 Finite element-based optimization

Finite element-based optimization techniques were first developed by UCLA Professor, Lucien Schmit in the 1960s. He recognized the potential of combining optimization techniques with finite element analysis for structural design. Today, three types of finite element-based optimization approaches are often available within commercial FEA software: sizing, shape and topology optimization. These approaches for structural optimization are differentiated by their use of different design variable types.

2.1 Sizing optimization

Sizing or parameter optimization typically uses element cross-sectional dimensions as design variables [5]. These include parameters such as thickness, area, moment of inertia, and others.

2.2 Shape optimization

Shape optimization involves determining the optimal profile of a body, shape and/or size of a hole, fillet or any other boundary [6]. Scale factors of perturbation are the design variables. The perturbation is the allowed nodal displacement of the shape to be optimized.

2.3 Topology optimization

Topology optimization involves the optimal distribution of material within a structure. Unlike shape and sizing optimization, topology optimization does not require an initial design. Typically, the design process starts with a block of material called
the design domain. The design domain is comprised of a large number of candidate elements, and the topology optimization process selectively removes from the domain those unnecessary elements. The design variables in topology optimization depend on the type of material model used in the finite element analysis. There are two general approaches: density and homogenization.

2.3.1 Density approach
In the density approach, presented by Bendsøe [7], the design variables \( x_e \) are the element relative densities or volume fraction (fraction of solid material). The material model, for each finite element, is based on heuristic relationships between design variables and material properties (i.e. density and Young’s modulus). Simple relationships that have been used, are

\[
\rho_e = x_e \rho_0 \\
E_e = (x_e)^p E_0,
\]

where \( x_e \) is the design variable, \( \rho_0 \) and \( E_0 \) are the original density and Young’s modulus of the material, \( \rho_e \) and \( E_e \) are the density and Young’s modulus of the element, subscript \( e \) is the element number, and \( p \) is the penalization power where \( p \geq 1 \). This material model leads to an isotropic material [6]. In theory eqns (1) and (2) are true only if the design variables are \( 0.0 \) or \( 1.0 \). If \( x_e = 1.0 \) then the element is needed, if \( x_e = 0.0 \) then the element can be removed from the model [8].

2.3.2 Homogenization approach
In the homogenization approach, presented by Bendsøe and Kikuchi [9], each element is a microstructure. The design variables are the parameters of the microstructure. In two dimensions, the microstructure consists of millions of unit square cells oriented at an angle \( \theta \). Each cell has a rectangular hole defined by side lengths \( a \) and \( b \). The design variables correspond to the three parameters: \( a \), \( b \) and \( \theta \). The material model leads to a more general orthotropic material [6].

The code, Optistruct, originally developed by Kikuchi et al., and now being enhanced by Altair Computing, uses the homogenization approach [10]. The software GENESIS, from VR&D, uses the density approach [8].

3 Methodology

3.1 Finite element model

The finite element analysis and topology optimization software GENESIS is used to drive the topology design of the interbody fusion implant. The implant will be inserted within the annulus fibrosus of the disc after removal of the nucleus pulposus (i.e., percutaneous nucleotomy). Figure 2 provides a conceptual illustration of the implant within the disc.
The design domain for topology optimization is constrained by the geometry of the annulus fibrosus. In this study, as figure 3 depicts, a symmetric design domain composed of 8256 eight-noded solid CHEXA elements is used. The mechanical properties: Young’s modulus $E_0$, density $\rho_0$ and Poisson’s ratio $\nu$, correspond to that of the candidate implant material.

![Design domain](image)

Figure 3: Design domain

The vertebral bodies above and below the implant, are considered rigid elements. The upper vertebra is modeled by one rigid element RBE2 that spans the compressive half of the implant. The lower vertebra is modeled by fully constraining the bottom of the design space.

The topology optimization process is performed for compression, flexion/extension and lateral bending. We impose the nominal values most often reported in the literature: 400 N for the compressive load, and 7.5 Nm for the moments. These moments are applied in the center of the upper vertebra located 25 mm above the upper surface of the design domain.

