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

Team 13
Derek Holyoak
Alexander Werne
Benjamin Roberts

Clients:
Dr. Krystyna Gielo-Perczak (BME Program, University of Connecticut)
Phone: 860-486-0370

Dr. Sangamesh Kumbar (UConn Health Center)
Phone: 860-679-3955

Dr. Gloria Kolb (UConn Health Center)

Dr. Cato Laurencin (UConn Health Center)
Phone: 860-679-2594

University of Connecticut
Storrs, CT 06269

UConn Health Center
263 Farmington Avenue Farmington, CT 06030
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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.

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 joint stability post surgery due to successful surgical techniques, the remaining patients have persistent pain or knee instability that may require additional surgeries to correct this issue.
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 additional 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 pose 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.

2 Project Design

2.1 Introduction

This section will describe the process by which we arrived at our optimal design. As shown in Section 1 of the report, there was a lot of prior research that needed to be completed in order to begin thinking of ideas for the design of our device. Much work was done to find the existing patents on fixation devices for ACL reconstruction surgery and to understand how many of the various types of surgeries actually work. Essentially, we needed to know the direction of the holes that were drilled in both the tibia and femur, where the appropriate location was to insert the fixation device and graft tendon, how previous devices locked into place, and which types of graft tendons were used for existing surgeries. Furthermore, much research was put into the actual forces and moments that are experienced by the ACL. This proved to be quite difficult, as many research articles use differing moments and loads. The goal for our device is to make it be able to withstand worst-case scenario forces and moments. Lastly, we needed to make sure that the novel polysaccharide-derived material that we would be using has sufficient mechanical properties to be used for ACL fixation device. Once all of this information was collected and verified, we were able to start thinking of some alternative designs that might prove to be sufficient for our task.
2.1.1 Alternative Design 1

This design aims to create a more stable and bioactive alternative to the Endobutton, where only one end of the patellar bone-ligament-bone graft is anchored to tibial tunnel with a biodegradable interference screw. The other end that passes through the femoral tunnel will be secured using this novel design. There are two opposing issues that can occur in graft placement depending on how the procedure is completed: laxity or stiffness. Oftentimes with interference screws and the Endobutton, you can develop these loosening or stiffness issues due to the variable surgical techniques employed with these devices. The following device satisfies the need for a stabilization device that does not allow slippage, but also provides a certain degree of flexibility to create the optimal amount of tension in the autograft.

During ACL reconstruction surgery, there are a few main components that are constant across all techniques that were integrated into the design of this device. First, a hole is drilled entirely through the tibia and femur at an angle to simulate the attachment points of the native ligament. This is often 10mm in diameter, and the tunnel allows for smooth passage of the crimped bone graft which is often about 9mm in diameter. With regard to the endobutton, this device utilizes the idea of two different sized drills: a smaller drill to pass entirely through both bones and a larger drill that is only passed through the entire tibia and bottom half of the femur cavity. This allows for the placement of the Endobutton. In our design, the standard 10mm drill and a larger 14mm drill will be used to create a large opening on the outer cortex surface of the femur. By creating a ledge or lip on the upper tunnel opening, this will serve as a “table” for our device to sit on and stabilize the graft below.

Second, a hole is usually drilled in one bone block so that surgical thread can be passed through. This allows for the surgeon to pull the graft through the tunnel to the correct anatomical placement height. This design takes advantage of this concept to stabilize the graft to our device. In the surgical schematic shown in figure 1, the thread simultaneously pulls the graft through the bone tunnel and correctly aligns the holes of the graft with the holes in the device. Once aligned, this thread is used as a guide wire to place a hollow cylinder made from the same biodegradable material into the graft-device combination. This will effectively fasten the graft into our device once the cylinder is locked into place. The thread can then be easily pulled out of the surgical site if biodegradable suture thread was not used.

This setup with prevent any inferior translation through the bone tunnel, yet there is nothing preventing this device from superior translation. In order to solve this issue, a gear component on the superior surface of the device was created. When a screwdriver is placed in the gear’s socket and turned to the right, this will move the two blades on either side of the gear outwards into the surrounding bone tunnel. Since the blades are double ended and can be extended in either direction, this allows further flexibility during surgery through alternative blade placement depending on the integrity and thickness of the surrounding bone. When fully engaged, these blades will have passed into the bone, further securing the device. A view of the device can be seen in Figure 2 below from the top surface, showing this gear mechanism.
Figure 2. On the right, a three-dimensional view of the device. On the left, a transverse view of top of the device, with schematic showing the gear component to prevent superior translation along canal.

