Alternative Design Report

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

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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 rilled 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 1. 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.

Figure 2. On the left, a three-dimensional view of the device. On the right, a transverse view of top of the device, with schematic showing the gear component to prevent superior translation along canal.
Alternative Design 2

Another main 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 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 3 (above): Gear mechanism* Figure 4 (above): Top view of interference screw*
Figure 5 (above): Side view the head of interference screw (without tiny screws)

Figure 3 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 4 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 5 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 1 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 6. 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.

Sources:
Figures 3 and 4 include images from the following websites:
http://science.howstuffworks.com/transport/engines-equipment/gear4.htm