THE PENNSYLVANIA STATE UNIVERSITY
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DEPARTMENT OF MECHANICAL ENGINEERING

ADJUSTABLE FIXTURE FOR ANTERIOR CRUCIATE LIGAMENT SURGERY

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ABSTRACT

Anterior cruciate ligament reconstruction surgery has been able to reliably reproduce stability in the knee similar to the pre-injured knee. However, in the long-term, the knee cartilage begins to degrade due to shifting in contact pressures, which leads to the onset of osteoarthritis. The purpose of this study is to describe the design for a device that can allow surgeons the capability to adjust the tension of an ACL graft during surgery. It includes the identification and utilization of key factors towards concept generations and design considerations. These designs are compared against each other and qualities will be taken and incorporated into the final design. The final design is connected to a strain gage and tested to see the accuracy and adjustability. Implementation of the device is also tested with an ACL graft in a knee model to understand its feasibility. This device may be useful in standardizing ACL surgeries, reduce reconstruction surgery time and rates, and better understanding the onset of osteoarthritis.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

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Chapter 1

Introduction

An anterior cruciate ligament injury is caused by extreme loadings on the leg coupled with twisting, usually seen in rapid direction changes or landings from jumping. Prevalent primarily in athletes and those in the military, ACL injuries also occur in individuals with weak quadriceps muscles that cannot properly absorb the impact of everyday walking.

Approximately 20-50% of these patients develop osteoarthritis (OA) 10-15 years following their injury. Osteoarthritis, a disease of developed joint inflammation, is one of the most critical conditions in the joints. It is characterized by a degradation of articular cartilage and a hypertrophy of osteophytes or bone growths. This results in significant risk factors for mobility and day-to-day activities. Currently, the onset of OA is not well-established. An innumerable number of variables contribute to this disease, of which include age, sex, obesity, and loading; however, the specific cause of OA remains elusive and it is difficult to isolate and identify a single or major cause of OA. Any attempts to be able to better understand the alarming rate of arthritis prognosis fall short as it is difficult to understand what factors contribute towards this disease. It is especially difficult because of different procedures each surgeon favors. Current ACL surgery techniques were developed in the 1980's, and surgeons have been hesitant to change anything as they are comfortable with the current procedures. The big issue with ACL reconstruction surgeries is that in terms of restoring knee stability, surgery does a great job in allowing the patient to return to normal life. However, 10-15 years following injury,

reconstruction surgery fails to address other aspects of the knee, causing degenerative diseases to develop.

OA is also associated with health and treatment cost concerns. OA is a disease that has no clear fix, and currently, only a total joint replacement would benefit patients diagnosed with OA. These cases are rare because of the exorbitant costs and the need for joint-matching for appropriate candidates are the only options for the most severe cases of OA. For the common patient with OA, treatment can be found in the form of non-pharmacological and pharmacological modalities. Non-pharmacological methods include exercise programs such as weight loss activities, rehabilitation or physical therapy, and even the use of electromagnetic field therapy. Pharmacological treatments, on the other hand, include the use of acetaminophen, aspirin, and other anti-inflammatory drugs. Both methods are only temporary solutions to mitigate pain, and do nothing to repair the damaged cartilage.[1] Overall, the costs of these treatments over the course of a lifetime, coupled with a lack of evidence of effectiveness create a major issue that researchers face in the pursuit of a better understanding of this disease.

Because of the different variables that surgeons must consider in surgical technique along with their preferences and technique, it is difficult to make any correlations and conclusions about what may cause OA. In particular, one of the most fluctuating factor between surgeries is the variations in graft tension applied during surgery. Surgeons have no consistent technique of applying the graft tension or even a way to quantify how much they are applying, and are left with their own discretion to tension as much as possible. More reliable methods need to be implemented in order to assess the results of the surgery and to correlate them to a predetermined setting set by the surgery. A method of standardization could help improve the quality of surgeries as well as offer a better way to characterize any factors that vary between surgeries.

Together, if the mechanics of the knee and the effects of ACL surgery are better understood, it can help solve the mystery of OA.

Specific Aims

Design and fabricate force sensing and adjustable fixtures for the ACL.

The fixture will have an adjustable device that can vary the length, and consequently, the tension of the graft. Attached to the device will be a form of force sensing mechanism that quantifies the amount of applied tension.

The result of this study can further our understanding of the onset of OA. The only way to confidently recognize the impact of initial graft tension is to standardize the procedure of implementation. From there, a relationship can be better made to relate the changes in tension over time to changes in joint contact, and subsequently, cartilage degradation. Only after reliable studies have been completed can we conclude whether initial graft tension can potentially play a role in the pathogenesis of OA.