Figure 3. On the left, a coronal view with surgical schematic detailing the method of securing the bone-ligament graft within the biodegradable device. On the right, a saggital view with transverse tunnel opening for placement of cross-bar.
Alternative Design 2

Another problem with interference screws on the market is that they fail to stay in place and tend to become loose after a period of time, resulting in constant friction between the screw-to-bone interface. This second alternative design improves the design of the interference screw, by adding a unique locking mechanism within the screw head, itself. The procedure to implant the screw will be similar to current techniques with only one additional step (securing the locking mechanism into the bone).

From the outside, the device will look like a simple screw, made from the novel degradable polysaccharide, with one major exception. The difference lies on the screw head. Instead of the top of the interference screw looking like a normal screw head, there will be four tiny screws facing outward, each of them securely locked by an extension coming out of the head of the screw. There will be a screw hole in each of these semi-circular attachments, to allow the passage of the four tiny screws. The four tiny screws will be pre-placed into these screw holes prior to surgery, and then drilled into the bone post-implantation. The purpose of these tiny screws is to lock the interference screw in place, so that the screw threads are not the only aspect of the design that secures itself. The difficult part is to make these tiny screws come out of the screw head after the interference screw is in place in the femur or tibia. However, this has been considered, and a special tool will be made to insert these tiny screws into the bone.

This tool consists of a simple gear mechanism, the will lock itself into the tiny screws, whose heads also are a gear. The gear from the tool will lock simultaneously to the gear-like heads of the four tiny screws, and once twisting begins, the screws will gradually move outwards into the bone. The gear on the tool will be larger than those on the tiny screws, so that as rotation occurs, the gears will remain locked in place as the screws travel farther into the bone.

Figure 4 (above): Gear mechanism*  Figure 5 (above): Top view of interference screw*
Figure 4 shows how each of the tiny screws will be drilled into the bone once the interference screw has already been implanted. The tool will have a larger gear, which will lock into the gears on the tiny screws, and rotation can begin. As it rotates, all of the gears on the head of each tiny screw will be simultaneously drilled into the bone.

Figure 5 shows a top view of the actual device. On top of the screw head, there will be the four tiny screws, which are held in place by extensions coming from the head of the interference screw. The tiny screws will move through these extensions into the bone by the unique gear mechanism.

Figure 6 shows a side view of the head of the interference screw before the tiny screws have been set in place. The design of the extensions includes filleted edges, so that there are no jagged edges to causing any abrasions or other harmful side-effects.

Alternative Design 3

As with the other two designs, it is our desire that the patellar tendon will be the graft used for this design since we believe that the tendon graft with bone blocks attached will result in the optimal recovery of the joint and joint function. This design will prevent two flaws found in
current fixation devices: excess graft stiffness and graft tunnel motion. Interference screws are most commonly used as fixation devices. These screws often result in the graft becoming too stiff. If the graft is too stiff it may develop micro tears which may result in a rupture of the graft. Graft tunnel motion occurs when the forces acting on the graft cause it to move longitudinally and sagittally which can be detrimental to the recovery process.

This design will consist of two halves of a hollow cylinder divided longitudinally as seen in Figure 7 below. The outer surface of the cylinder will be threaded so as to be screwed into the graft tunnel. The two halves of the cylinder will be placed around the graft with the bone block sitting on top of the cylinder once the two halves are joined. In order to join the two halves of the cylinder, pegs on the joining surfaces of one half will fit into holes on the joining surface of the opposing half. The diameter of the bone block must be greater than that of the hole in the cylinder so as to prevent graft retraction through the tunnel when a force is applied. The bottom of the cylinder will contain slots for the placement device to fit into so that it can be screwed into place.

