



EML 4551 Senior Design Project

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BACHELOR OF SCIENCE
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Spinal cage

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This report is written in partial fulfillment of the requirements in EML 4511. The contents represent the opinion of the authors and not the Department of Mechanical and Materials Engineering.

Ethics Statements and Signatures

The work submitted in this B.S. thesis is solely prepared by a team consisting of Christopher Dominguez, Justin Crisp, and Peter Medrano and it is original. Excerpts from others' work have been clearly identified, their work acknowledged within the text, and listed in the list of references. All of the engineering drawings, computer programs, formulations, design work, prototype development, and testing reported in this document are also original and prepared by the same team of students.

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Abstract

Spinal cages are fairly new in the medical world and are increasing in popularity as a method to cure several types of spinal conditions. Cages are being used as an aid in a surgical procedure known as spinal fusion. Fusion of the spine has been around for nearly a century and it is the surgical technique of joining two or more vertebrae together in both humans and animals. This method was first introduced to cure problems such as scoliosis and kyphosis of the spine. As an increase of back problems arose in the span of the century, so did the demand for new technologies to help the victims of these spinal conditions. According to the American Chiropractic Association, an estimated 31 million Americans suffer from back problems today. The ACA predicts that up to eighty percent of the population will experience back problem at one point in their lives. Some of those conditions may be treated with pain killers and physical therapy. For more severe conditions, an alternative solution must be found to help people who experience pain that is too much bare.

1.Introduction

1.1 Problem Statement

As a team of engineers we face many obstacles when it comes to a design project when developing a unique product such as an expandable spine cage. Organization and ethical responsibilities are two of the most important things we must consider when embarking into a project such as this. With that being said our main purpose of this project is not only to design a new expandable cage but also the tools that will be needed to aid the installing of the device. Our objective will be to formulate the methods in which these tools will be used to place the system in its desired location.

1.2 Motivation

Living in today's world we are surrounded by many levels of advancements in technology.

As engineers, our job is to seek solutions to the problems at hand in today's world by looking for new innovative ways to help people. With millions of people suffering from back problems in America and around the world, our team has taken the initiative by utilizing what we have learned from our mechanical engineering courses and applying it to a medical aspect. Our new approach to designing an expandable spine cage will not only help people restore their back, but it will also be motivated by being able to make the device more affordable by creating a "one size fits all" cage for adults.

1.3 Literature Survey

1.3.1 History

Methods for fusing spine segments to cure unstable posture or immobilizing of painful vertebral motion segments have been used for many years. Within the past two decades, practice of spine fusion has grown with the increase of new technology. In particular, more spine cages have been developed and implemented within the past 20 years than ever before. Today, more than 300,000 spine fusion surgeries are estimated to take place each year in the United States (Becker, 2003).

Fusion is a method first introduced by Russel Hibbs and Fred Albee in 1912 to cure tuberculosis of the spine, also known as Pott's disease. Both surgeons used the method of harvesting autogenously bone graft fuse the posterior joints together. The bone graft was often taken from the pelvis and from the posterior surface of the lamina to fuse the posterior facet joints (Peltier).

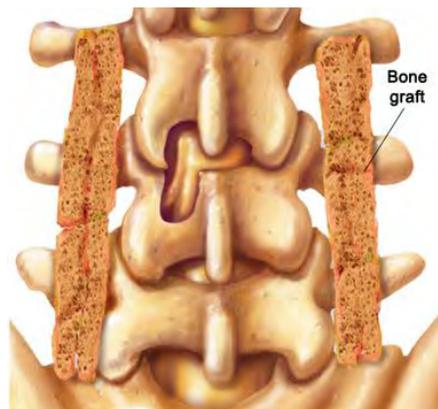


Figure 1: Example of one bone grafting approach (Mayoclinic)

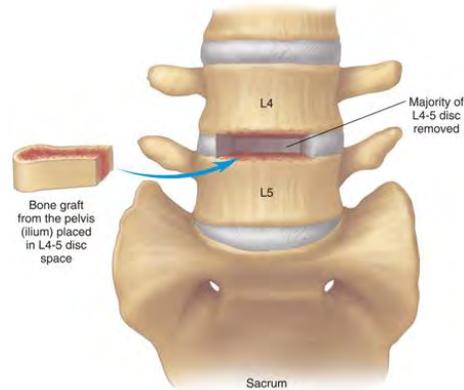


Figure 2: Bone graft from Pelvis (James Disability Law , n.d.)