Chapter 2

Literature Review

Knee Anatomy and ACL Rupture

An anterior cruciate ligament (ACL) injury is one of the most common knee injuries that greatly affects the function of knee. Supporting the knee along with the medial, anterior and posterior cruciate ligament, the ACL does most of the work holding both the tibia and femur together. The anatomical configuration of the human body allows these nearby ligaments and other muscles to help in absorbing the force due to day-to-day activities. It is the case when the body places sudden and intense amounts of strain on the knee that the ACL is forced to withstand causing it to tear.[2] While 70% of these ACL injuries occur during non-contact situations, nearly all of ACL injuries are due to abnormal loadings on the knee at an awkward position. Usually, this scenario occurs following an explosive move for which the person cannot brace for landing or distribute the weight properly upon impact.

Because the ACL is hidden within the knee, it is difficult to isolate and strengthen it in order to withstand greater loads. As a result, a great majority of these incidents occur in adolescents to young adults, due to their high levels of activity. Reconstruction is highly recommended for return to physical activity as well as for day-to-day activities, followed by an intense rehabilitation and recovery period. The long recovery period, lasting anywhere between 6-12 months, is attributed to a slow healing process at the site of injury. Following surgery, when

a replacement ACL has been inserted, the cells and blood vessels behave differently from the rest of the body, and are unwilling to heal at a fast rate.[3]

ACL Repair Techniques

While reconstruction has been widely chosen as the treatment for knee stability in ACL-deficient knees, there still remains cases of around 8% of reconstruction patients with reoccurring instability or graft failure. These patients may undergo revision surgery in order to adequately stabilize the knee. These failures are attributed to arthrofibrosis, traumatic arthoris, extensor mechanism dysfunction, and recurrent instability which are due to technical failures, biological factors, and trauma.[4] Of all of the variables that are at risk to the failure of the ACL surgery, surgical implementation is one that surgeons can mostly control, and accounts for 77% of annual reasons for revision. These technical errors can include tunnel placement, notchplasty, tensioning, graft fixation, graft material and all dictate the stressors placed on the graft and fixations due to loading. Tension is perhaps the most fluctuating factor in surgeries, as surgeons use solely their own discretion in tightening the replacement graft. In a study made to test the reproducibility of graft tensioning in a device similar to what subjects would experience, O'Neill found that the standard one-pull technique was not consistent from trial to trial (Appendix A). This method relies solely on the surgeons' own interpretation of graft stiffness.[5] Because of this, graft tension has gained interest in the scientific community to determine the effect of initial graft tension on the outcome of the surgery. The initial graft tension greatly affects the locations, contact points of the joints, and the overall long-term degradation of the cartilage. Numerous studies have been done studying the effects high or low tensions have on the stability of the

ruptured knee and found mixed results.[6,7,8] However, there lacks evidence of the impact of high or low tensions on compressive forces, knee laxity, and joint function. Initial graft tension and its effects on the contact mechanics have not, to our knowledge, been characterized. Additionally, there are also no known mechanisms that can set the tension to a predetermined value and no evidence of standardization currently used.

Problems With ACL Repair

An estimated 80,000 ACL injuries occur each year in the United States, of which 50,000 are treated with reconstruction surgery at an average of $17,000 per procedure. The biggest cost, however, is the risk of degenerative diseases in the knee following injury, in particular posttraumatic osteoarthritis (OA).[9] OA is a degenerative joint disease due to degraded cartilage. The abnormalities are easy to detect, but the exact cause and the rate of progression of OA still remains elusive. The strongest risk factors for the degradation of cartilage and onset of OA include loading, aging, the presence of chondrosis, or other long-term swelling, inflammation, or stiffness in the joints.[10] What is even less known is how the introduction of ligament injuries increases the risk of OA to 20-50%. It does remain clear that some mechanics of the knee are never restored, and can cause the degenerative changes in the knee and lead to the pathogenesis of OA. ACL rupture or similar severe ligament injuries can cause irreversible damage to the articular cartilage, subchondral bone, or menisci. Subchondral bone lesions can develop at the site of the joint compression, leading to abnormalities and severe bone bruising. Additionally, intra-articular bleeding can occur following rupture, greatly affecting the inflammatory pathways and the bone's ability to heal. Many studies have shown that a rupture to the ACL can greatly

affect the loads and stresses placed on other ligaments on the same knee, altering the static and dynamic forces and subsequently causing instability. A follow-up study of those who suffered a ruptured ACL found that 27% of patients had an acute form of meniscal tear and 90% form of chronic meniscal tear that developed post rupture. These meniscal tears can greatly increase the risk of OA. The injury to the ACL itself can cause damage to the knee, but subsequent injuries and tears can worsen or even accelerate the degenerative condition of the knee.[11]

