Novel Polysaccharide-derived Fixation Device for Anterior Cruciate Ligament (ACL) Reconstruction

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Executive Summary

This project involves the design and fabrication of a unique fixation device for reconstructing the anterior cruciate ligament (ACL). The device will be made of a novel polysaccharide that is both biodegradable and biocompatible. The geometry and features of the device will be unique compared to other fixation devices in the market, and it will provide more stability and produce less painful side effects. The overall goal of the project is to provide patients who suffer from ACL injuries with a reliable, easily implanted, and painless fixation device, so that they can fully recover and continue with their normal daily activities as quickly as possible. This project incorporates both computational design and testing, followed by the construction and verification of the device. The overall cost of the project will most likely be around $500, but it is not finalized yet because synthesizing the material may be quite costly. Overall, this device will have material properties and mechanical features that other fixation devices lack, which will make this project succeed.

1 Introduction

Injuries to the anterior cruciate ligament (ACL) occur in approximately 95,000 people every year, and can be debilitating for individuals who lead a very active lifestyle. The ACL is vital to maintaining knee stability and coordinating the kinematic motion of the knee. The knee joint is a bone-to-bone junction that has ligaments and muscle attachment sites that surround the interface to prevent any abnormal motion. As seen in Figure 1 to the right, there are four main ligaments that have a unique function in knee stabilization: anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) within the knee cavity, lateral collateral ligament (LCL) on the outside of the knee and medial collateral ligament (MCL) on the inside of the knee. ACL is a common injury due to its specialized function and insertion sites on the femur and tibia. It restrains about 85% anterior translation of the tibia with respect to the femur, with relatively lesser restraint against inward and outward rotation.

The ACL is most often torn or in severe cases ruptured when an athlete encounters a disruption while they are decelerating, where these quick motions are often commonplace in agility sports such as soccer and football. These disruptions can take many forms including player-to-player contact or an uneven surface. While many ACL tears can recover through careful rehabilitation and re-stabilization of the knee, complete ruptures of the tendon are often surgically corrected. Due to the invasive nature of this procedure and potential for failure during rehabilitation, it is vital that the tendon placement itself is stable. While about 80-90% of the
patients will regain stable knees post surgery due to successful surgical techniques, the remaining patients have persistent pain or knee instability that may require additional surgeries to correct this instability.

Overall, the surgery and the materials involved, while generally effective, have still not been perfected. In order to reconstruct an ACL, interference screws are generally used to secure a graft within the tibia and femur. Many of these screws are made from metals or polymers, which both cause problems after the surgery has taken place. Metal screws do not degrade, and if the metal remains in the body for too long of a period, the implant may both weaken the bone due to stress concentration and/or become loose due to constant friction on the bone-implant interface. Because of this, metal screws may need to be removed and may require sequential surgeries to correct the problem. Bioabsorbable screws, on the other hand, are made from various polymers and composite materials, which ideally wouldn’t have these compatibility issues. Unfortunately, the degradation byproducts of these polymers are acidic and have an adverse effect on the surrounding tissue at the surgical site. In conclusion, interference screws are not a perfect solution for ACL reconstruction.

Many other fixation devices, besides interference screws, have been used to reconstruct the ACL. These devices have been used with success, but not all surgeons are willing to work with them, because of difficulty to implement the device and they are not as available as interference screws. Some of these devices are, however, an excellent alternative to screws, and provide a solid foundation for future designs for other fixation devices. Of course, there are still multiple problems associated with these devices, including metal staying in the body for too long of a period and loosening of the actual implant causing the graft to be insecure, similar to the problems that screws propose. However, with the correct bioabsorbable material and a combination of features from already existing products, as well as some innovative ideas, it is possible that a better fixation device can be designed for ACL reconstruction. The device should be both biocompatible and bioabsorbable. It should not degrade into any harmful byproducts, and it must provide the appropriate mechanical stability for the surgical application.

1.1 Background

Our client has requested a new design for a fixation device using a novel biodegradable material that has recently been developed. The material is a polysaccharide derivative that has been used for other applications such as dialysis membranes and wound care systems, yet there is uncertainty about the applicability to the high stress environment in anterior cruciate ligament (ACL) reconstruction surgeries. Polysaccharide derivatives have both exceptional strength and biocompatibility, but also have the potential to be osteoinductive. The aim for our project is to design a mechanically stable, biocompatible, and bioactive fixation device made from this novel polysaccharide derivative. Mechanical testing will be required in order to understand the stresses placed on the device for ACL reconstruction surgery. Ideally, the device will maintain its integrity during placement into the bone and eventually degrade so that the patient’s native bone can maintain stability of the tendon placement.
1.2 Purpose of the project

Our client has expressed the need for a new design for a fixation device due to issues with current devices. Currently, the gold standard on the market for fixation devices in ACL reconstructive surgery is the interference screw due to simplicity and affordability. Despite the success of interference screws on the market, they pose significant design flaws indicating a need for new, innovative designs for fixation devices. We propose to design a new fixation device that will be superior or comparable to current devices on the market in terms of stability, biodegradability and simplicity.