### 3.2 Elasticity analysis

The topology optimization problem is developed through an elasticity analysis of the finite element model. Using linear elasticity and the principle of virtual work, we have,

$$ \mathbf{F}_G = \mathbf{K}_G \mathbf{U}_G, $$

(3)
where $U_G$ and $F_G$ are the global node displacement and force vectors, $K_G$ is the global stiffness matrix. The total potential energy is given by

$$V = U + \Omega,$$

(4)

where $U$ and $\Omega$ are the internal and external potential energies respectively [11]. The internal or strain energy is

$$U = \frac{1}{2} \sum_e u_e^T k_e u_e,$$

(5)

where $u_e$ is the element node displacement vector and $k_e$ is the element stiffness matrix. Using eqns (3) and (5) the optimization problem can now be stated.

3.3 Optimization problem

The design task is formulated as a topology optimization problem where the objective function is minimize strain energy $U$. The optimization problem is constrained by a maximum allowable mass fraction of material that can be used to obtain the final topology of the implant. The optimization problem can be stated as

$$\begin{align*}
\min & : f = \sum_e u_e^T k_e u_e \\
\text{s.t.} & : \sum_e \rho_e = m_f \\
& : K_G U_G = F_G \\
& : x_{\text{min}} \leq x_e \leq 1.0
\end{align*}$$

(6)

where $f$ is the objective function, $m_f$ is the mass fraction constraint ($0.0 < m_f < 1.0$), $x_{\text{min}}$ is the lower limit for the design variables, and $e = 1, \ldots, 8256$. Using the density approach given by eqns (1) and (2), eqn (6) can be expressed in terms of the design variables $x_e$. In particular, the element stiffness matrix $k_e$ can be written as,

$$k_e = (x_e)^p k_0,$$

(7)

where $k_0$ is the original element stiffness matrix of the material. The penalization power is typically $p = 3$. This approach, used by Sigmund [12], requires a non-zero design variable to avoid singularity conditions, typically $x_{\text{min}} = 0.001$.

GENESIS has implemented several different relationship functions between design variables and material properties [8]. By default it uses eqn (1), but instead of eqn (7) it uses

$$k_e = q k_0 + (1 - q)(x_e)^p k_0,$$

(8)

where the penalization power is typically $2.0 \leq p \leq 3.0$. The parameter $q = \frac{E_{\text{min}}}{E_0}$, where $E_{\text{min}}$ is the minimum value that Young’s modulus is allowed to take, and $0.0 < q \leq 1.0$, where typically $q = 10^{-6}$. 


There are several approaches to solve the structural optimization problem given by eqn (6). Some of the most common techniques include: Approximation concepts for structural optimization [13], Optimality Criteria (OC) [14], Sequential Linear Programming (SLP), and Method of Moving Asymptotes (MMA) [15]. GENESIS has incorporated approximation techniques [8].

3.4 Implementation

The final topology of the implant must allow a proper space for the bone graft element to grow into the vertebral bodies. Previous implant designs show that this space corresponds to a mass fraction between 35 and 50% of the design domain.

Topology optimization is performed for three load cases: compression, flexion/extension and lateral bending. Each load case is solved using an independent finite element model and particular mass fraction constraints. The corresponding final topologies for each load case, will be superimposed taken into account symmetry conditions. The superimposed topology used to generate a CAD model of the final implant. The final mass fraction of this implant must be close to 35 percent and no higher than 50 percent. It also must be a continuous body that permits smooth flow in its interior.

Finally, this implant is analyzed using finite element technique. Three load conditions must be applied: compression, flexion/extension and lateral bending. The results are compared to the best previous implant design. Most of the studies over the spine column use as standard certain standard loads. In most of the cases, these loads include: 400 N for compression and 7.5 Nm for flexion/extension and lateral bending moment applied over the upper vertebra. These are the values used in this work for topology optimization procedure and finite element analysis.

4 Results

4.1 Topology optimization for three load cases

The topology optimization problem is solved for each of the three loading conditions: compression, flexion/extension, and lateral bending. Multiple optimization trials are performed for each load case where the required mass fraction is varied.

A distributed compressive load of 400 N was applied over the upper surface of the design domain. The topologies for 40, 20 and 10 percent mass fraction constraints are illustrated in figure 4. The final topologies include arch like support throughout the structure. The solutions for the 20 and 10 percent of mass fraction trials include simple transverse arches in the central region.