Figure 7. Assembled device with graft and bone-block

Once in place, the threads on the cylinder will be what holds the device in place. With threads along the length of the device, there should be no longitudinal movement in the graft tunnel. The diameter of the tunnel should be slightly smaller than that of the graft so that the graft fits snugly but not too tightly as to prevent any stretch. This will limit the longitudinal graft motion and entirely prevent sagittal graft movement. Since there will be limited longitudinal graft motion, the graft will maintain the optimal amount of stiffness. This will prevent damage to the graft, ensuring a better recovery. The bone block on top of the device will regrow in place and the novel polysaccharide material will degrade over time leaving only the graft.
2.1.4 Choice of Optimal Design

The three alternative designs all had some advantages and disadvantages making the optimal design difficult to determine. We ultimately agreed that alternative design 1 was the design we would pursue. Alternative design 2 incorporated four small screws on top of the interference screw that would insert into the surrounding bone after the device is placed into the femur. We decided that this design was implausible as the four screws would be very small and difficult to manufacture. Also at the necessary size they might not provide the appropriate mechanical properties for this application. Alternative design 3 was also deemed implausible for this application. For this design the graft would be placed between two adjoining halves of a cylinder with threads on the outside surface. The bone block would sit on top of the cylinder and the device would be screwed into the bone tunnel. We realized that this design was not sound as the only thing securing the graft to the fixation device was the difference in diameter between the bone block and the hollow cylinder. With enough force, the bone block could be pulled through the hollow cylinder which would require further reconstructive surgery.

Economic:
The fixation device is a cost-effective project. The main expense is the synthesis of the novel polysaccharide material. However, we were informed that we would receive a five pound donation of the material free of charge from the health center. This will allow us to fabricate all of our parts via molding in the machine shop. To create the molding, itself, based on our CAD design, may have a significant cost, but it should not fall outside of our budget. Some additional factors are materials for the prototype, machine shop time, and some other miscellaneous items. All of the software, including SolidWorks, ANSYS, and Dreamweaver, will be provided by the University of Connecticut School of Engineering. The overall budget should not be an issue.

Environmental:
The environment of the device is an integral part to this project. The material has already been tested to ensure that it adapts to the physiological conditions of the knee with respect to osteoinductivity. Mechanical testing has already been completed on the material, but the material in its final design has not been categorized for the specific stresses of the knee. Once the fixation device has been fabricated, it will need to be kept in a cold atmosphere to prevent the degradation of the material.

Sustainability:
Once the device is implanted in the body, there should be no reason for any future maintenance. The fixation device will naturally degrade, and enough bone will grow to keep the graft in place, so the patient can completely recover.

Manufacturability:
The plan is for the fixation device to be used for numerous ACL reconstruction surgeries. The manufacturability of the device should not be an issue, once the exact molding platform has been
fabricated and enough of the material has been synthesized. Since the material is relatively expensive, we will do our initial prototyping with a cheaper material such as aluminum, but we will create a mold later in the process to verify the mechanical integrity of the polysaccharide-derived material. The material has been shown to maintain its strength during heating, so it will easily mold to the shape we require.

**Ethical:**
The material being used is a polysaccharide derivative and is not derived from anything that would pose ethical threats to people from any race, religion, or ethnicity. It also does not require any biological testing or stem cell placement, so it should pass through the FDA relatively quickly compared to other bioactive devices.

**Health and Safety:**
The fixation device will be used in surgery, which always poses a threat to the patient’s well-being. The surgery for this particular device, however, will be as ergonomic as possible, as the patient’s safety is always of utmost concern. Furthermore, implant failure is a possibility, but due to the unique locking mechanism in the design, this should be of minimal risk. Since failure during placement is also a possibility, we will incorporate into our design an easy method to remove the device and replace it with a new one, which isn’t necessarily possible with current fixation devices on the market.

**Social and Political:**
Because there are so many other products in the market that are being used for ACL reconstruction, it may prove difficult to market this new fixation device. We will have to show the FDA that our device compares to other fixation devices in order for approval for usage. The process should be simplified, however, since the material eliminates the need for stem cell incorporation and stem cell culturing.

