

TensiFix™

A Novel ACL Graft Reconstruction Fixation Technique

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INTRODUCTION

A graft must be fixed to return the knee to an optimal stability. Although it would seem that graft strength is the most indicative property for ACL reconstruction stability, it is actually the strength of the graft fixation to the bone. (Urbibe, Arango, Frank, and Kiebzak, 2013) Fixation gives the graft bone tunnel interface necessary stiffness and strength (Woo, et al. 2000). There are many different fixation devices available, such as interference screws, soft tissue washers, suture-post constructs, simple staples, cross-pins, and titanium buttons (Woo, et al., 2000). Since the graft selection depends on the circumstance of the patient, different fixation techniques must be used as well. The current gold standard for fixation is the interference screw against a bone plug (Brand, 2000). One study suggests the most stable knee reconstruction is when the interference screw is positioned close to the articular surface with central and distal fixation (Ishibashi, et al., 1997).

Furthermore, the tibia position relative to the femur when the graft is fixed has a considerable effect on the kinematics of the knee and the *in situ* force of the new graft (Hoher, et al., 1999). Specifically, when the graft is fixed at 30° knee flexion, with a 67N posterior tibial load, the resulting knee kinematics is closest to the native knee (Hoher, et al., 1999).

Graft Tension

Joint kinematics and *in situ* forces of the graft while the knee moves are considerably altered by the initial tension of the graft (Woo, et al., 2000). If the initial graft tension is low, there necessary joint stability will not be provided (Woo, et al., 2000). Conversely, high initial graft tension would hinder joint motion (Woo, et al., 2000). The initial tension is suggested near 44N but this is controversial since the native ACL force is unknown (Woo, et al., 2000)

Problem

Currently, surgeons must rely on their own strength to add tension to the ACL graft prior to fixing the graft. Once the graft is fixed, there is no way to add more tension if it is needed. Since surgeons must individually tension each graft, there is a lot of variance between graft tensions across all ACL reconstruction patients.

Furthermore, over time, the graft naturally loses tension with patient usage. There is no method to re-tension a graft other than performing a new ACL surgery.

Our Device

The TensiFix™ fixation device allows the surgeon to fix a graft at both ends, and then add more tension on the femoral side. When the graft loosens over time, a patient can choose a minor surgery where the surgeon goes back to the original graft and tighten TensiFix™, thus adding more tensions without performing another major surgery.

SPECIFIC AIMS

Manual pulling or tensioning devices at the tibia are currently used as a means for surgeons to supply tensions to the graft upon fixation. A study performed by Arneja et. al showed that there is an ideal amount of tension to have in a hamstring graft upon reconstruction to promote the most anatomically accurate results post surgically. By being able to adjust the tension in the graft using the TensiFix™ device after tibial fixation, surgeons can more easily reach this desired tension goal, allowing for ACL reconstructions to be closer to optimal.

Additionally, significant tension loss is observed in ACL grafts after reconstruction due to deficiencies at the tibial fixation site; when the tension in the ACL decreases, this allows for anterior translation of the joint (Grover, et.al, 2005). In order to add stability to the knee and decrease this anterior translation, the TensiFix™ offers surgeons the ability to perform a follow-up, minimally-invasive surgery that adds tension at the femoral fixation site, overall increasing the tension in the graft.

Finally, with the current button fixation techniques, the dimensions of the femoral tunnel play a large role in the effectiveness of the fixation (Simonian, et.al, 1998). For example, if the tunnel is drilled with a larger diameter or with a greater depth than anticipated, it is possible the button will shift around and become oriented in a way that does not evenly distribute the load applied to it. The screw-containing barrel feature of the TensiFix™ acts to maintain the suture and consequently the graft line of action nearer to the center of the femoral tunnel. This creates an aperture-like securement of the femoral end of the ACL graft without the soft tissue damage associated with aperture fixation techniques.

INNOVATION

Post surgically, ACL grafts have been seen to lose tension due to normal cyclic loads applied during rehabilitation (Singhal, et.al, 2005). As the tension in the graft decreases, the knee's ability to translate anteriorly increases; an occurrence meant to be minimized by the ACL reconstructive surgery (Grover, et. al, 2005). With current fixation techniques, the amount of tension in the graft immediately after surgery is dependent on that which the surgeon can provide in the tibial fixation. With our device, the surgeon is able to add additional tension to the graft at the femoral site after both ends of the graft are fixed.

