BME 4900 Final Report

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

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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 below, 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.

![Diagram of knee joint with labeled ligaments](image.jpg)

**Figure 1:** Rear view of a left knee joint

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. Therefore, 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. There are, however, multiple problems associated with these devices, including metal staying in the body for too long of a period and loosening of the actual implant that causes the graft to be insecure. Hence, they propose similar problems to those of interference. 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 simulations and finite element analysis 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 comparable or superior to current devices on the market in terms of stability, biodegradability and simplicity.

1.3 Previous Work Done by Others

1.3.1 Products

Currently there are many products on the market used by orthopedic surgeons for anterior cruciate ligament reconstruction. These devices are used to fix the graft tendon in place, ultimately restoring natural knee motion and support. These products range from metal or bioabsorbable interference screws all the way to button-like locks. The screw design incorporates a tapered profile along the entire length of the screw in order to fit securely and fill the tunnel. A 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 bone block of the graft is attached. This loop is then attached to the EZLoc and the graft attaches to the titanium fixation device which 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

This is a patent for a bioresorbable interference screw that provides superior fixation strength and promotes fast healing during reconstructive ligament surgery. The screw features a tapered tip for ease of placement as well as a hollow core in which the placement device fits into via radially extending slots.

**Endobutton continuous loop for bone tendon with double loop knot**

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

The Endobutton consists of a button-like fixation device and a tough string that secures the ACL graft tendon. Essentially, a small hole is made in the bone block that the string goes through. The string is then double-knotted around the button device, which then rests against the outer femur, holding the graft in place on the femoral side via tension. On the tibial side, an interference screw is generally used. This patent has been used because of its excellent flexibility properties, but sometimes, the button can become loose since it is not locked into place; it is simply resting against the femur.

**Method and apparatus for performing ACL reconstruction**

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

This patent outlines a procedure for ACL and PCL reconstructive surgery. It includes steps for the drilling of tibial and femoral graft tunnels and how to use guide-wires to place fixations devices such as interference screws.
1.4 Map for the rest of the report

In the second section of the report we will discuss the overall project design with regards to the alternative designs and the optimal design. Then we will provide descriptions for each of the subunits of the optimal design. In the third section of the report we will underline the realistic constraints of our design including: engineering standards, manufacturability, economic and environmental to name a few. The fourth section will pertain to safety issues involved in the design, manufacturing, prototyping and testing of our device. The fifth section will include our evaluation of the impact of our device on medical industry as well as patient health care. In the sixth section we will discuss the areas in which we have gained knowledge throughout the duration of this project. We will provide a detailed budget for the project in the seventh section. The eighth section will list each group member’s contribution to the overall project as well as a description of each of the individual contributions. We will conclude the report in the ninth section with a conclusion that will provide any clarifications as well as an emphasis of the major points we hope the reader will take away from the report. Also we will include our source references, acknowledgments and our appendix in the tenth, eleventh and twelfth sections respectively.