Optimal Design Report

Optimized cervical plate design

Based on biodegradable natural polymer material Project

Team 12
Andrew Carney, Casey McDermott, Kyle Ward

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
1 Optimal Design Project 12

1.1 Introduction

Our design is an approach to fixing the spine with a degradable plate following anterior cervical spine surgery. When an intervertebral disc is herniated or bulged it can press against the spinal nerve and cause severe pain for the patient. Anterior cervical fusion surgery involves removal of the damaged disc followed by insertion of a bone graft or substitute that will fuse the vertebrae together. The plate is then screwed into the fused vertebrae. Anterior plates were first introduced to aid in multi-level spinal fusion to fixate the graft and spine but are now widely used in one-level fusion to decrease recovery time from the procedure. The majority of plates still used today are made out of titanium which must either be left in the patient permanently or require a second surgery. Our design hopes to use a novel polymer to create a biodegradable plate that stills meets the mechanical properties necessary for the plate.

![Figure 1. Anterior Cervical Fusion](image)

To be certain our design meets the industry standards we will be utilizing ANSYS FEA program to design our plate and simulate the loads that it would undergo in the body. Our design must follow the natural curvature of the spine as not to prevent any natural motion. Other challenges we face include creating an integrated locking system for the 4mm screws to prevent them from backing out. The screws will be locked in place using the flexible properties of the polymer to snap into place. The new plate must not be larger than the current plate design to prevent affecting the patients comfort prior to degradation.
<table>
<thead>
<tr>
<th>System</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plate</td>
<td>Provide support to the graft and vertabrae</td>
</tr>
<tr>
<td>Locking System</td>
<td>Keep screws in place and prevent backing out</td>
</tr>
<tr>
<td>Screw</td>
<td>Secure the plate to the vertabrae</td>
</tr>
</tbody>
</table>

1.2 Subunits

1.2.1 Cervical Plate

The first and most important part of our design is the cervical plate. The plate will be made out of molded cellulose acetate.

![Chemical structure of cellulose acetate]

**Figure 2:** Shows the chemical structure of cellulose acetate.
Table 1: Shows the mechanical properties of molded cellulose acetate.

This piece will fit on the anterior side of the patient’s cervical vertebrae to allow for the spinal fusion when an intervertebral disc is herniated. This plate will span the range of three cervical vertebrae and incorporate six separate screws.

The plate will be 18 millimeters wide, 2.5 millimeters thick and approximately 35mm tall, however the height will ultimately depend on the length needed for each individual patient. For the purpose of our design, we will be assuming a 35 millimeters height which is the average length of a two-level spinal fusion plate. The plate will also have a 5° degree of alignment (dga). The degree of alignment describes the natural curve that the plate will have which will allow it to fit flush against the natural curve of the cervical vertebrae.
Figure 3: Shows the 5° dga that the plate will have when looked at from the top down.

The plate will feature two holes for the screws on each of the vertebrae. These holes will be spaced 5 millimeters apart and will be 5-6 millimeters wide. These holes will also be slightly tapered, with a smaller diameter on the bottom of the plate and a larger diameter on the top. This will allow the screw head to sit flush with the plate and eliminate any possible movement or shifting that could occur. On the distal side of each of the screw holes will be 1.5-2 millimeters of space.

At the midpoint between the sets of screw holes will be an additional hole which will be situated directly on the midline of the plate. This hole serves two functions; it allows for the surgeon to see and operate on the intervertebral discs while putting the plate in place, and secondly, it allows for more of the body’s fluids to reach the area where the fusion is going to take place. This allows for the hydroxyapatite to encourage the synthesis of bone more rapidly. These holes will be 5.2 millimeters in diameter and will be hexagonally shaped.

Figure 4: Shows the design layout from a top view of the cervical plate.

The last major innovation this design will feature is the inclusion of inlets located on either side of the medial openings and between the two screw holes on both the top and the bottom of the plate. The indents on the sides of the plate will be two millimeters deep and four millimeters long. The indents on the top and bottom of
the plate will be 1-1.5 millimeters deep and 3 millimeters wide. These indents would allow for the use of less material, saving money on the production of the plate. It would also allow for the surgeon to have more space to operate when putting the plate into place.