IMPACT

TensiFix™'s surgical importance lies in its ability to allow the adjustment of the graft after it has already been fixed in place. Currently, ACL reconstruction grafts are tensioned by manually pulling on the graft before fixation (Fu, Cohen 2006). This method can have many pitfalls. For example, variability in graft tension is associated with manual tensioning, as manual methods have been proven to be

irreproducible from patient to patient (O'Neill, et al 2011). Also, fixation after tensioning limits the surgeon's inability to further tension the graft if need arises. Thus, if the graft were to either not have enough tension initially or lose tension over time due to factors such as lengthening due to cyclic loading, the surgeon would have to redo the reconstruction to add tension to the graft (Harvey, et al. 2005). TensiFix™ functions like a regular Endobutton, allowing the surgeon to manually tension and fix the graft using the current manual method. However, should the fixed graft somehow lose tension, TensiFix™'s tensioning screw can be backed out of its barrel, re-tensioning the graft. Thus, the surgeon is not forced to redo the entire reconstruction to tension the graft.

SIGNIFICANCE

TensiFix™ is able to easily increase the tension during the ACL reconstruction. It addresses the need for a reliable way to increase the tension in knee ligament reconstruction surgeries. It uses an adjustable barrel-screw mechanism that is capable of adding tension to an existing graft. The TensiFix™ consists of three components: an externally threaded suture retainer, an internally threaded hexagonal barrel and a flat button retainer as shown in Figure 1.

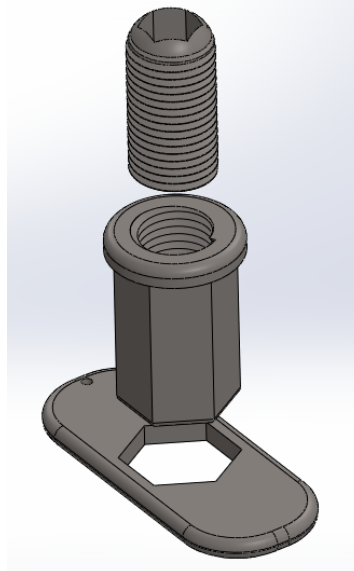


Figure 1: The TensiFix™ device is composed of three separate pieces – an externally threaded suture retainer, an internally threaded hexagonal barrel and a flat button retainer.

The device comes pre-assembled before being implanted. The surgeon will thread a suture through the hexagonal hole in the flat button and through the externally and internally threaded barrel. The suture is then attached through the hole for each component. The barrel will come pre-assembled in the lowest position possible to allow for the greatest range of tension to be applied. The suture is then looped through a double bundle graft.