1.3 Previous Work Done by Others

1.3.1 Products

There are a variety of products in the market, currently used by orthopedic surgeons for anterior cruciate ligament reconstruction. These products range from metal or bioabsorbable interference screws all the way to button-like locks. Arthrex, Inc. currently has a bioabsorbable interference screw on the market. The screw design incorporates a tapered profile along the entire length of the screw in order to fit securely and fill the tunnel. As mentioned in the introduction, one drawback to interference screws in general, for both metallic and bioabsorbable, is their tendency to slip back through the tibial or femoral tunnel, significantly reducing the fixation strength of the system. Biomet, a medical device company, currently markets a femoral and tibial fixation device called the EZLoc. Basically, the EZLoc incorporates a loop which the graft is attached to with a locking mechanism. The graft, either from the patellar tendon or hamstring tendon, attaches to the titanium fixation device and is pulled through either the femoral or tibial tunnel. Once through the bone, a locking mechanism protrudes from the device preventing the graft from retreating back through the tunnel. Another device on the market called the Endobutton by Smith & Nephew functions similarly to the EZLoc. When using this device, surgeons thread the graft through a titanium loop and pull the graft through the tunnel using a guide-wire. Once through the tunnel, an auxiliary wire attached to the device is pulled and the device locks on the cortical surface of the femur. Both methods are advantageous for the following reasons: they do not cause wear or abrasion of graft as opposed to interference screws and they do not rely as heavily on the strength of local bone for mechanical stability, which is beneficial for patients suffering from osteoporosis. However, there are noticeable disadvantages of these devices, which include: decreased stiffness in the overall graft fixation and the possibility of graft tunnel motion. There are two types of graft tunnel motion that can lead to enlargement of the tunnel and a decrease in bone formation, both around and inside the tunnel. The first type is called longitudinal graft motion, characterized by protraction and retraction of the graft through the tunnel. The second type is called sagittal graft motion in which the graft moves from one side of the tunnel to the other during normal knee motion. All of these
problems that occur with the current products in the market suggest a strong need for an alternate fixation device.

1.3.2 Patent Search Results

Bioabsorbable interference screw for endosteal fixation of ligaments

Patent number: 7322986
Filing date: Apr 4, 2005
Issue date: Jan 29, 2008

Endobutton continuous loop for bone tendon with double loop knot

Patent number: 7530990
Filing date: Jul 20, 2004
Issue date: May 12, 2009

Method and apparatus for performing ACL reconstruction

Patent number: 7736364
Filing date: Feb 2, 2006
Issue date: Jun 15, 2010

2 Project Description

2.1 Objective

The device will have a completely new geometry as compared to other fixation devices for ACL reconstruction surgery. The purpose of the device is to allow for the insertion of a new tendon, called the graft, to replace a ruptured ACL in the knee. The device shall be inserted in between the tibia and femur, along with the tendon graft, via arthroscopic surgery. Once surgery is complete, the device will securely hold the graft in place, and it will not become loose until it completely degrades. The degradation time is over a year, which allows time for the tendon graft to completely heal. Ultimately, the patient will have a fully recovered knee.

One of the major components of this design is the use of a novel polysaccharide material. The material being used does not degrade into any harmful byproducts that cause adverse inflammation in the body. This is an advancement compared to other bioabsorbable fixation devices, because many of them degrade into acidic byproducts, which oftentimes harm the body
in a variety of ways. Another major component of this fixation device is the locking mechanism that is being introduced. A commonly occurring problem with previous devices is the loosening of the device after a long period of time, which causes severe pain for patients. Our device will contain a novel locking mechanism, which does not move or shift until the material has degraded and the graft is fixed in place. Lastly, the geometry of the design will be superior compared to designs in the past. A new material that has a slightly lower mechanical integrity compared to previous materials is being used for this device, which means the new geometry must account for this difference in mechanical strength.

2.2 Methods

This project will entail four essential steps, which include designing and computationally testing three alternative fixation devices, fabricating the optimal device, and mechanical verification. Each of these steps is explained in more depth below. Furthermore, a block diagram has been constructed to show our plan for the design project, which can be seen in Appendix A.