This approach was used for many years but proved to be unsuccessful due to the poor stability of using bone to fuse spinal joints as well as the unwanted side effects of bone grafting procedures. It wasn't until 1940, when a neurosurgeon by the name of Ralph Bingham Cloward introduced his technique of Posterior Lumbar Interbody Fusion (PLIF). This method allowed fusing two vertebral bodies together into a single motion segment while maintaining them separated to allow the decompression of neural structures. This progress proved to be a milestone in spinal neurosurgery by introducing the approach that is still widely used today known as the Cloward Procedure. As technology advanced, so did the methods of Interbody Fusion. In 1987, the first non-bone implant was introduced in Europe with the Charite III Disc. The replacement disk was made of two metal alloy endplates and a unique sliding core and is still used today as a popular artificial disk replacement. It is inserted between two vertebrae to help restore disc space height (Spine Health , 2013)



Figure 3: Charité artificial disc (Mayoclinic, n.d.)



Figure 4: Front and side view of Charité artificial disc (Mayoclinic, n.d.)

Today, various spinal cages are commonly used for interbody spinal fusion. Companies such as Zimmer, Stryker, DePuy and Ulrich and many more are all using different designs to meet the demand for spinal cages. According to the American Chiropractic Association, 31 million Americans (Jensen M, 1994) alone have back problems and predict that as much as 80% of the population will experience back problems at one point in their lives [4]. For patients with more severe spinal problems such as tumors, deteriorating disks or disease, spinal cages are being approved and implemented more often.

2. Project Formulation

2.1 Overview

It is estimated 33 million people (Jensen M, 1994) suffer from lower back pain caused by many factors. Many of these factors can be improved or completely levitated by spinal fusion surgeries. A spinal fusion is a safe alternative to many ailments such as sprain ligaments, strain muscles, rupture disks, and irritate joints, all of which can lead to back pain but in the past, the procedures for spinal fusion have not kept up with the changing technological advances of the 22nd century. The common approach to spinal fusion calls for custom pieces in different sizes that are shaped before the surgical procedure starts. These pieces are called spinal cages. They are non-adjustable, flat plates and come in numerous shapes and sizes for different body types. All of the flat plates or cages, except for one, go unused and are discarded, for they were custom sized for the particular patient. The disposal of custom sized pieces is not efficient or

cost effective so many companies are turning to adjustable spinal cages to alleviate the unnecessary disposal of expensive materials.

2.2 Project Objective

The objective that we set out to accomplish is the design of a expandable spinal cage system that takes the advantages of an adjustable spinal cage system but without many of the constraints or negative aspects of existing spinal cage technology. We will see all the aspects in the process of designing a product with the notion of having a completed product that is ready for mass production.

3. Design Alternatives

3.1 Conceptual design

The base design for the expandable spinal cage consists of four main parts; the top and bottom plates which sit on the healthy vertebrae; the outer cylinder; and then the inner cylinder. These are the four main parts of the design but it is not by any means the only parts of the design. The device itself needs to be expandable with an adjusting lever or turning screw. It must be easy to adjust during the surgery and have the locking power to hold the weight of the person that it has been installed in.

3.2 Design Alternative 1

Here is an example of spinal cage that is already in the market. It is designed by Depuy Spine which is spine specialization subsidiary under Johnson and Johnson. Here you can see the top and bottom plates and the inner and outer cylinders.



Figure 5: Depuy Spine, 2003

3.3 Design Alternative 2

Here is an example from a company called Elite Surgical. Again, the pieces are generally very similar with a top and bottom plate, inner cylinder, and outer diameter cylinder. This model is called the Biolign VBR.



Figure 6: Elite Surgical, 2013

3.4 Proposed design

Our design will have the best aspects of current technology with our tweaks and unique designs to make a better product for patients and physicians.

4. Project Management

4.1 Timeline

Tasks	January	February	March	April	May	June	July	August	September	October	November	December
IP research	■	■										
Building Strategy		■	■									
Concept development		■	■	■	■							
Engineering design				■	■	■	■					
Design Validation					■	■	■	■				
Production Drawing						■	■	■	■	■		
Prototyping								■	■	■	■	
PT Testing										■	■	
Complete											■	■

Table 1: Projected Timeline

4.2 Project Responsibilities

DESIGN & ENGINEERING		
I.P. SEARCH		
BUILD DESIGN STRATEGY		
CONCEPT DEVELOPMENT	Peter	Chris and Justin
ENGINEERING DESIGN		
DESIGN VALIDATION		
PRODUCT DRAWINGS	Justin	Peter and Chris
PROTOTYPING & TESTING		
RAPID PROTOTYPING		
PROTOTYPE TESTING	Chris	Justin and Peter

Table 2: Project Responsibilities

5. Engineering Design and Analysis

5.1 Analytical Analysis

Analytical analysis will be entirely performed when a completed concept development is finalized and accepted. The analysis will be performed on the weight the device needs to hold up during the fusion process, the anticorrosion capabilities of the chosen material, and internal stresses of the device. More analysis will be needed and completed as needed.