One of the biggest debates is whether the choice of ACL reconstruction or conservative treatment has any changes in the increase of OA. Because of the variability in patient qualities, as well as surgical techniques and implementations, there have been mixed results and a lack of clarity in terms of which type of treatment is better.[11] One of the biggest difficulties is establishing a meaningful correlation between ACL treatment and a host of variables, of which include: surgical technique, timing of surgery following injury, body type, gender, and conditions of the ACL deficient knee. If the patient wishes to return to a relatively active lifestyle, however, the ACL reconstruction does a great job in replicating the stability of the knee pre-injury and has become the gold standard for treatment for athletes. Factors that influence the outcome of an ACL reconstruction include choice of graft material, bone tunnel placement, graft tension, anatomical graft fixation, and graft fixation strength.[12] However, significant problems arise in terms of restoring the normal joint kinematics in the short term. Studies have shown that greater translational and rotational laxity exists of the reconstructed knee. But what are the changes after rupturing the ACL that increases the chance of OA? Stergiou et al. suggests that more demanding exercises than walking can introduce excessive anterior and rotational loading on the knee, leading to abnormal loading at the cartilage interface.[13] A 3-D model of the femoral and tibial cartilage found that the progression of OA could be associated with a shift in the

normal load bearing regions of the knee joint during normal function, due to kinematic changes.[14] This highlights the importance of restoring proper alignment and gait during ACL reconstruction. Some studies have pointed to damage in surrounding menisci and ligaments, or a greater strain that these ligaments experience in order to make up for the strength in the ACL. Other studies have proposed that while the knee stability has returned to pre-injury status, the alignment of the bones and the contact points in the cartilage have been shifted, creating potential for the degradation of cartilage to occur. Overall, the factors used to complete a successful reconstruction might fail to restore proper knee kinematics, which can result in varying load bearing mechanics, and consequently damage to surrounding tissues and muscles.

Outlook

For those who wish to immediately return to day-to-day activities, ACL reconstruction has proven to properly restore knee stability. However, cases have shown that ACL reconstruction is not a method that mitigates the risk factors of OA, and even may increase the rates of OA. Understanding OA has always been limited, and the relationship between injury and joint degeneration has yet to be clearly defined. However, factors such as joint stability, congruity, and alignment all contribute to changes in chondrocyte clusters and subchondral bone abnormalities.[15] This is a dilemma that requires better ACL reconstruction procedures, a better understanding of ways to maintain a healthy stability as well as properly restoring gait mechanics and kinematics. Because of the variations in graft tension during surgery paired with a lack of evidence of its effect, there is a need to create a device that can better standardize and quantify

procedures. This proposed device could decrease the need rates of reconstruction surgery as well as shed light on the relationship between knee kinematics and the pathology of OA.

Chapter 3

Concept Generation and Design Considerations

Device Properties

When initially coming up with a design of a device to control the tension, we thought of a device that would have adjusting capabilities post-surgery. We had thought that this device would remain inside the knee, and would allow surgeons to adjust months following surgery. After consulting with doctors from Nittany Medical Center, we learned that only after a few weeks, the bone surrounding the graft would calcify, making our device's main purpose useless. While our device would not have the capabilities to continuously be adjusted, the surgeons were still receptive to the idea of being able to adjust immediately post-operatively. We found that reconstruction surgery, done following the initial surgery, is a rather common procedure to make up for inadequacies in the procedure. Surgeons undergo the Lachman and Anterior Drawer tests in order to test the integrity of the ACL by applying posterior to anterior forces on the tibia. Our device would allow surgeons to make the appropriate adjustments of the laxity of the ACL without having to remove and replace the graft, therefore minimizing the chance for errors, as well as speeding up the process.

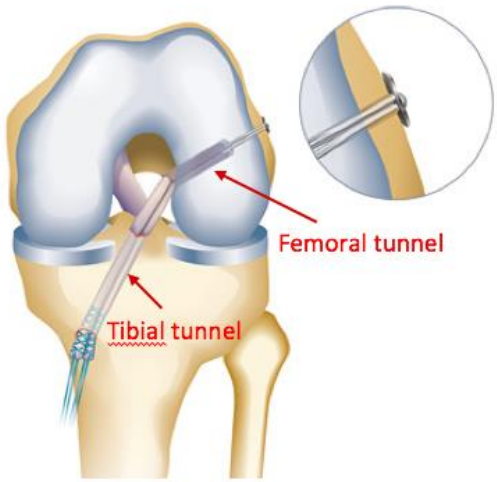

Figure 1. Shown in the femoral tunnel is an endobutton.[16]

The traditional fixtures are a combination of endobutton and interference screws. The benefits of an endobutton allow a strong fixation between the outer most part of the bone and the graft (Figure 1). The endobutton has been the gold standard for soft tissue graft fixation because of its stability and low chance of contribution to graft failure. One drawback is that while using the endobutton with the graft, the surgeon must pretension the whole graft before sliding it through the bone tunnels. This is particularly an issue because when surgeons pretension the graft, they are solely at their own discretion. In a study attempting to replicate the same amount of tension applied by 6 surgeons using the standard one-pull technique found that none of them were able to reproduce the same value.[4] Couple this with variabilities such as graft choice, thickness, and patient size, and this could potentially introduce factors that could delay recovery or create graft failure. This also could present issues once the surgery is completed if the surgeon performs Lachman and Anterior Drawer tests and finds that the knee is too loose or tight. In order to avoid removing screws, posts, fixtures, or stitches, a device that allows immediate adjustments in tension could save surgery time and avoid errors. The endobutton also has

drawbacks because knots need to be made in order to be securely fastened to the graft. The process of making the knots could create a change in the predetermined tension that the surgeon desires. Our idea to be able to increase or decrease the tension in the graft would introduce a factor of consistency into these surgeries. On the other hand, interference screws utilize torsional and insertion strength to fix the bone to the graft (Figure 2). While this provides a stronger fixation than the endobutton, there is less room for error and offers no capability to adjust the tension or length of the graft.