2.21 Computational Design

To begin, computer-aided design will be utilized to make computational models of the device. SolidWorks will be the program of choice. Geometry of the design will be the most important factor in the design aspect. The mechanical properties of the design will fit the needs for ACL reconstruction. Using a slightly weaker polysaccharide material, the device will have a superior geometrical design compared with those on the present-day market. The designs in SolidWorks will be uploaded into the finite element analysis program to verify the mechanical integrity of our design, along with the specific mechanical characteristics of the polysaccharide material.

2.22 Computational Testing

Once the designs of the fixation device are complete, computational testing of the device will begin. The simulation of mechanical testing of the design is integral before choosing which of the three alternative designs to fabricate and mechanically verify. The simulation program of choice is ANSYS. The testing includes compression, tensile, and rotational testing. There are ASTM (American Society for Testing and Materials) standards for the minimum amount of force a fixation device must be able to withhold for ACL reconstruction purposes. We plan to test the design according to these standards, using ANSYS. If the design meets the ASTM criteria, we will continue to the fabrication step.

2.23 Device Fabrication and Re-design

Once we decide on the optimal design, we will fabricate a prototype of that design. Based on our work from SolidWorks, we will transfer the geometries from the computer to reality. The prototype will be made of a material with similar mechanical properties of the novel
polysaccharide material, so that we do not waste a significant amount of the new material, since making the material, alone, is quite an arduous process. The prototype will be functionally tested. If the prototype proves to be successful through the mechanical tests, then the design will be fabricated using the novel material, and further verification will commence. If the device fails, the design step will be revisited.

2.24 Mechanical Verification

The mechanical verification required for the fixation device will mimic the computational analysis performed in ANSYS. Our final product will be able to withstand forces, according to ASTM standards. This verification will be performed using a uni-axial testing machine, as well as a rotational testing machine. Once the device performs as desired, in regards to mechanical strength, it can be passed on to the client for further verification if necessary. At this point, our goal for the project will be complete, and the fixation device will potentially be able to be used for ACL reconstruction surgery.

Figure 2. Illustrative design for device showing issue of anchoring the tendon within the bone cavity.
3 Budget

Overall, the main expense for the development of our product will be the novel polysaccharide material obtained from Dr. Sangamesh Kumbar’s lab at the University of Connecticut Health Center, but this cost is unknown at this time due to information privacy issues. We will only require this material for injection molding and mechanical strength validation during the second semester, which also requires a small fee through the school machine shop. Prior to building the device made with the novel material, we will use aluminum stock in order to create prototypes for the fixation device. The aluminum is about eight times as strong in tension than the polysaccharide material, yet it will still serve as an easy material to manipulate for our design process. A small investment will be made in an anatomically accurate model of the knee, which will be used during the design process to maximize device simplicity and also as a presentation tool. Below is a summary table, which is 35% underestimation of the expected expenditures as required.

<table>
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<tr>
<th>Material</th>
<th>Price</th>
<th>Pricing Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software (SolidWorks and ANSYS)</td>
<td>$0</td>
<td>School of Engineering</td>
</tr>
<tr>
<td>Hardware (UTM Tester)</td>
<td>$0</td>
<td>School of Engineering</td>
</tr>
<tr>
<td>6061 Aluminum square (2 in x 2 in x 4 ft stock)</td>
<td>$95.80</td>
<td>metalsdepot.com</td>
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<td>Labor Fees for mold creation</td>
<td>$50</td>
<td>SoE Machine Shop</td>
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<tr>
<td>3B Scientific A82 Functional Knee Joint Model, 4.7” x 4.7” x 13.4”</td>
<td>$72.00</td>
<td>Amazon.com</td>
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<td>Polysaccharide Material (Synthesis fees)</td>
<td>TBD</td>
<td>Dr. Sangamesh Kumbar</td>
</tr>
<tr>
<td><strong>Total Price (without material)</strong></td>
<td><strong>$217.80</strong></td>
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4 Conclusion

This proposed product is superior to competitors for a number of reasons. First, the product is made of a novel polysaccharide material that degrades into harmless byproducts. Furthermore, the device uses a unique locking mechanism, which will prevent the device from shifting post-implantation and ensure that the graft is securely held in place. Lastly, the device has a one-of-a-kind geometry, which incorporates the mechanical properties of the new material and features of previous designs that have proven useful. Once the design has been fabricated, it will be turned over to our clients, and they will use the device as needed. The fixation device will be used for surgical applications and has the potential to supersede its competitors due to its unique features. The budget should not be an issue, as most of the cost will revolve around synthesizing the novel material. This fixation device is an opportunity to even further advance the process of ACL reconstruction. It will give people who suffer from these injuries the chance to fully recover and lead their normal daily lives once again.