

Optimum design of an interbody implant for lumbar spine fixation

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Abstract

A new minimally invasive surgical technique for lumbar spine fixation is currently in development. The procedure makes use of an interbody implant that is inserted between two vertebral bodies. The implant is packed with bone graft material that fuses the motion segment. The implant must be capable of retaining bone graft material and supporting spinal loads while fusion occurs. The different load conditions analyzed include: compression, flexion, extension, and lateral bending. The goal of this research is to obtain an optimum design of this interbody implant. Finite element-based optimization techniques are used to drive the design. The multiobjective optimization process is performed in two stages: topology optimization followed by shape optimization. As a result, the final design maximizes the volume allocated for the bone graft material and maintains von Mises stress levels in the implant below the stress limit. The finite element-based optimization software GENESIS is used in the design process.

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1. Introduction

The spinal column consists of 24 separate bones, called vertebrae, plus the fused bones of the sacrum and the coccyx. Intervertebral discs are located between the vertebrae. An intervertebral disc is composed of a fiber-like outer lining called the *annulus* and a gelatin-like inner core called the *nucleus*. The discs serve as shock absorbers, load distributors and spacers. As the spine ages, the nucleus loses its ability to hold water, which results in decreased ability to absorb shock and a narrowing of the nerve openings.

Many disc disorders are difficult to treat through non-surgical methods. Lumbar fusion is the most common surgical procedure for alleviating pain associated with disc disorders. The objective of this technique is to stabilize the spine and, therefore, eliminate the relative motion of the vertebrae adjacent to the degenerated disc(s). Lumbar spinal

fusion involves the use of bone the graft material along with medical instrumentation such as cages, hooks, plates, rods and screws. The bone graft grows in and around the instrumentation, forming a structure similar to reinforced concrete. There are several types of spinal fusion surgery options described in the literature. For a review, see [1].

The degenerative changes within the disc account for the majority of chronic lower back pain treated in spine clinics. Lower back pain is one of the most common and significant musculoskeletal problems in the world. In the US, for example, some studies have shown that 80% of Americans will experience lower back pain in their lifetime [2]. In the 1980s and 1990s, the rate of lumbar fusion surgery increased over 60% in this country [3]. Currently, it is estimated that more than 500,000 spine surgeries are performed each year in the US alone [4]. The failure rate after lumbar fusion has been reported to be as high as 37% [5,6]. This has motivated the development of new surgical procedures.

The trend in spine surgery is the application of minimally invasive procedures. In contrast to existing procedures, minimally invasive techniques utilize tiny percutaneous incisions through which small and specialized instruments are inserted. The research presented in this paper 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

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Nomenclature

$\mathbf{d}_i$	element node displacement vector	V_0	volume of the design domain
$\mathbf{D}$	global node displacement vector	v_i	element volume
E_0	elastic modulus of the material	V_f	final volume of the design
E_i	variable element elastic modulus	V_s	initial volume of the design for shape optimization
$E_i^{\min}$	minimum value of E_i	V_t	initial volume of the design for topology optimization
$\mathbf{F}$	global node force vector	U	strain energy
$\mathbf{f}_i$	element node force vector	x_i	element relative density (design variable for topology optimization)
K	number of design variables in shape optimization	$x_i^{\min}$	minimum value of x_i
K	global stiffness matrix	y_k	perturbation vector magnitude (design variable for shape optimization)
k_i	element stiffness matrix	$y_k^{\max}$	maximum value of y_k
M	variable mass of the design	$y_k^{\min}$	minimum value of y_k
M_0	mass of the design domain	ω_j	weight coefficient for load case j in topology optimization
m_f	fractional mass, volume fraction, or mass fraction	ρ_0	density of the material
M_f	final mass of the design	ρ_i	variable element density
M_s	initial mass of the design domain during shape optimization	$\hat{\sigma}_j^f$	maximum von Mises stress for load case j in the final design
N_s	number of elements in model for shape optimization	$\hat{\sigma}_j^s$	maximum von Mises stress for load case j in shape optimization
N_t	number of elements in model for topology optimization	$\hat{\sigma}_j^t$	maximum von Mises stress for load case j in topology optimization
p	penalization power		
q	ratio between $E^{\min}$ and E_0		
S_f	fatigue stress		
V	variable volume of the design		

fusion implant. The function of this implant is to house the bone graft material and ensure the structural stability of the motion segment while the bone graft heals. The healing process can take several months. The design of this type of device is usually accomplished by trial and error using finite element analysis. These ad hoc approaches are time consuming and might not lead to an optimum design.

This work applies finite element-based structural optimization methods to design the interbody fusion implant. The goal is to obtain an optimum design that is constrained to support the mechanical stresses while maximizing the volume available for bone graft material. The optimization process is performed in two stages. The first stage seeks to minimize strain energy under mass fraction constraints using a topology optimization technique. The second stage seeks to minimize mass under stress constraints using a shape optimization technique. GENESIS, a finite element-based optimization software, is used to drive the design process.

Topology optimization is being used more often in recent studies to find preliminary, sometimes completely innovative, structural configurations that meet specific conditions, i.e. the objective function and constraints. Shape optimization is used to fine-tune the preliminary design using a more defined geometry. This work provides a short overview of these finite element-based optimization techniques.

2. Finite element-based optimization techniques

Finite element-based optimization techniques were first developed by Lucien Schmit, a UCLA Professor, in the 1960s [7]. He recognized the potential of combining optimization techniques with finite element analysis (FEA) for structural design. Today, three types of finite element-based optimization approaches are available within commercial FEA software: *parameter optimization*, *shape optimization* and *topology optimization*.

Parameter optimization uses physical properties as design variables. It strives to find the optimum value of these properties in the constitutive elements of the structure. Typically, cross-sectional parameters are used as design variables. These parameters include thickness, area and moment of inertia, among others.

Shape optimization involves determining the optimal profile or boundary of the structure. Two of the most common approaches to performing shape optimization are the *basis vector* and the *grid perturbation* approach. The basis vector approach requires the definition of different trial designs called basis vectors. The design variables are the weighting parameters that define the participation of each basis vector in the design process. On the other hand, the grid perturbation approach requires the definition of

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