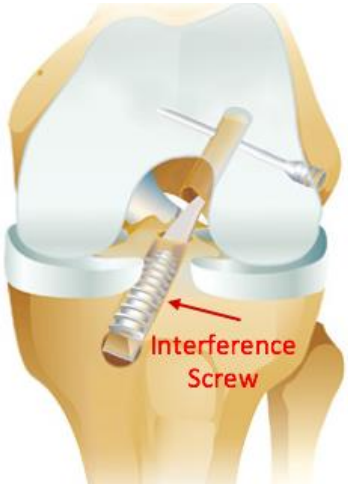

Figure 2. Interference screw used to interlock the femoral tunnel with the ACL graft.[16]

Our proposed design would still offer the fixation strength that the endobutton or interference screws provide, as well as being able to seamlessly adjust the length of the graft. These factors, along with the device being minimally invasive, body compatible, and easy to use and implement were all key to the concept generation of this device. We recognized that the

device had to be easy to implement and work with in order for surgeons to be willing to use it during surgery.

Designs

Our initial design was a modification of the endobutton except it had an exterior knob that would pull the rope according to how much the device extended (Figure 3). While the device was simple, it introduced a protrusion that would be on the outside of the bone. This would be problematic as the patient could have complications with the device making contact with other tissue within the knee.

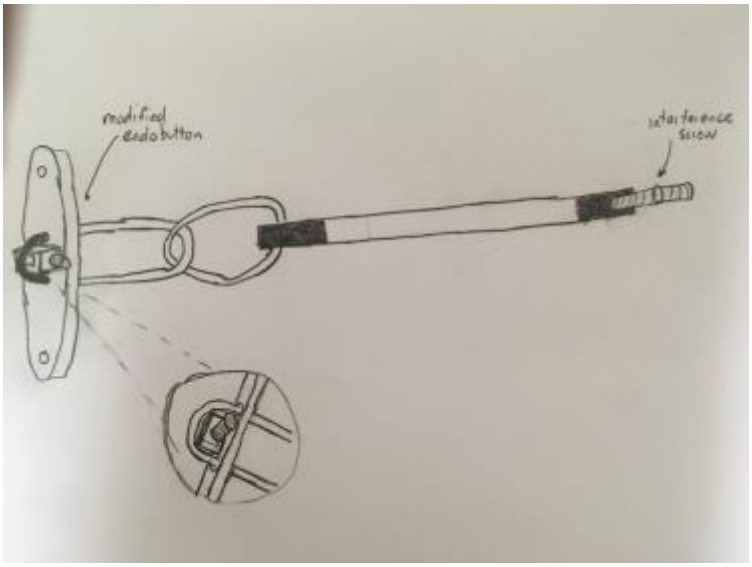

Figure 3. Sketch for initial idea for adjusting device. This device is to be mounted in a knee model.

Our second design had similar capabilities to a turnbuckle (Figure 4). A standard turnbuckle consists of two screws that are attached to loops. This design is unique because it offers the ability to extend a loop by the turn of the screw. We figured our device could have, on one side, a loop for the suture to be attached to, and on the other side, a fastener to the exterior of

the bone. While this could make modifications inside the bone, unlike our first design, a concern we had was that any adjustments to the screw could cause the graft to twist.

Figure 4. Turnbuckle design that inspired fixture ideas.

Our third design idea had to offer the capabilities of not being outside the bone as well as resist any torsion and twisting placed on the graft when the length of the graft was changed. We kept the idea of a screw, but in order to resist any twisting, we inserted a key hole for which the device can be locked and prevented from rotating. Thus, when the screw is used to extend the device, it will only be able to slide in the axial direction.

SolidWorks Design:

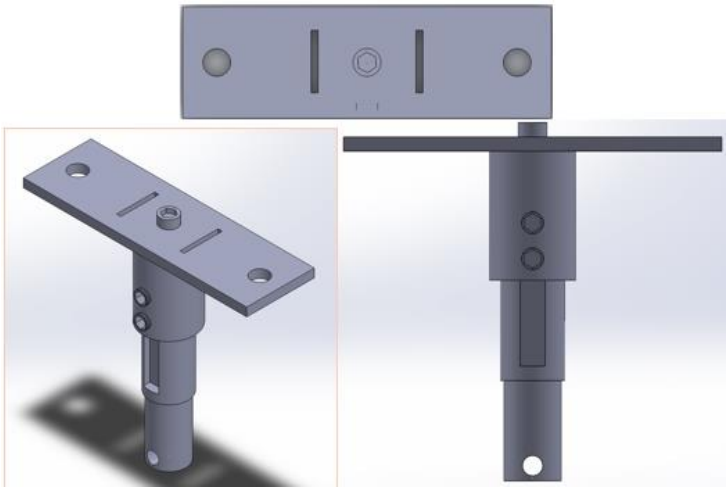

Figure 5. SolidWorks Views of Version 1.