Figure 5: Shows the design of the plate from the side view.

To test the design we will be using the program ANSYS Workbench. ANSYS provides a fully functioning platform for building custom object and analyzing them. ANSYS Workbench provides a framework for design exploration and optimization by enabling parametric modeling of geometric configurations, mesh controls, material properties, and operating conditions, leading to an automated simulation process. It also serves as a full finite element analysis software. This allows the user to test the object when the system is static, dynamic and to also account for heat transfer. These properties make it an ideal tool to use for building our plate.
Figure 6: Shows one of the test of half the plate (thinner model) in finite element analysis.

Figure 7: Shows a wider model of our plate with a smaller middle opening.
Figure 8: Shows a thicker model of the plate under stress.

The three examples above show the different ways we were able to use ANSYS to determine which of our designs would best meet our needs. By adjusting the thickness, width, and the differing sizes of the attributes we were able to determine what the best dimensions. We will use ANSYS to test the mechanical limits and properties to ensure that our design will be successful before it is ever made.

For our design to be successful, our client wished that the plate meet current market standards so that it can measure up to what other current cervical plates can do. For us, this meant we must first look at the mechanical properties of current plates used on the market.

Ti-6Al-4V

<table>
<thead>
<tr>
<th></th>
<th>Ultimate Tensile Strength</th>
<th>Ultimate Tensile Yield</th>
<th>Elastic Modulus</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>950 MPa</td>
<td>880 MPa</td>
<td>114 GPa</td>
</tr>
<tr>
<td></td>
<td>183k psi</td>
<td>128k psi</td>
<td>16510k psi</td>
</tr>
</tbody>
</table>

Table 2: Shows the mechanical values for Biomet’s Ma-An plate (titanium).

Table 2 shows the mechanical properties of a plate made of high grade titanium.
These plates are exceptionally strong and are able to withstand more than the necessary force required to support the spine during fusion. These are the most commonly used plates currently due to their durability. Unfortunately, these plates are not biodegradable and are permanently implanted into the patient. We took these numbers as a high point for what our plate must withstand as most doctors say the strength far exceeds what is needed to support the vertebrae.

**PLLAPDLA**

<table>
<thead>
<tr>
<th></th>
<th>PLLA/PDLA</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultimate Tensile Strength</td>
<td>45 MPa</td>
<td>6530 psi</td>
</tr>
<tr>
<td>Ultimate Yield Strength</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Elastic Modulus</td>
<td>3 GPa</td>
<td>435k psi</td>
</tr>
</tbody>
</table>

*Table 3: Shows the mechanical values for Inion’s Plate which is biodegradable (polymer).*

Table 3 shows the mechanical properties of a biodegradable plate that is currently on the market and has been approved by the FDA. This plate has been used in patients but is not favored by doctors due to the fact that it is not quite strong enough to support the load it needs to and because the components it degrades into can be harmful to the spinal area. For this reason, we took these to be an absolute minimum standard for our plate to meet in order to be successful.

For our plate, we want to at least match the numbers for ultimate tensile strength, ultimate yield strength and elastic modulus of the Inion plate. Ideally, we would like to see our plate exceed the numbers of the Inion plate and have an ultimate tensile strength of around 90 MPa, an ultimate yield strength of 10%, and an elastic modulus of 6 GPa. Once again, those numbers are an ideal desire; the plate must only meet the numbers that the current Inion plate has to be viable for use on the open market.