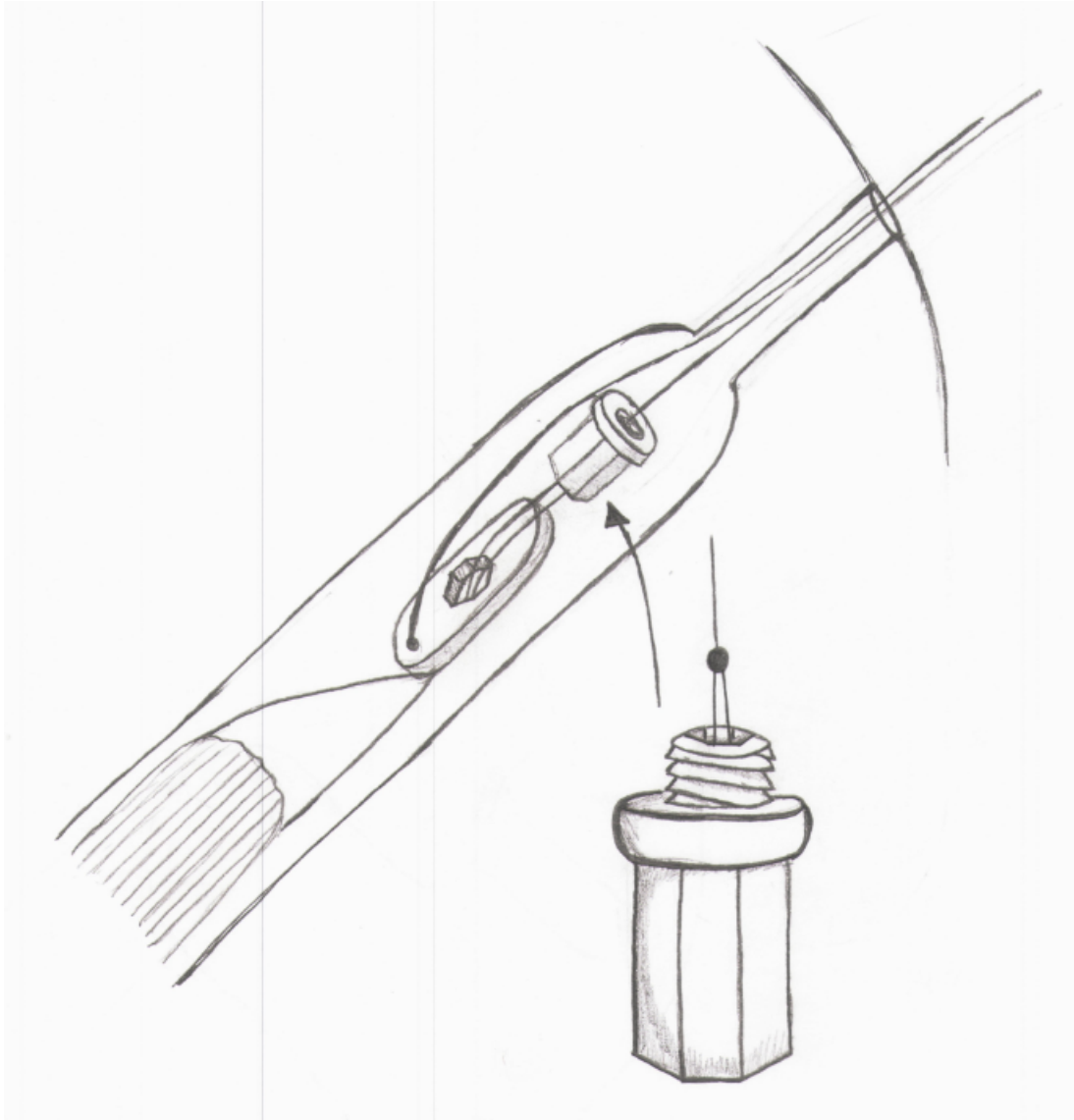


Figure 2: Example of device insertion

The device with the graft attached to it will be pulled through the end of the femoral tunnel and mounted at the end of the tunnel. The surgeon then places the barrel/retainer assembly into the hexagonal button and the graft is threaded through a femoral tunnel similar to the currently used EndoButton procedure. The TensiFix™ is then screwed out. It has the added benefit of being able to be adjusted post operatively. This allows surgeons to increase the graft tension in a quick and measureable way.