### 2.2 Optimal Design

#### 2.2.1 Objective

Our device will be implemented on the femoral side during ACL reconstructive surgery. After the graft tunnel has been drilled, it will be overdrilled from the femoral cortex. The diameter of our device will share the diameter of the overdrilled tunnel. This will prevent longitudinal translation back through the graft tunnel during normal knee movement. The overall shape of the device will be cylindrical and will have the bottom half hollowed out. This will provide a cavity in which the bone block of the graft tendon will reside. A unique locking mechanism will be incorporated to fixate the graft to the device. This will necessitate the creation of a hole horizontally oriented hole to be created in the bone block. Sutures will be threaded
through the holes of the bone block and through corresponding holes in the cylindrical bone block casing. Once this is complete a hollow locking pin will be passed along the suture and through the device and bone block locking the two together.

This process must be completed after the graft has been pulled through the graft tunnel in the femur and is protruding from the femoral cortex. After the graft has been fixed to the fixation device, the knee will be flexed which will pull the fixation device into the graft tunnel on the femoral side. Since the femoral tunnel will be overdrilled to a greater diameter the fixation device will fit into the tunnel until it no longer protrudes from the femoral cortex. The smaller diameter tunnel underneath the graft will prevent any movement of the graft. Next the knee will be extended and the surgeon will pull the graft through the tibial graft tunnel. The surgeon will pull the graft until it has the proper tension and then an interference screw will be placed in the tibial graft tunnel fixing that side of the graft to the surrounding bone. Both our fixation device and the interference screw will be composed of the novel biodegradable material. Ideally, the patient will undergo a shorter period of rehabilitation in comparison to other fixation devices currently on the market. The block diagram seen in Figure 8 below shows the entire process.
2.2.2 Subunits

The system we have designed incorporates the following six components: bone block casing, locking pin, stabilization rails, rail driver, interference screw and the replacement graft. Our unique fixation device will be placed on the femoral side of the joint while the interference screw will be placed on the tibial side. The fixation device we have designed necessitates the use of the a bone-tendon-bone graft. Our system requires the harvesting of the patellar tendon as opposed to a graft being taken from the hamstring tendon as it is not feasible to obtain a bone-tendon-bone graft from this location. On the tibial side of the knee joint, an interference screw will be placed to fix that end on the graft in place.

After harvesting the graft, the surgeon will need to create a 3 mm diameter hole in the bone block and thread the string or suture through this hole with which the bone block can be pulled through the graft tunnel. Once the bone block has cleared the femoral cortex the ends of the string can be threaded through the holes in the cavity of the casing. The string will be pulled taught in order to pull the bone block into the cavity of the casing. Without releasing tension the locking pin will be threaded onto one end of the string and pulled through the hole in the side of the casing, through the bone block and out of the other side of the case locking the bone block in place. Once this has been completed the device can be placed in the enlarged tunnel on top of the femoral cortex.

The surgeon will then place the rail driver into the opening on top of the casing engaging the threads of the driver with the grooves on the stabilization rails. Once the threads of the driver and stabilization rails are engaged, the surgeon can apply torque to the rails driving them into the surrounding bone. The rails will feature sharpened ends in order to penetrate surrounding bone without applying too much force. Also there will be lines inscribed on the rails to indicate how far the rails should be inserted into the bone. Each sharpened end of the rail will have a notch in which bone will slowly fill in. The purpose of this is so that the stabilization rails will not be pushed back into the bone block casing. Once the rails are secured in the bone and the rail driver has been removed from the device, the hole on top will be filled with bone cement. The device can be seen in Figure 9 below.
1.2.1 Bone Block Casing