### 1.2.2 Locking System

While the cervical plate is the base of the device, there are a few different accessories that are attached to the cervical plate that are essential to its function. The most important of these accessories is the locking system for the screws that keep the vertebrae in place while fusion is occurring. The locking system is meant only to keep the screws from moving during the time of implantation. This is necessary because one of the major issues and concerns with the cervical plate is keeping the system locked in place. If the plate were to come loose before fusion of the vertebrae is fully completed, there is a
very good possibility that the vertebrae would also become loose and not allow the discs to fully regenerate as they are meant to. There are a few different ways in which the cervical plate could lose its tight hold on the vertebrae in the spinal cord including things such as early fracture to the plate, but the most common problem during the fusion process is for the screws to back out of the vertebrae they are attached to. If the screws back out of the vertebrae, it is normally due to the fact that the locking system has failed because the locking system’s only true function is to hold the screws in the correct location.

In order to hold the screws in place, six locking mechanisms are included in the optimal design of the device. In doing this, we have decided to create individual locking mechanisms for each of the six screws that will be used within the device. In the alternative design, it was discussed whether there should be individual locking systems or if three of them would suffice, having each locking system located in between a pair of screw holes horizontal from one another. It was ultimately determined that optimally, it would be a safer and more efficient system if each screw corresponded to its own locking mechanism. This was decided because if each locking system only needs to support a single screw rather than two, then it is only forced to bear half of the load that it would have to otherwise. Because ensuring that the screws do not back out of the vertebrae is the one and only concern when creating the locking system, there is no reason to risk having them be any less mechanically strong than they possibly can be.

The main reason that the mechanical strength of the locking system is such a major issue is because the locking mechanism will be created with the same polymeric material as the cervical plate. This is necessary to do because the locking mechanism, just as the cervical plate, must be created with a biodegradable material so that it can dissolve into the body. If the locking system was designed with a metal as it normally is, when the cervical plate degraded away into the body, the locking mechanisms would simply be left to bounce and clank around within the body. This is obviously not an ideal situation and it could cause possible harm to the patient. Because the locking mechanism is made of the biodegradable polymeric material, it is obviously at a mechanical disadvantage to the same locking device if it were made of a metal. Most cervical plate systems are made entirely of metal, specifically titanium, making the mechanical strength of the system much greater than one made of a biodegradable material. The reason for why this is so relevant is because these devices made with titanium still have problems and issues with the screws backing out of the vertebrae and jarring the system loose. Knowing this, it is imperative that we take all possible precautions to ensure the locking system, and all components of the system for that matter, are as mechanically strong as they possibly can be.

The individual locking mechanisms will each be placed within the six screw holes located in the cervical plate. Each of the six locking mechanisms will be identical to one another, just as the screw holes mimic one another as well. The locking mechanisms will
be centered in the z direction, allowing equal space on each side of the locking system. The thickness of the cervical plate is not able to exceed 2.7 mm and it was decided to create an optimal design at a thickness of 2.5 mm. Because of this, the locking mechanisms will not exceed 2.0 mm in thickness to automatically allow at least some space on each side of the locking system. This is done because if the locking mechanism was allowed to span the full thickness of the cervical plate, it would be possible for the locking mechanism to move in the z direction and possibly come loose from the cervical plate. By leaving a bit of room on each side of the locking mechanism, the cervical plate will be able to press down on each side of the locking system, essentially constraining it in place.

The locking systems will follow the shape of the screw holes that they will be located in. The screw holes are designed to accommodate 4.0 mm screws. Because of this, the diameter of the screw holes, and thus the locking mechanisms, are a little greater than 4 millimeters. The locking systems will also rotate almost fully around the screw hole, containing only a small gap in one area of the device, not allowing the locking mechanism to complete 360 degrees of rotation. This design is the main cause of how the mechanism achieves its goal of immobilizing the screws. It essentially creates what can be seen as a locked position and an unlocked position. When the locking system is rotated past a certain point, it locks into place and will not allow rotation in the opposite direction. During the procedure, the surgeon will have to screw the locking screws into the vertebrae to lock the system into place. As the screws approach their final location, they will also move the locking system and click it into the locked position. Once this has occurred, the screws will not be allowed to move in a counter-clockwise direction, making it impossible for the screws to back out of the vertebrae.