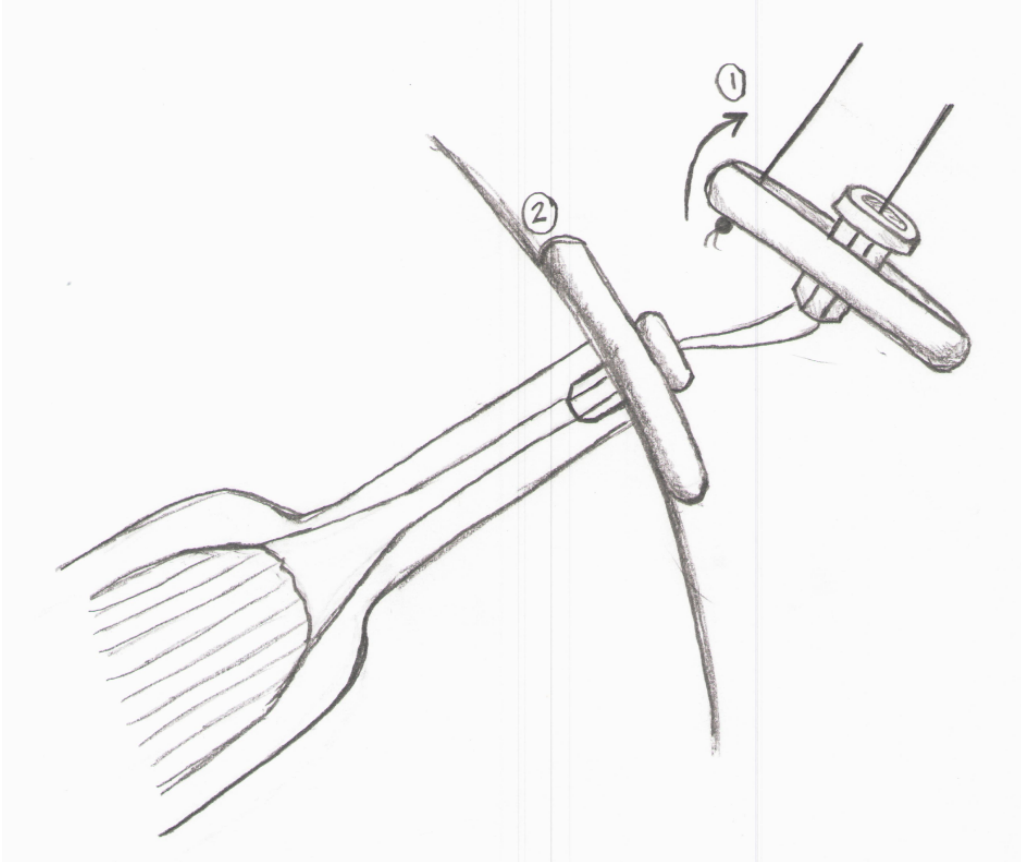


Figure 3: Flattening of the device on the exterior of the femur

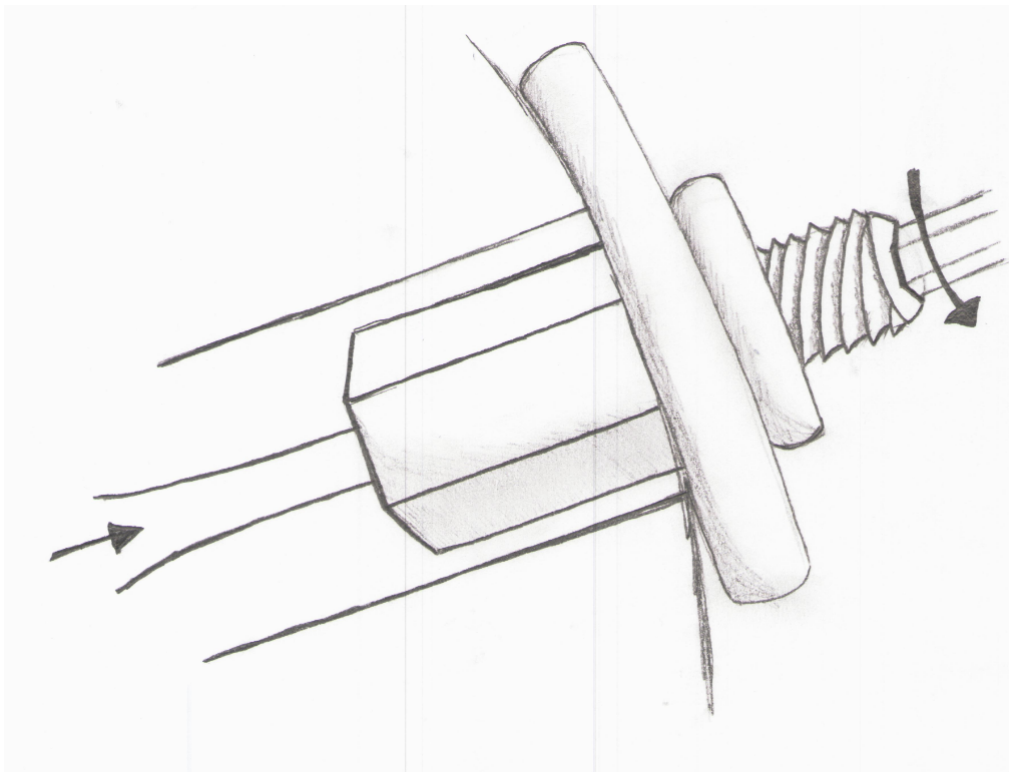


Figure 4: Final tensioning of the graft using the device

APPROACH

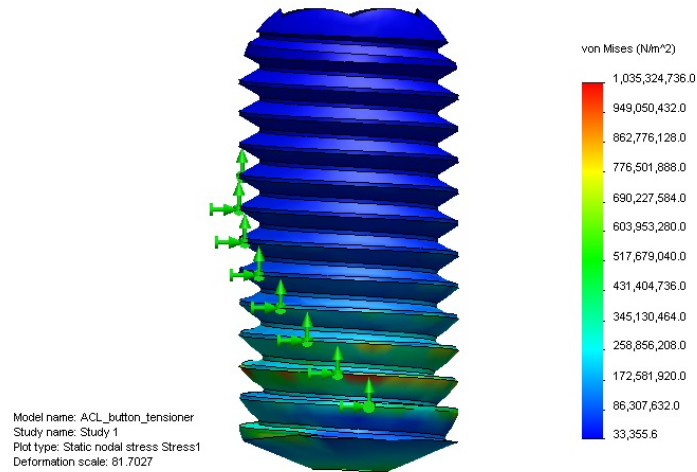
Testing our fixation technique will involve a multi stage process of mechanical testing, *in vitro* testing, and *in vivo* testing. First, the part will be tested for its success independent from its assembly. In other words, the implant will be tested independently from biological systems in order to preliminarily determine its success in the expected loading condition. The next step is testing the part for its success in its proper assembly. This is accomplished through a series of *in vitro* tests that test the efficacy of the device with the proper loading when integrated into the proper biological system. Lastly, the part, integrated into the whole assembly, is tested in the proper environment. This is done via a series of *in vivo* tests will be performed to test the effectiveness of the device with several mammalian species.

Mechanical testing of the design will be performed to see if the design is able to maintain its integrity in loading conditions similar to those it would undergo when used in ACL fixation. Similar to the work Chao et. al performed on tibial locking screws, these tests will be performed outside of a biological system to maintain focus on the mechanical strength and design of the device. These tests will include a physical simulation of the expected loading condition and finite element analysis. In this case, loading conditions will reflect the tensile stresses in the system.