A moment of 7.5 Nm is applied on top the upper vertebra for the load cases of flexion/extension and lateral bending. Two different models are considered in each case. In order to span the compressive half of the implant, half of the vertebra is not considered in the respective models. Figures 5 and 6 show the finite element layout and final topologies for the 20 and 10 percent mass fraction trials, for the two moment loading conditions. The final topology corresponds to the darker vol-
Figure 4: Compression (a) $m_f = 0.40$ (b) $m_f = 0.20$ (c) $m_f = 0.10$

Volume shown in the figure. In each case, the final topology includes two bands or walls. One is located across the center and the other at the edge. The central wall is stressed with the highest shear force, while the outer wall is stressed with the highest compressive load.

Figure 5: Flexion/extension. (a) FE layout (b) $m_f = 0.20$ (c) $m_f = 0.10$

Figure 6: Lateral bending (a) FE layout (b) $m_f = 0.20$ (c) $m_f = 0.10$

4.2 Final topology

The final topology is obtained by superimposing the topologies of the 10 percent mass fraction trials for flexion/extension and lateral bending with the 20 percent mass fraction trial for compression loading. Each of the flexion/extension
and lateral bending topologies are mirrored about symmetry planes prior to being superimposed. This superimposed topology of flexion/extension and lateral bending uses 25 percent of the available mass fraction. This topology forms a base (figure 7 (a)) onto which we superimpose the compression loading topologies.

Figure 7: Superimposed topologies (a) Base. (b) $m_f = 0.35$. (c) $m_f = 0.28$.

In figure 7 (b) the topology for the 20 percent mass fraction compression trial is superimposed onto the base. The final superimposed topology uses 35 percent of the available mass fraction. Figure 7 (c) depicts the topology of the 10 percent mass fraction trial for compression superimposed onto the base. This topology uses only 28 percent of the available mass fraction. Based on the results of the topology optimization studies a candidate geometry more suitable for manufacturing is then generated. In this geometry all walls are connected and weak columns are eliminated. The final shape uses 35 percent of the available mass fraction and is shown in figure 8.

Figure 8: Candidate geometry

4.3 Finite element analysis

To illustrate the benefit of applying topology optimization for the design of the interbody fusion implant, the results obtained in this study are compared to candidate designs generated using a trial and error approach for geometry design. A finite element analysis of the best implant generated by trial and error is compared to the new candidate implant proposed from the topology optimization studies. Both have similar volumes close to 35 percent of the available mass fraction. The combined loading conditions of the finite element analysis are the compressive
load (400 N), the flexion/extension moment (7.5 Nm), and the lateral bending moment (7.5 Nm). The compressive load is distributed over the top surface of the implant, and the moments are applied at the center of the top surface of the upper vertebra. The vertebra is modeled as a rigid element. The lower surface of the implant is completely constrained. Table 1 compares the values (in S.I.) of the finite element analysis for the optimal implant topology to that of the previous best design using relative values listed as a percentage. The analysis includes maximum nodal displacement, maximum elemental strain energy and maximum von Mises stress. We observe a significant decrease (i.e., improvement) in all three metrics of performance. The maximum von-Mises stress, nodal strain energy and nodal displacement are significantly lower for the optimum topology.

Table 1: Analysis of the new implant and percentage values relative to the old implant (units in S.I.)

<table>
<thead>
<tr>
<th></th>
<th>Displ</th>
<th>S Energy</th>
<th>vM Stress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression</td>
<td>4.0e-6</td>
<td>87%</td>
<td>0.3e-6</td>
</tr>
<tr>
<td>Flexion</td>
<td>19.1e-6</td>
<td>44%</td>
<td>23.0e-6</td>
</tr>
<tr>
<td>Extension</td>
<td>19.1e-6</td>
<td>79%</td>
<td>23.0e-6</td>
</tr>
<tr>
<td>L. Bending</td>
<td>16.4e-6</td>
<td>67%</td>
<td>9.75e-6</td>
</tr>
</tbody>
</table>

5 Conclusions

A candidate geometry for an interbody fusion implant is obtained using topology optimization methods. The topology optimization seeks to minimize strain energy subject to allowable mass fraction constraints. The implant is subject to three different loading cases and individual topologies are superimposed to obtain candidate geometries. The use of the mass fraction constraint allows designers to directly control the available volume for bone graft material in the interbody fusion implant. The implant is designed to restrain bone graft material while maintaining proper intervertebral spacing during spinal fusion. In comparison to previous implant design studies using finite element analysis, the new candidate geometry provides better structural stability for the load conditions of compression, flexion/extension and lateral bending.

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