The appeal about the endobutton is its ease in feeding through the tunnels of the tibia and femur. This device has a limitation in that it would not be able to be fed through the tunnel, and would have to be on the end of the graft and last to be fed through the tunnel. This means that an endobutton, screw or other fixator must be used after the graft is passed through the bone tunnels.

Structural Integrity Factors

The device should be able to withstand 15-40N of force. This force will be all transmitted to the bond made by the epoxy. Increasing the contact surface area can create a bond that is strong enough to support the needed force.

The femoral and tibial tunnels are drilled 20mm and 30mm deep with 10mm given for tensioning. Overall the graft should be approximately 70mm long. This means that both of the

ends of the graft should be sufficiently in the tunnel in order for the patient to heal properly. To ensure this, we had to make sure our device was not at most half the length of the tibial tunnel. The tibial tunnel is approximately 9mm wide. Our device needs to have a small diameter for the device to fit the hole, as well as a rather small cylinder thickness to pick up larger values of strain.

Chapter 4

Materials and Methods

Equipment and Materials Used

The equipment needed for an accurate strain reading includes a Strain Gage Indicator, strain gage, lead wires, solder iron, and solder. In this methodology, we used a Model P-3500 Strain Indicator from Vishay Micro-Measurements. The specific model is not as important, as any models that have proper calibration can be used. For the strain gage, we used a 1-axis linear gage 120 ohm resistance, with a 1.5mm grid. Any strain gage with 120, 350, or 1,000 ohm resistances would work, as long as they correspond to type of built-in Ohm gages on the strain indicator. The lead wires are used to directly connect the strain gage to the posts of the strain gage indicator. Although a breadboard may make it easier to map out the wires, efforts were taken to minimize the number of connections as possible, as the strain gage equipment is extremely sensitive.

The machines needed for making the product are a lathe, vertical milling machine, and bandsaw. The lathe is used for radial trimming of the rod, as well as axial drilling and tapping of the male part. The vertical milling machine is used for trimming the top of the head, as well as drilling vertical holes, drilling and taping the female part, and making the keyhole for the male part. The bandsaw is used to cut the metal pieces into the dimensions desired. While sharp and able to cut through most metals, the bandsaw may not cut the piece precisely, so I had to account for this and file the piece afterwards to reach the right size.

Materials for Device:

- Alloy Steel Socket Head Cap Screw 2-56, 3/8” Long
- 6061 Aluminum Sheet 0.40” Thick, 6” x 6”
- 6061 Aluminum Rod
- Alloy Steel Cup Point Set Screws 2-56, 3/32” Long
- 5 minute epoxy

A large sheet of aluminum was purchased relative to the size of the device in order to have the ability be able to make multiple heads that would be flush with the tibial tunnel. The socket head cap screws and cup point set screws were chosen to be 2-56 thread sizes because Penn State’s Learning Factory’s smallest tap drill would be able to accommodate that thread size. We selected epoxy as our bonding substance, because of its relative ease of use with metals, and its resulting strength. Super glue can be used as a substitute but the bond it forms can be brittle and easily be broken.

Machining Procedure

Figure 6. Design of Female Part.

The female part, shown in Figure 6, is used to help the male part from rotating, as a set screw will be inserted into the threaded hole and fitted into a key hole. Working with the metal rod, I used the lathe to trim the outsides to an appropriate diameter (~6.3mm). While working with such small dimensions, I was careful to be slow and steady with the lathe. Because of the limited thickness of the rod, I made sure to have as little of the rod propped out of the lathe, so that when bringing the cutting tip towards the rod, the tip did not push the rod and cause the piece to deflect. Additionally, I slowly ran the lathe over the rod several times to make the cuts as even as possible.

Next, again with the lathe, I drilled the insides of a hole axially for the male part to fit in (diameter ~4.2mm). I did not immediately use the 0.1660 inch drill size, which would correspond to the desired diameter. While drilling holes, I used a counter sink center piece to make an indent into the piece, so that upon contact with the metal, the drill would not slide and the piece would not fracture due to a sudden force. I then started with a smaller drill size and

gradually increased the size to create a well-centered, straight hole. Following this, I used the bandsaw to cut the piece (~4mm). Because the bandsaw is a rather thick blade, I had to make the cut around 4.5mm to compensate for the thickness of the blade. I then finished the edge of the cut with the filer to obtain a flat side. Lastly, to drill the hole for the set screw, I used the milling machine. Because the end mill uses a vice grip to hold the piece, and this piece is rather thin, I made sure that the vice grip did not overtighten so that the piece is not deformed.

Figure 7. Design of Male Part.