Located below is a picture of the type of locking system that will be used within our device. While it is not the exact design of the cervical plate that will be used, it is useful to show the locking system and how it is utilized in the device.
1.2.3 Locking Screws

The locking screws for this system are provided by our client. The screws are 4mm in diameter with 6 full threads, roughly 15mm in length, with a head 5mm in diameter and 2mm thick. These screws are self tapping which means they do not require a pre-drilled hole. We will need to take into account both the screw hole size, placement, possible trajectory and the locking system into our design. The plate will consist of two screw holes per level, six overall. The screw holes will be countersunk so they fall flush with the plate. The holes will be placed in the further mechanically possible corners and edge of the plate as to allow for maximum mechanical strength toward the inside of the plate. Currently the screws will be drilled perpendicular to the plate but the possibility of a trajectory may help increase the security. Previous designs with titanium plates involve a trajectory which may also help prevent screws from backing out. Another aspect to the screw is the possibility of either unicortical or bicortical insertion. Unicortical is only drilled partially through the vertebrae while bicortical is all the way through. [1]Previous studies have been performed and show increased strength with bicortical but it is in question due to risks posed by the bicortical screw interfering with the internal carotid artery.

2.0 Realistic Constraints

*Engineering Standards

2.1 Economic Constraints

There are many different constraints that must be considered when designing the cervical plate device. Economically, there are not too many factors because it is a very
inexpensive project overall. The only thing that must be limited is the number of manufactured devices for testing purposes. Because the plates must be designed individually for patients, many different lengths and sizes of devices must be tested to ensure that they will all efficiently work. This will be done by using the program ANSYS. Within the program, we are able to create, test, and analyze the mechanical strength of the cervical plate using any different geometry that might possibly be needed.

2.2 Environmental Constraints
When dealing with environmental constraints, the main concern is ensuring that the device is biocompatible and will not cause any adverse reactions from the host tissue. The material being used to create all parts of the device is a biodegradable polymer that is made up of mostly cellulose, along with hydroxyapatite. Both of these materials are biocompatible and will not cause any negative effects from the body. Along with the initial material being biocompatible, it must also not cause any adverse reactions from the body as the polymer degrades. The polymer chosen for the design also has biocompatible degradation products to address this issue and make sure that the body does not react negatively at any time.

2.3 Sustainability Constraints
Another major constraint that needs to be considered is sustainability of the device. All parts of the device must remain intact until the vertebrae have fully fused. Fusion normally takes up to one year to occur so the polymer must not degrade for at least this long. The amounts of cellulose and hydroxyapatite combined were used in order to ensure that the polymer would last for a long enough time. Along with this, the polymer also undergoes surface degradation as opposed to bulk degradation. Bulk degradation can lead to early failure of the device because the entire material degrades at the same time, making a fracture or break possible. Surface degradation removes the outer layer first and slowly degrades to the middle of the material, sustaining the mechanical integrity of the material for a longer period of time.

2.4 Manufacturing Constraints
The foremost manufacturing constraint, spoken about briefly above, is the necessary variability of the size and dimensions of the cervical plate. Because all people are unique and have different attributes such as height, the distance between vertebrae in the spine changes from person to person. To account for this, the length of the cervical plate and its overall geometry must be changed to make sure that the screws of the device are positioned in the correct location. The second manufacturing constraint to consider is the actual process of manufacturing the device. Based on the material and the design parameters, the device will be manufactured by either injection molding or compression molding.

2.5 Ethical Constraints
There are not really any concerning ethical constraints that pertain to the design of
our device. Ethically, the only constraint is to ensure that our group creates a safe and healthy product for the public, but these issues will be covered below in the health and safety section. Otherwise, the only ethical concern that may arise would be during possible in vitro and in vivo testing of the product. Regardless of what negative effects it would have on the release of our product, it is an engineer’s ethical responsibility to report any and all testing results. While we do not plan or expect any negative side effects to occur during testing, anything can happen during the process and that is the reason that testing of the product is necessary to begin with. If anything were to happen, the food and drug administration (FDA) would be notified to ensure that we act in an ethical manner.

