Project Statement & Specifications

Optimized cervical plate design

Based on biodegradable natural polymer material Project

Team 12

Andrew Carney, Casey McDermott, Kyle Ward

Project 23

For

Dr. Krystyna Gielo-Perczak

Dr. Sangamesh Kumbar

Dr. Cato Laurencin

Ms. Gloria Kolbe

Sangamesh G. Kumbar Ph.D.
University of Connecticut Health Center
263 Farmington Avenue
Farmington, CT 06030-3711
Phone: 860-679-3955
Statement of Need

Our clients Dr. Sangamesh Kumbar and Ms. Gloria Kolbe conduct research at the University of Connecticut Health Center and are looking to complete their design for a cervical fixation plate to support the fusion of vertebrae. DDD is a disease that affects the intervertebral disc of the spine. When these discs are damaged due to trauma or old age they can put pressure on spinal nerves. Currently, in order to solve the problem surgeons remove the damaged disc and put in place a bone graft to fused the two vertebrae together. The process of fusion of the graft can take up to a year before it can fully bear the necessary weight. Commonly a titanium plate is used but this not ideal because it requires a second surgery to remove the plate. To overcome this Dr. Kumbar and Ms. Gloria Kolbe want to design a biodegradable plate based on a natural polymer material that will dissolve away safely once the graft is fused. The issue with a polymer plate is its weaker mechanical properties compared to titanium so the plate must be designed to enhance its mechanical strength.

Introduction and Overview

The purpose of the project is to design a cervical plate that will hold the graft in place while fusion of the vertebrae occurs, usually about a year. The plate should then degrade away without causing any further harm or inflammation to the surrounding area. Lastly, the plate should be designed to keep the fixating screws in place in the vertebrae.

The plate we wish to create will use a biodegradable polymer containing natural cellulose and calcium phosphate. This material is biocompatible and will degrade safely into glucose. The material will be processed and created by either injection molding or compression molding. The plate will be designed for a two-level fusion system which involves fusing three vertebrae and two bone grafts. This increases the stability of the patient’s spine. The two-level fusion will include three set of holes to accompany six screws that fixate the plate to the vertebrae. The screws will be formed with the same polymer as the plate and degrade away at the same rate. To keep the screws from backing out of the vertebrae a locking system will be incorporated into the plate.
The CAD program ANSYS will be used to create an optimal design for the plate. To allow for minimal manufacturing, ANSYS will be used to simulate all loads and forces that the plate will encounter when inserted into the human body. Using these simulations, a plate will be designed to optimize its mechanical strength to withstand the loads that will be placed on the plate, as well as the screws within the system.

Other plate designs use either titanium or different biodegradable polymers which differ because of their degradation products. PLA and PGA are commonly used, but are not as efficient because they break down into acidic compounds that can cause inflammation, as well as lowering the pH of surrounding tissue, causing necrosis. Also, these types of plates undergo bulk degradation, meaning that the entire material will degrade simultaneously, which can result in premature failure if the plate breaks apart too soon. This is not the case for a cellulose based polymer, as it will not undergo bulk degradation. The locking system for this project is also quite unique because the plate will be made with a polymer. Because titanium is normally used, the locking system for the screws must also be metal. By using a degradable polymer, there is great flexibility for the locking system, allowing for different possibilities in the material and design of the locking system.

**Realistic Constraints**

Economic restraints include the inability to produce multiple physical designs and test them, luckily ANSYS will be used to virtually test or design ideas. Environmentally the plate must be biocompatible and degrade into products that cause no adverse reactions. In regards to sustainability the plate must last in the body for up to a year. The material can be processed using either compression or injection molding. When manufactured the dimension of the plate must be custom based on the patients’ anatomy. The plate must be designed to allow for a safe surgical process and properly sterilized. The plate must also be comfortably placed inside the patient. Political constraints are the most important in that the design must pass FDA testing and approval to be allowed to the public.
Questions

1.) What type of locking mechanism best secures the screws?

2.) How does the size of the screw affect the design of the locking system?

3.) What is the best way to format the holes and screw place?

4.) Which geometry of the plate will give us the best properties with the smallest thickness?

Specifications

Material:
Composition: Cellulose Acetate
20 wt% Hydroxyapatite 80 wt% Cellulose

Mechanical:
Length: 35mm (based on patients’ anatomy)
Width: <18mm
Thickness: <2.7mm
Tensile Strength: >45MPa
Elongation at break: 5%
Tensile Modulus: >3GPa
Degree of alignment: 5°

Electrical: N/A

Environmental:
Storage Temp: Room Temperature
Operating Temp: Body Temperature

Software:
User interface: Keyboard, Mouse, ANSYS, SolidWorks
Hardware interface: Monitor
Computer requirements:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating system</td>
<td>Windows 7/Vista/XP SP2, Mac OS X</td>
</tr>
<tr>
<td>Processor</td>
<td>2 GHz Pentium 4 Intel based processor</td>
</tr>
<tr>
<td>Memory</td>
<td>1 GHz</td>
</tr>
<tr>
<td>Safety</td>
<td>N/A</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Sterilization</td>
</tr>
</tbody>
</table>