The male part, shown in Figure 7, is the piece that will only slide in the z-direction as the set screw from the female piece will fit in the slot and prevent this piece from rotating. Similar to the female piece, I used a lathe to trim the outsides of the rod to the appropriate diameter (~4.1mm), such that there is an adequate tolerance for this piece to fit in the female part. Next, an appropriate hole size was drilled in order for the hole to be tapped for a 2-56 thread. Following that, I used the bandsaw to cut the piece off the rod (~5mm), again making sure to overcompensate the length due to the thickness of the bandsaw blade. This piece was then fitted

into the milling machine where an end mill was used to take out the key hole slot (~2.3 mm wide), enough such that the thickness of the set screw can fit. Lastly, I drilled a hole at the end of the device so that the sutures can loop through the piece and be connected to the ACL graft.

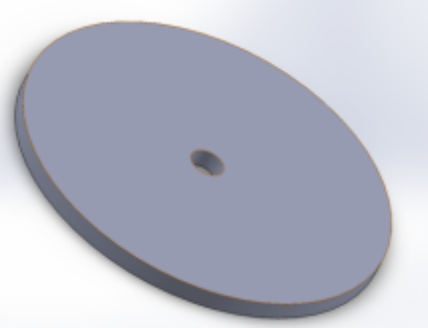

Figure 8. Design for the Head of the Device

The head of the device will cover the tibial tunnel and be supported by the outside of the bone as it prevents the device from falling within the tunnel. Using the bandsaw, I cut a 10mm by 10mm square piece from the aluminum sheet, which will adequately cover the 9mm diameter tibial tunnel, and filed the edges in order to give the piece a rounded shape. Next, a 2.20mm diameter hole was drilled in the center of the piece in order for the screw to pass through. Finally, I bonded the head piece and the female piece together with epoxy by applying directly where the surfaces come into contact. I also added epoxy to the edges of the female part to increase the amount of bonding. I made sure to apply pressure immediately within the first 10 minutes and was cautious to not shift the pieces and break the forming bonds.

Strain Gage Surface Preparation

Materials:

- Cotton Swabs
- Neutralizer
- Conditioner
- Strain Gage

Surface preparation is important to avoid contamination of the results. It is also essential to have a chemically clean surface and proper surface alkalinity to make bonding easier. Because the device was just recently machined, proper degreasing needs to be implemented to remove any oil, contaminants, or chemical residues. First, I used a filer to perform surface abrasion in order to remove any loosely bonded adhesives (tapes, glue, paints) and to develop a surface that will be suitable for bonding. For rough surfaces, this step is crucial to have a relatively flat and uniform surface such that the largest surface contact area can be made with the strain gage. After abrasion, a conditioner was applied to the gaging area to further dislodge any oxides or mechanically bound contaminants. Lastly, M-Prep Neutralizer 5A was used to neutralize the surface with an alkaline solution. This finalizes the cleaning process and leaves the surface at the appropriate pH level for optimum bonding.

Strain Gage Bonding and Installation

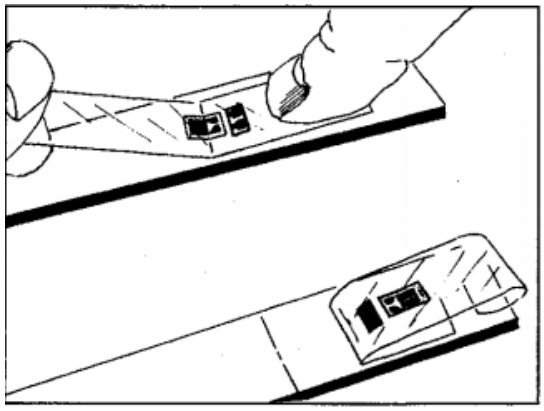

Figure 9. Strain gage installation: using the tape to prevent air pockets.[17]

First, I placed the strain gage on the bonding area. Then, I stuck a piece of tape on the whole area, pressing from the bottom of the piece of tape to the top. This assures that there won't be any air bubbles in the tape-gage interface as shown in Figure 9. Then, peeling back the tape so the whole strain gage is removed from the surface, I deposited the epoxy resin and hardener mixture on the bottom of the strain gage surface. Next, by applying firm pressure to the tape and gage, I pressed on the tape such that the strain gage made contact with the device, the epoxy spread out evenly, and any air pockets are removed. This ensures that the strain gage makes complete contact with the device and will result in the best possible reading. I continued to apply pressure on the gage for 10 minutes such that the glue was able to successfully bond the gage to the surface without moving or sliding the gage. Finally, I removed the tape at an angle, being careful not to pull too hard such that the gage is pulled off with the tape.