2.6 Health and Safety Constraints

It is extremely important to ensure that the health and safety of the patient is being considered. This begins by making sure that the cervical plate system is properly cleaned and sterilized before it is implanted in the body during surgery. Also, as discussed above, the material being used is biocompatible and is very safe to implant into the body. Along with this, the cervical plate must be designed so that there is no discomfort for the patient while it remains in the body. In order to do this, the plate is designed to be quite thin. Patients seem to feel discomfort whenever the plate thickness is greater than or equal to 3 mm. Because of this, the optimal design parameters do not allow the cervical plate to exceed 2.7 mm. The cervical plate is also designed to have no sharp edges or anything that could poke and prod the patient to cause any discomfort.

2.7 Social Constraints

We have not found any social constraints that would pertain to our cervical plate device. None of the materials that are used to create the cervical plate are objectionable to people in the general public. They are not materials that are debated such as the use of stem cells, for example. The surgical procedure and use of cervical plates to cure degenerative disc disorder are also not objectionable to the general public as far as we know.

2.8 Political Constraints

Finally, political constraints must be considered when designing the device. Possibly the most important constraint, the cervical plate must get the FDA to approve it before it can be placed on the market. The FDA has long and rigorous testing that a medical device must pass before they will allow the device to be used on the general public. This will normally include in vitro testing as well as in vivo testing to ensure that the device is safe and has no negative side effects.

3.0 Safety Issues
Many of the common safety issues are not relevant to our project because the cervical plate design does not contain the necessary components to cause these possible hazards. For example, there are no circuit boards or electrical work within the design, and therefore, there are no electrical safety issues. The main safety issue that our design must account for is mechanical safety issues. The cervical plate must be able to withstand the mechanical forces and loads that the body places on the plate during the time of fusion. If the plate is not mechanically strong enough, fracture could occur due to the forces and stresses of the body. This is obviously a main safety issue with the cervical plate because the vertebrae would not be able to stay in place if fracture occurred, leading to fusion not taking place.

Similarly, the locking system must also be mechanically strong enough to hold the screws in place in the vertebrae. A common problem that occurs during fusion is the screws backing out of the vertebrae, causing the entire device to loosen and fall out of place. This is due to the locking system either accidentally rotating into the unlocked position or not being mechanically strong to hold the screws in place.

Other than mechanical issues, the only other safety issues involve the host reaction to biomaterials as well as the degradation of the device. Unlike the majority of cervical plates on the market, which use metals such as titanium, our design uses a biodegradable polymer that is made up of cellulose and hydroxyapatite. Both of these materials are biocompatible, so there will be no host reaction to the device. The design must also ensure that there will not be a host reaction to the device while it degrades. The polymer being used undergoes surface degradation as opposed to bulk degradation. When a polymer undergoes surface degradation, it slowly erodes, starting with the surface of the material and slowly removes layer after layer until the entire material has degraded. This is much safer than using a polymer that undergoes bulk degradation because bulk degradation can lead to early fracture and failure before fusion has fully occurred. Whenever using a material that is biodegradable, there is a safety issue involving the host reaction to the degradation products of the original material. The biodegradable polymer being used for the cervical plate device degrades away into biocompatible products. Therefore, there will not be a negative host reaction to the biodegradable polymer or to the degradation products of the material. When considering thermal safety issues, there is no cause for concern as the device only has to withstand normal body temperatures, which the polymeric material is easily capable of doing. There are no safety issues regarding things such as chemical hazards or radiation.

4.0 Impact of Engineering Solutions

With the creation of this new cervical plate design, there will be an impact from
engineers to the medical world as well as to the general public. There is a lot of room for new applications because of the material that is being used for the cervical plate design. It is a fairly new polymer that has been patented by our client. This means that as of right now, it is not able to be used by the rest of the general public. Knowing this, it shows the possibilities of being used in a multitude of different ways within the engineering community.