The fixation device that will be used on the femoral side will be a much more complex design than the interference screw that will be implemented on the opposing tibial side. The main challenge in ACL surgery is to create the appropriate amount of tension in the graft so that it simulates the body’s own ACL. This cylinder will serve as a stable anchor for the tendon to be stretched to the appropriate tension. A 20mm tall cylinder will be created with a 10 mm long cavity that is drilled from the bottom face. The bone block is usually crimped to 9mm and will be fixed within this inner cavity of the device. A horizontal tunnel will be drilled through the side of the casing wall that is 3mm wide to house the locking pin described below. The bone block will also have a matching tunnel diameter that will align with the casing tunnel. The purpose of the hole is such that a locking pin can be placed through the tunnel created by the combined casing and bone block, locking the graft into the casing. The cylindrical casing will have a diameter of approximately 14 mm while the diameter of the tunnel will be roughly 10 mm. The graft tunnel will need to be overdrilled on the femoral side so that the casing will have a cavity to sit in. This difference in diameter between the graft tunnel and bone block casing will prevent the casing from being pulled through the graft tunnel inferiorly during knee flexion.
As mentioned beforehand, it is also important to prevent superior translation of the graft along the femoral tunnel if the device is to successfully integrate the patient’s surrounding bone into the material scaffold. The casing will contain a locking mechanism on the superior surface that will assist in stabilizing the device within the tunnel. See section 1.2.3 and 1.2.4 for further description of the locking mechanism. In order for the rails to successfully lock the casing into the surrounding bone tunnel, a stable housing needs to be created for the rails. As seen in the figure below, a hole is drilled in the superior surface of the bone block casing so that the surgeon can easily guide the bevel gear hand tool. There are also two rectangular tunnels on either side of this cavity that each of the stabilization rails will rest in. As seen in Figure 9, the rails will be surrounded by four faces in order to limit any movement in the x and y direction, and to only allow movement in the z direction into the surrounding bone. The size of the rail tunnel is snug with the rails, allowing the surgeon to easily place the rails but not to allow slippage. Once the rails are engaged, this hole in the top surface will be filled with bone cement to prevent the rails from receding and also to prevent clotting and connective tissue from impacting the function of the internal mechanisms.

Figure 10. SolidWorks image of bone block casing used to secure the bone block
1.2.2 Locking Pin

As described in the previous section a hole will be drilled through the casing as well as the bone block. During the surgical procedure a string will be threaded through the hole drilled in the bone block and it will be pulled through the graft tunnel while the knee is fully flexed. Once the bone block has been pulled through the femoral cortex the strings will be threaded through the cavity of the casing and out of the horizontal holes in the casing. Then the strings can be utilized to pull the bone block into the cavity of the casing. Figure 12 shows the SolidWorks model for the locking pin. Once this is done, the string will assist in guiding the locking pin through the bone block and casing thereby securing the bone block within the cavity of the casing. This process can be seen in Figure 3. The horizontal hole that the locking pin will sit in can be seen in Figures 10 and 11 towards the bottom of the device. Once the string has been removed, the device can be placed into the enlarged section of the graft tunnel on the femoral cortex. The locking pin will be roughly 3 mm in diameter. This will ensure that the hole drilled through the bone block will not be so large that it negatively affects the mechanical integrity of the block. Meanwhile the mechanical properties of the locking pin will be sufficient enough to withstand the stresses that it will undergo during normal knee movement. After fabrication of the locking pin, it will undergo three-point bending tests in order to determine the strength of the component. After implantation,
normal knee movement will provide a downward force on the middle of the pin. The pin will need to have the adequate mechanical properties in order to support the stress applied.

![Image](image_url)

**Figure 12.** Locking pin inserted through the bone block casing and drilled hole through bone block.

### 1.2.3 Stabilization Rails

The locking mechanism previously mentioned will incorporate two rails that will travel through the center of the casing approximately 5 mm deep from the top of the casing. These rails will feature complementing grooves on the angled side in which the teeth of the rail driver will fit. An opening on the top of the casing will be made with two openings on the inside. The openings will be the contact points between the grooves on top of the rails and the teeth of the rail driver. The rails will be placed in the casing prior to surgery, and they will fit snugly enough that the surgeon does not have to worry about accidental displacement. After the bone block has been fixed in the cavity of the casing with the locking pin, the surgeon will place the device into the bone tunnel. Then the surgeon will place the rail driver into the opening on top of the casing in order to engage the teeth of the rails. The rails will also be designed so that the ends will be sharp. As you can see in Figure 13, two-thirds of the rail is grooved and flush with the surrounding track that it sits in. The other third of the rail is tapered to a point, with the flat surface of the “knife” on the inferior or bottom side. Torque will be applied to the rails with the rail driver, driving the sharpened ends into the surrounding bone. Once fully engaged to the specified depth, the entire system will be locked into place. The sharpened ends of the rails will have a notch, similar to the design of a harpoon as seen in the figure below, in which bone will begin to grow into during recovery. This is to prevent the rails from receding back into the bone block casing by bone formation around the rails. If the fixation of the rails in the surrounding bone was not maintained the rails could retreat into the casing. If this were to occur, the device
could become loose jeopardizing the integrity of the system and preventing effective bone regeneration in place of the biodegradable material.