Strain Gage Indicator

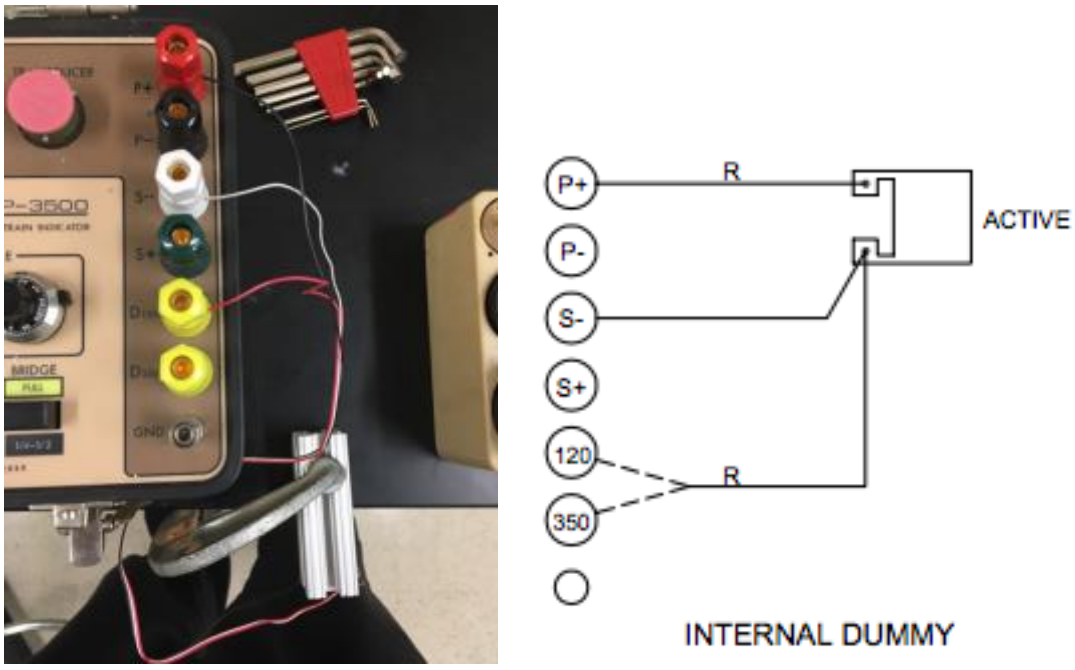

Figure 10. Lead wires hooked up to strain indicator posts.[17]

The Model P-3500 has multiple features for portable strain gage analysis. With capabilities of quarter-, half- and full-bridge shunt calibration, this strain indicator offers a precise regulated bridge excitation supply and gauge factor controls.[16] For this test, I used a simple quarter bridge shunt calibration. From the strain gauge leads, a three-wire connection was made for the quarter bridge setup. As shown in Figure 10, the red and white wires are connected to one gage lead, while the black is connected to the other. I then connected the black wire to the P+ binding post which is the excitation supply for the system. The white and red wires are attached to the white and yellow binding posts respectively, which are used for the shunt calibration. Next, adjust the amp zero such that the reading is zero and set the gage factor setting according to the gage factor of the strain gage, for this case, 2.13. Finally, making sure the

instrument is set to read a quarter-bridge, I pressed run and the indicator was ready to test strain measurements.

Knee Model

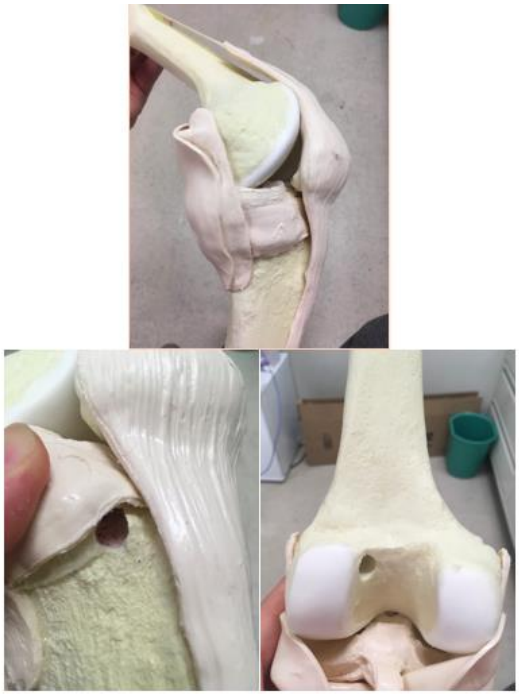

Figure 11. Knee model used to fit device.

The knee model used is an arthroscopic knee insert from Sawbones shown in Figure 11. Custom made out of polyurethane foam, this knee model is similar to cancellous bone and hold similar mechanical properties to normal bones.[18] It includes the MCL, ACL, PCL and allows the full range of motion up to 120 degrees. With the help of doctors from Nittany Medical Center, holes were drilled on the femur and tibia at a 60-degree angle relative to the normal. The intraarticular length of the tibial tunnel is 30mm, the femoral tunnel 20mm, with 30mm of space in between. The tibial sockets were drilled with a 9mm diameter drill, while the femoral tunnel was drilled with a smaller diameter drill which opens to a 9mm tunnel on the inside of the bone.

Chapter 5

Results and Discussion

Version 1

Figure 12. Machined Product for Version 1.

The piece, shown in Figure 12, was oversized and too long for the tunnel of the femoral bone. The length of Version 1 was just about the length of the femoral tunnel (~20mm), so we realized we needed to decrease the length of the device in order for the graft to have adequate space to calcify with the bone. Most of the adjustment could be made in decreasing the length of the female piece in Figure 12(c).