The material used to create the cervical plate is made up of cellulose and hydroxyapatite, but more importantly, it undergoes surface degradation and breaks down into biocompatible and harmless products. Within the field of cervical plate systems, there are a few that use biodegradable polymers; the majority of these are made up of polylactic acid (PLA) and polyglycolic acid (PGA). There are two major advantages of the biodegradable polymer used on our device that can cause a major impact within the field. Firstly, PLA and PGA based biodegradable polymers undergo bulk degradation rather than surface degradation. Because this causes the entire material to degrade at the same time rather than degrading layer-by-layer from the outside, it allows for the possibility that the device will fracture before it is meant to. Surface degradation is a much more useful property within this field, as well as with other applications such as drug delivery. The second advantage of the polymer we have used for our optimal design is that the degradation products of the polymer are harmless and biocompatible. Polylactic acid and polyglycolic acid have acidic degradation products that can cause a host reaction when the material degrades.

Another major impact that may be caused by this device is the fact that it can save time and money for the general public and medical facilities. Right now, the majority of cervical plate systems that are placed in patients are made of a metal, such as titanium. Because this is a non-degrading material, it means that once fusion of the vertebrae has fully occurred, the patient must either undergo a second surgery to remove the device or they must decide to simply continue living with a titanium plate attached to their spinal cord. Using a safe, biodegradable polymer such as the one being used in our optimal design, this is no longer an issue. The cervical plate and screws will simply degrade away into the body after fusion has occurred, making it unnecessary for patients to spend the money on a second surgery, as well as not requiring the hospital and doctor to take the time and money to perform the extraneous procedure.

All of these applications are realistic prospects for the cervical plate device once it is completed. The device in itself has the possibility of becoming the new standard procedure for curing degenerative disc disorder with a plate implant. Along with this, the material used to create the device has many possible applications that have not been discovered yet, as it is a newly used polymeric material that has only been researched for its applications to this field of study so far.
5.0 Life-long Learning

Researching and beginning to design this project has taught us a multitude of knowledge, as well as engineering techniques that were not previously known. We firstly learned about the background of cervical plate implants and the reason why they are necessary. The implants are needed because of degenerative disc disorder, or DDD, which is a disease that can cause extreme pain and discomfort for people as the vertebral discs in their spine degrade. Degradation of the vertebral discs can happen because of trauma, but it will occur over the course of a person’s life regardless of what precautions are taken. While time will automatically take its toll on a person’s vertebrae as well as the rest of the body, only a portion of people will suffer from degenerative disc disorder. When a person does suffer from the disorder though, a cervical plate and screws such as the one designed by our team must be implanted to hold the vertebrae of the spine together, allowing them to fuse to one another and create a stronger attachment. We have learned about the current techniques used to create cervical plates and the main concerns and issues that are problematic within the field at this time as well.

Along with the general knowledge about our design project and the field of study it falls into, we have also learned about many different engineering applications that are used in the process of designing our device. The most prevalent application we have learned about in designing our device is how to use the program SolidWorks. With none of the group members having experience using the program, we have learned how to create parts from scratch, combine parts into an assembly, and create drawings to enable the manufacture of the designed parts and assemblies. It is an extremely useful tool to learn, as almost all engineering companies use some type of computer-aided design (CAD) program. Therefore, whether it is designing the part yourself, or being able to analyze the parts and drawings to manufacture the part, almost all engineers must be at least somewhat familiar with a CAD program such as SolidWorks. Similarly, our design project also requires us to learn and become proficient with the program ANSYS. Another CAD program, we will be using the program almost continuously throughout the course of designing our device in order to create, test, and analyze our cervical plate. ANSYS will be used to test our cervical plate and ensure that it will be mechanically strong enough to withstand the forces and stresses placed on it by the body. We have also learned about helpful tools for organizing and documenting work done on the project. For instance,
having to continually keep a log of work done in our lab notebook is very useful not only because it helps keep track of all work that has been done, but also because it is a necessary tool when doing research and design in order to acquire a patent. Finally, we have learned to organize our work by using Microsoft Project to keep track of when and what we work on.

6.0 References