For the physical simulation of the system, the device will be set on a substitute for cadaveric bone – for example, Chao et. al used high molecular weight polyethylene tubes. The button of the device will lie against the bone substitute, the barrel's head flat against it. The length of the barrel will be in the hexagonal hole of the button and predrilled hole in the bone substitute of similar diameter. The tensioning suture retainer screw will be in the barrel. A suture will be attached to it and hang through the hole to the other side of the bone substitute. Forces will then be applied to the suture to simulate both maximum static loading conditions and cyclic loading conditions similar in magnitude to those found in the knee. For static loading, the forces applied could be anywhere in the range of 2000 to 4000 Newtons to simulate the ultimate failure loads of different grafts with allowance for a factor of safety. For cyclic loading, a sinusoidal loading of amplitude about 20% of the static loading range could be applied to simulate the daily tensile loading of the ACL (Harvey, Thomas, & Amis, 2005).

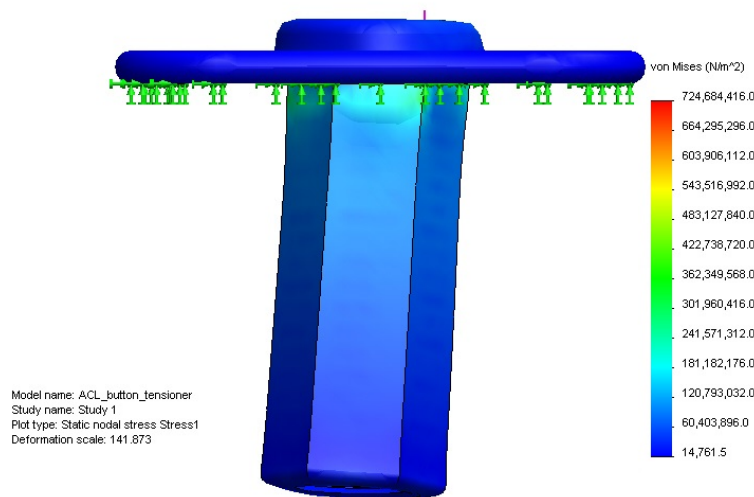
Finite element analysis of the system will be conducted with use of commercial software. Forces of the same magnitude range used in the physical simulations will be applied to the assembly to determine where the stress lies in the part and if the part would be likely to fail under the loading conditions. In the example analysis below, the button and barrel were examined separately from the tensioning screw due to software constraints, but both under a tensile force of 3000 N – the average ACL graft ultimate yield strength. The simulations show a max stress of about 1000

MPa on the threads of the suture retainer and 7000 MPa on the neck of the threaded hexagonal barrel in the button and barrel assembly. Results like these would then be used for predictions of the outcomes of physical tests or as a comparison to the results of the physical test (Chao et al., 2007).