5.2 Major Components

The expandable spinal cage consists of 4 major components. The top plate that rests on the upper portion of the spinal cage. The bottom plate, or base, that sits on the bottom portion of the device and rests on the closest open portion of the exposed vertebrae. Finally, the cylinders that move inside one another. This is the adjustable portion of the cage and all cages generally have a similar setup where a tube goes inside another tube allowing for the expandability.

One other component that is needed but not designed yet is the moving part that moves the inner cylinder up and down. This mechanism can also serve as the locking piece that holds the device in the upright position during the installation.

5.3 Structural Design

The final structural design is based on the final engineering design that fit our design criteria and specifications. The testing on the conceptual design will also allow for the finalization on the final structural design. The structural design will have to be structurally sound and meet the strict requirements of inner body atmosphere as well as the large governing bodies, such as the Food and Drug Administration.

6. Prototype Construction

6.1 Prototype System Description

To aid in the rapid prototyping of our expandable spinal cage we will be using both selective laser sintering (SLS) and stereo lithography (SLA). The SLS method is one that uses a high powered laser to melt the outer layer of a material layer by layer based of a 3-D description. The material is comprised of plastic, metal, ceramic and mainly comes in a powder form. This method does not require a support structure during the modeling portion due in part to the shape being surrounded by untouched powder at all times. The SLA method or prototyping on the other hand uses a curable resin to form the shape or the desired model. This method also employs a laser to heat and solidify the out layer of the resin and ultimately form the shape. It does this layer by layer until the desired 3-D shape has been achieved. Our

prototype will be comprised of four main parts two base plates one being on the bottom and one on top, Also a base cylinder and lastly the expanding portion of the cage. The final prototype will be comprised of titanium so that it can be properly tested and validated and will serve as our final assembly.

6.2 Prototype Design

6.2.1 Base Plate

The base plates of the expandable spinal cage will be the main portions of the spinal cage that will grab and hold on to the vertebrae. This will ultimately hold the cage in place between the two sections and allow the fusion to begin. Each plate will have a number of teeth that will aid in grabbing the bone most likely digging a little into the vertebrae which in turn will ensure that the system stays in place will the fusion process goes on. These base plates will also have the most allowable area as possible to ensure the system is stable in between the two vertebrae and to also help with any forces that the spinal column can and will carry.

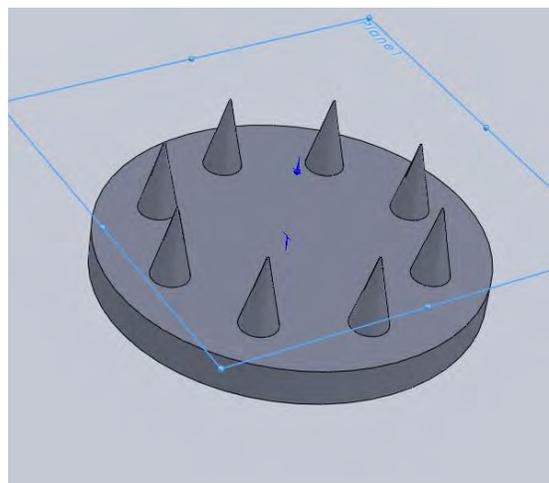


Figure 7: Base Plate

6.2.2 Base Cylinder

The base cylinder will be the only portion of the cage to which the surgeon can and will hold the system with the required tools. This portion of the device will also include pathways through the shape that will allow the bone graft material to grow out of and around. The base cylinder's main function after support of course will be to facilitate cell growth through its openings and also aid in the expansion and contraction of the upper cylinder. Lastly the base cylinder will have a threaded gear system which will be used to expand or contract the moveable portion of the spinal cage to the desired length.

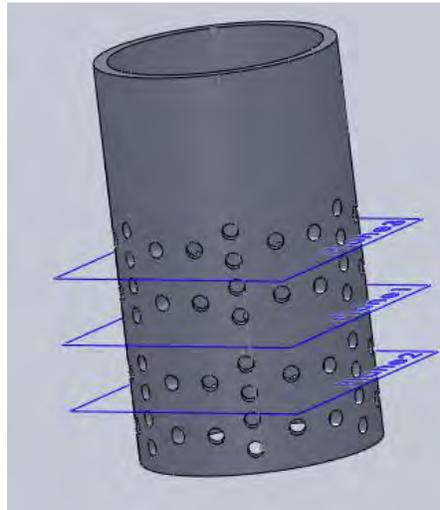


Figure 8: Base Cylinder

6.2.3 Expanding Cylinder

The top cylinder of the spinal cage will be the only moving portion of the whole system. It will slide in and out of the base cylinder to whatever length desired by the surgeon. This expanding portion will be attached to the upper basest plate. This portion of the system will

have threads along its length and along with the gear system on the base cylinder will allow the movable portion to either expand or contract based on the required measurements.

