Final Report

Optimized cervical plate design
Based on biodegradable natural polymer material Project

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1 Introduction

1.1 Background

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. Degenerative disc disorder, or DDD, is a disease that affects the intervertebral disc of the spine. The intervertebral discs within the spine can be injured in many different ways, such as trauma. Along with this, degeneration of the discs in the spine automatically occurs as a person ages throughout life. While all intervertebral discs will degenerate over time, not all people experience DDD, which causes extreme back pain for the patient. Currently, in order to solve the problem, surgeons must remove the damaged disc and put in place a bone graft to fuse 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. While the process of fusion is occurring, something is needed to hold the graft in place. Otherwise, the graft would not be able to hold the vertebrae together and fusion would not be able to occur. In order to achieve this, a cervical plate is placed into the body. Using screws that enter the vertebrae, the cervical plate system is able to hold the vertebrae in place, allowing the bone graft to fuse the two vertebrae together. Most commonly, titanium metal is used to create the cervical plate and screws used in the device. This is not an ideal material to use because it requires a second surgery to remove the plate after fusion has occurred. To overcome this, Dr. Kumbar and Ms. Gloria Kolbe want to design a biodegradable plate that will dissolve away safely into the body once the graft is fused. To achieve this, they have created a natural polymer that is biodegradable. The issue with a polymeric plate is that it has weaker mechanical properties compared to a plate that is made of titanium, so the plate must be designed to enhance its mechanical strength.

1.2 Purpose of Project

The purpose of the project is to design a cervical plate that will hold the graft in place while fusion of the vertebrae occurs, which will usually take about a year to accomplish. Because the cervical plate system will be made with a biodegradable polymer, it must be designed to maximize the mechanical strength of the system. This is extremely important because if the system is not able to withstand the loads and forces placed on it by the body, the plate may fracture or loosen itself from the vertebrae. This would not allow the bone graft to fuse the two vertebrae together, making mechanical strength the main objective of the design. After fusion has fully occurred, the plate should then degrade away into biocompatible products, making it impossible for any further harm or inflammation to occur in the surrounding area of the body. Lastly, the plate should be designed to keep the fixating screws in place in the vertebrae. This is important because one of the major problems when using cervical
plate systems is that the screws will sometimes back out of the vertebrae and loosen the device from the spinal cord. A locking mechanism must be put in place in order to keep the screws in place.

The plate we wish to create will use a biodegradable polymer that contains natural cellulose, along with calcium phosphate, also known as hydroxyapatite. This material is biocompatible and will degrade safely into glucose, a biocompatible product that will not cause inflammation or damage to the surrounding tissue. The material will be processed and created by either injection molding, compression molding, or 3-D printing. The plate will be designed for a two-level fusion system, which involves screws being used on three vertebrae with two bone grafts between the vertebrae. This increases the stability of the patient’s spine, while also allowing for two degenerated discs to be removed and replaced at the same time. 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. There will be six locking mechanism for each individual screw, and will be located within each of the screw holes.

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. By using this program to simulate the forces of the body, the mechanical strength of the plate can be computed to ensure that the cervical plate system will be strong enough to hold the vertebrae in place during the process of fusion. 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. After the design has been optimized, the cervical plate system will be manufactured, using one of the methods mentioned above. It will then be tested using different techniques, such as tensile, compression, and torsion testing. This will ensure that the system is mechanically strong enough in real life, as well as within the computer modeling system.

1.3 Previous Work Done by Others

1.3.1 Products

Other plate designs use either titanium or different biodegradable polymers which differ because of their degradation products. Titanium is the standard material used because of its mechanical strength, but it is not an optimal material because it is not biodegradable and must be removed with a second surgery after fusion occurs. Within products that are biodegradable, PLA and PGA are the most commonly used materials, 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 cellulose based polymer undergoes surface degrad

degradation, causing it to degrade from the outside in, allowing it to keep its mechanical strength for a longer period of time. The locking system for this project is also quite unique because the plate system will be made with a polymer. Because titanium is normally used, the locking system for the screws is also created with metal. By using a degradable polymer, the locking system will also be made with the same polymer to ensure that the entire system degrades as one. With this change in material, it allows for great flexibility for the locking system and for different possibilities in the design of the locking system.

Zephir anterior cervical plate system

Zephir cervical plate system was one of the earlier designs patented with variable screw trajectory and orientation. The design was also impressive for its time due to the size which measured only 1.6mm thickness and 15mm wide while still maintain necessary mechanical properties. This is important because many patients often complain about the implant causing discomfort in the throat as well as difficulty swallowing. Another important aspect of the design is a locking system for the screws which keeps them from backing out and therefore keeping the plate in place.

Inion Cervical Spine system:

Inion Cervical spine system is a modern novel system that uses a degradable polymer to form the cervical plate and screws. As opposed to the normal titanium based designs, the polymer will degrade through the body once the bone graft has fused to support the spine. Inion’s current polymer design metabolizes into carbon dioxide and water once hydrolyzed.

1.3.2 Patent Search Results

Search results for anterior cervical plate system result in hundreds of results dating back a couple decades.

Patent: D603962

One such patent result gives us a two-level plate filed in 2009. This design claims an original design for a titanium plate more importantly specifying an original locking system. This locking system uses cuts in the plate to fixate the screw once it is drilled in a certain distance.
Another patent filled in 2005 claims various intricacies regarding the orientation and trajectory of the screw holes. These details also claim the system with a biodegradable polymer. This system however only deals with extra discal fixation of the sacral, lumbar and thoracic regions of the spine.

Patent: 6916320
A titanium plate that is unique in its design and use of an extra fixation screw. This plate minimizes plate surface area with a thin geometry but uses a third angled screw for each vertebrae. Our design will need the most plate material possible so a third screw is not optimal.

1.4 Map for the Rest of the Report

The rest of the report will take an indepth look at the final design, alternative designs and what lead to the design changes. We will look into the design constraints and parameters. We will dissect the sub-units and individual parts of the design. We will look into our simulations and testing of the successive designs. Lastly, we will describe in detail the factors that affected our design alterations including mechanical properties and ergonomics.