Educational Version. For Instructional Use Only

Figure 5: Finite element analysis of externally threaded suture retainer



Educational Version. For Instructional Use Only

Figure 6: Finite element analysis of button and internally threaded hexagonal barrel

The *in vitro* testing will involve testing of comparable mammalian knee joints. Comparison tests with existing fixation techniques will be performed to test properties such as maximum load and elongation of the tendon. Similar to Herrera et al., porcine femurs will be used for fatigue testing the fixation device, due to the similarities between human and porcine bone and their availability (Herrera et al., 2010). Additionally, canine bone could be a reasonable substitute to porcine bone due to its high biocompatibility with human bone, however it would be much more expensive and difficult to obtain and would only be used as an alternative (Aerssens, 1998). Additionally, the porcine flexor digitorum profundus tendons will be utilized due to their similar biology and biomechanical properties. Similar to the testing performed in Kousa et al., a variety of fixation devices will be used for biomechanical comparison. These would ideally include the EndoButton CL, Bone Mulch Screw, RigidFix, Interference Screws, the BioScrew, the RCI screw, and SmartScrew ACL (Kousa, Järvinen, Vihavainen, Kannus, & Järvinen, 2003).

Additionally, *in vivo* testing will be utilized to determine some of the mechanical features of the fixation device. Herrera et al. explore the difference between different diameters of screws for fixation, thus the same test will be performed on the fixation device to evaluate several mechanical parameters and their interaction with the graft and bone. These will include:

- Size of the holding plate to determine the minimum size required for mechanical stability and fixation strength
- Shape and size of the internal barrel and screw. This will test for biomechanical interaction between the devices and bone.

These will be initially determined through both virtual testing of the device and a calculation of the forces placed on the various pieces, and *in vitro* will confirm the results from those tests.

Tests will be performed using a Servohydraulic Fatigue System along with a fixture to allow for accurate placement of the femur (Herrera et al., 2010). One end of the graft will be fixed using the TensiFix™ device, while the other will be passed through a loop connected to the fatigue system. The specimens will be tested at a rate of 2mm/min according to the ASTM (American Section of the International Association for Testing Materials), as it sets the lowest limit for pull-out resistance and the dynamic friction is highest (Herrera et al., 2010). The testing will consist of a single-cycle load-to-failure test and a cyclic-loading protocol (Kousa et al., 2003). The



Figure 7: Example testing fixture with porcine tibia (Herrera et al., 2010)

test will be finished whenever either the graft or the fixture fail, and the resulting data will be collected and analyzed. An analysis of variance between the two groups will be performed to account for different size parameters. The results should assist with determining the optimal mechanical parameters of the device.

After sufficient *in vitro* testing is performed and approval is received from the appropriate bodies, an *in vivo* comparison with other fixation techniques will be performed. Ideally, the comparison will be performed with some of the most popular current approaches, specifically the *EndoButton CL*, *Cone Mulch Screws*, and *Interference Screws* (Kousa et al., 2003). Both a long-term and short-term studies should be performed to evaluate the human biocompatibility of the fixation technique and the long-term effects on the graft. A collection of patients will be randomly assigned a particular fixation technique. Then, for the short term, a period of approximately 18 months should be utilized to evaluate the immediate and most salient features from the fixation item. Because the majority of the healing occurs within the first two years, the results from the short-term test should be the most revealing (Kartus, Movin, & Karlsson, 2001). A longer test over a period of about 5 years would provide a complete picture of the fixation results (Krych, Jackson, Hoskin, & Dahm, 2008).

In addition to the *in vitro* testing for the optimal biomechanical properties of the device, different biomaterials will have to be explored. Due to the application this fixation device would have and the potential for adjustment due to elongation of the tendon, a non bio-absorbable material, such as titanium, would be utilized.

The TensiFix™ device is manufactured from a Titanium-Aluminum-Vanadium alloy. Alloys of these types are used very often for medical applications because of their biocompatibilities. These “medical titanium” alloys have high harmonizing factors, making them desirable for an implantation application (Supra Alloys, 2013). Along with integrating well with biological systems, these alloys are strong, lightweight, and offer similar elasticity and stiffness property values as human cortical bone (Supra Alloys, 2013.).

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