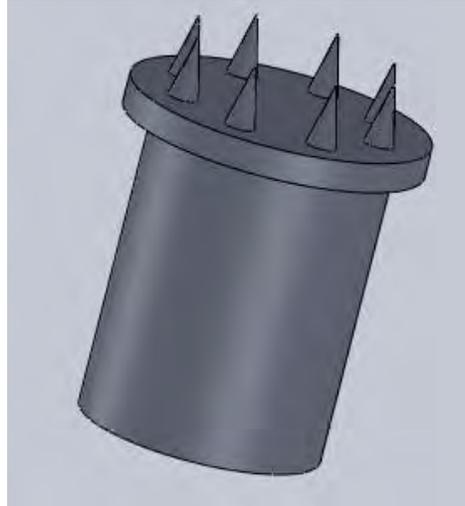


Figure 9: Expanding Cylinder

6.3 Plans for Tests on Prototype

Testing for our spinal cage prototype will be done with two main methods. The first of these will be done with computer aided design programs and finite element analysis software. In this processes we will design and test our spinal cage virtually and also analyze it to find the max loads, shear stresses also to include the factors of safety and failure rates. This vital step will allow us to redesign any component that does not meet the desired specification. This step will also save money in the long run due in part to the accessibility of the software from home and more importantly remove any flaws associated with our design. Lastly we will rapid prototype the design to incorporate an overall functionality test. In this process our aim is not at structurally testing the device but to see if it can actually function as desired. This means that

it expands and contracts, that it is the right size for the intend area of implantation and lastly is free of any discrepancies that would hinder future performance. Once these miles stones have been reached the final production step and validation will begin.

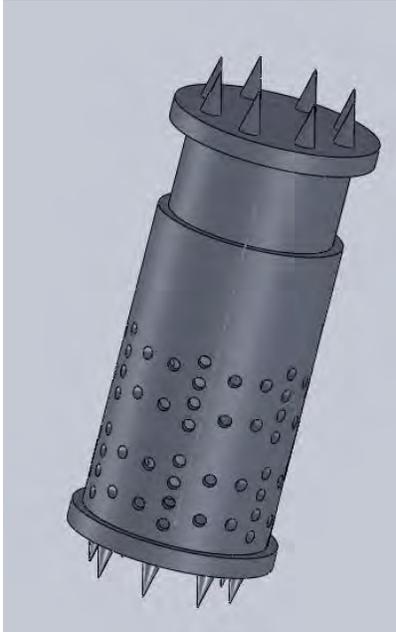


Figure 10: Proposed Expandable Cage

6.4 Prototype Cost Analysis

The following table shows each individual investment of man hours and associated cost for each category of our design process. The chart is a rough estimate of current values and predicted values for future cost and man hours.

TASK	DAYS	MAN-HOURS(x1)	COST(\$20/HR)	PETER MEDRANO		JUSTIN CRISP		CHRIS DOMINGUEZ	
				PERCENTAGE	HOURS	PERCENTAGE	HOURS	PERCENTAGE	HOURS
DESIGN & ENGINEERING	90								
I.P. SEARCH	15	75	1500	33.30%		33.30%		33.30%	
BUILD DESIGN STRATEGY	15	75	1500	33.30%		33.30%		33.30%	
CONCEPT DEVELOPMENT	15	75	1500	33.30%		33.30%		33.30%	
ENGINEERING DESIGN	15	75	1500	33.30%		33.30%		33.30%	
DESIGN VALIDATION	15	75	1500	33.30%		33.30%		33.30%	
PRODUCT DRAWINGS	15	75	1500	33.30%		33.30%		33.30%	
PROTOTYPING & TESTING	90								
RAPID PROTOTYPING	60	300	6000	33.30%		33.30%		33.30%	
PROTOTYPE TESTING	30	150	3000	33.30%		33.30%		33.30%	
TOTAL	180	900	18000						

Table 3: Cost Analysis Table

7. Conclusions

We have set out to design the best spinal fusion cage in the market and as long as we follow the steps in the design we should accomplish our objective.

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