Figure 13. Stabilization Rails

1.2.4 Rail Driver Tip

In order to drive the rails into the surrounding bone, we will need to design a device that will assist in doing so. The rail driver will maintain a design similar to that of a generic screw driver. The driver will have an ergonomic grip to provide comfort and support for the surgeon during this procedure. The tip of the driver will have a gear shape whose threads will fit into the grooves that the stabilization rails will have seen in Figure 14. Once the bone block casing has been placed into the femur the surgeon will need to place the rail driver on top of the exposed fixation device aligning the gear threads and apply a torque. The alignment of threads can be seen in Figure 15 below. This rotational moment will drive the sharpened ends of each stabilization rail into the bone surrounding the casing. Lines will be inscribed on the stabilization rails in order to indicate the necessary depth for the stabilization rails. The surgeon will be required to monitor these lines as a torque is being applied via rail driver to the rails.
Figure 14. Gear tip on the end of the rail driver used to displace the rails along the tunnel into the bone.

Figure 15. Superior view of the locking mechanism and how the gear meshes together.
1.2.5 Interference screw

![Interference screw image]

Figure 16. Smith & Nephew BIOSURE™ HA and BIOSURE™ PK Interference Screws

Our design project will focus more on the design of the mechanism described by the previous parts. However, we would like to design mechanisms for the fixation of the replacement graft for each the: tibial side and femoral side. The most common fixation device on the market is the interference screw. We will incorporate an interference screw for the tibial side in the graft fixation process. Our interference screw design will be similar to that of the ones shown above which are manufactured by the medical device company Smith & Nephew. Instead of typical rounded screw heads, our interference screw will feature shallow notches on the screw head which will assist in the fixation of the screw. After placement in the tibial side of the joint, bone will begin to form around the screw. Bone will form in the notches of the screw head, further securing the screw in place. The dimensions of the screw will be different in each case; however, the screw will need to be between 20 and 50 mm in order to maintain acceptable mechanical properties. Furthermore, the screw will ultimately be constructed out of the novel polysaccharide material, which is a major improvement to the interference screw. Biodegradable interference screws used in today’s ACL reconstruction surgeries tend to degrade into harmful by-products, which can potentially lead to infection. Because these screws will be made from the novel material, they will be more biocompatible than the interference screws currently being used.

1.2.6 ACL Graft

In order to obtain a clearer understanding of our design, it is necessary to visualize how the fixation device will work with the actual ACL graft. The image below shows the ACL graft attached to the bone blocks. This graft is obtained by cutting out a cross-section of the patellar tendon (which is then sutured back together). So, at this point, we have a graft that needs to replace the ACL. The fixation device is used to hold the graft in place, allow time for natural bone to grow into the pores of the device, and eventually, natural bone will replace the device as
the locking mechanism holding the graft in place. This leaves a healthy tendon to replace the ACL.

At this point, the main confusion is how exactly the device will hold the graft in place. As shown in the below image, the graft has two bone blocks at either end. With our device, a cylindrical hole will be drilled into the bone block that will remain in the femur (rather than the sutures shown in the image). This cylindrical hole will be drilled precisely so it matches up perfectly with the cylindrical hole in the bone blocking casing subunit. The bone block will be inserted into this casing subunit pre-implantation. The locking pin will be placed through the cylindrical holes in the bone block and the bone block casing, securely locking the two pieces together. Then, the graft along with the fixation device are placed through the femur. The graft is stretched to optimal length, and the bone block in the tibial side is securely locked into place with an interference screw, as shown in Figure 16 above.

The graft tendon shown in Figure 17 is essentially what will replace the torn ACL. Our device is an innovative method to secure the tendon in place. Once our device degrades under physiological conditions, the graft will be locked in place by natural bone, which will grow in the pores of our device as it degrades. The graft is overall the number one aspect of ACL reconstruction surgery. We chose the patellar tendon as our graft because the bone blocks on either end seem to be beneficial to holding the graft in place. Our device takes advantage of these bone blocks by using them to lock together with our fixation device, via a locking pin. The patellar tendon has very similar mechanical properties to the anterior cruciate ligament, and is therefore a good way to replace a torn ACL.

Figure 17. An ACL with two bone blocks on either end (part of the patellar tendon)