As seen in Figure 12(a), the head is perpendicular to the piece. Ideally, the head should not be perpendicular to the body of the device as the tunnel in the bone is angled 60 degrees and that the outside of the bone is a curved shape, so the head would extend outwards from the hole.

I realized that the surface area of the head piece can be decreased further such that the head still rests on the outside of the bone.

Version 2

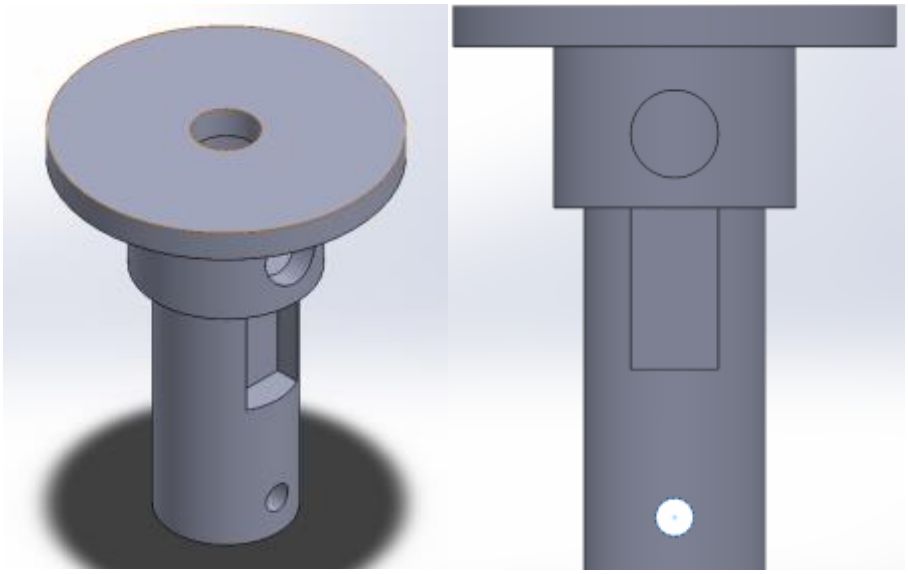

Figure 13. Isometric and side view of version 2 in SolidWorks.

For this version, as shown in Figure 13, I decreased the length of female part from 8mm to 4.5mm, the length of male part from 10mm to 5mm, and the surface area of head piece such that it will still be flush with the bone. Because the strain gage is to be fitted on the male part, and the strain gage's length is approximately 4 mm, I accounted for the male piece to have enough clearance such that the strain gage's thickness will allow the male piece to slide in the z-direction relative to the female piece.

Figure 14. Machined Product.

Version 2 proved to be more difficult to machine than Version 1 because of the smaller dimensions and less metal to work with. However, the device's longest length was less than half the tibial tunnel, and the head lay flush along the outermost of the bone, so the from Version 1 were successful and the structural integrity factors from before have been met. Additionally, Version 2 allows 3.85mm of adjustments, an adequate amount of displacement to vary the tension in the graft.

Table 1. Dimensions of Version 2

Dimensions	**Length (mm)**
Shortest Extension	10.15
Longest Extension	14.00
Widest Diameter	6.35
Width of Slot	1.73
Length of Slot	4.89

Calibration Data

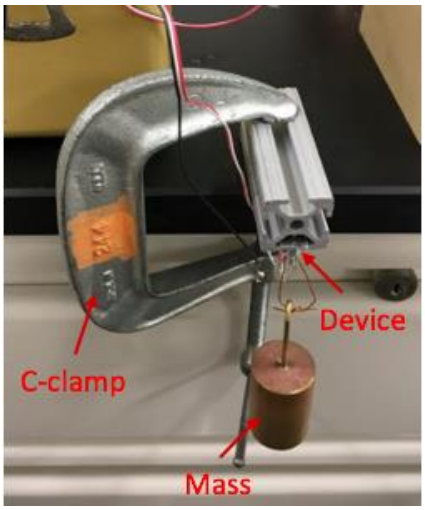

Figure 15. Setup of device hooked up to a strain indicator and with a hanging mass to test for strain values.

With the strain gage bonded to the bottom portion of the device, a three-wire setup was bonded to the strain gage lead wires, as mentioned in the Methods section. To set up the device for testing, I used a c-clamp attached to a bar and to the table as shown in Figure 15. The bar also has a slot on the bottom that allows the device to slide into and be hung. From there, a wire loop was attached to the bottom of the device where masses were hung to test the strain experienced by the device. This setup hangs the device from its head and allows the mass to transmit its force directly to the device.

Table 2. Strain Gage with Test Weights

Mass (g)	Strain Reading (με)
50	5
100	10
200	25
400	45
500	55
700	77
1000	93
1200	111
1500	125
1700	142

The results of strain values due to different masses are shown in Table 2. In order to get accurate values while testing, the masses were kept stationary so that the strain readings are not oscillating. The values correspond to tension values up to 17N of force. Below in Figure 16, these values are plotted together and reveal a 98.25% agreement with a linear relationship.

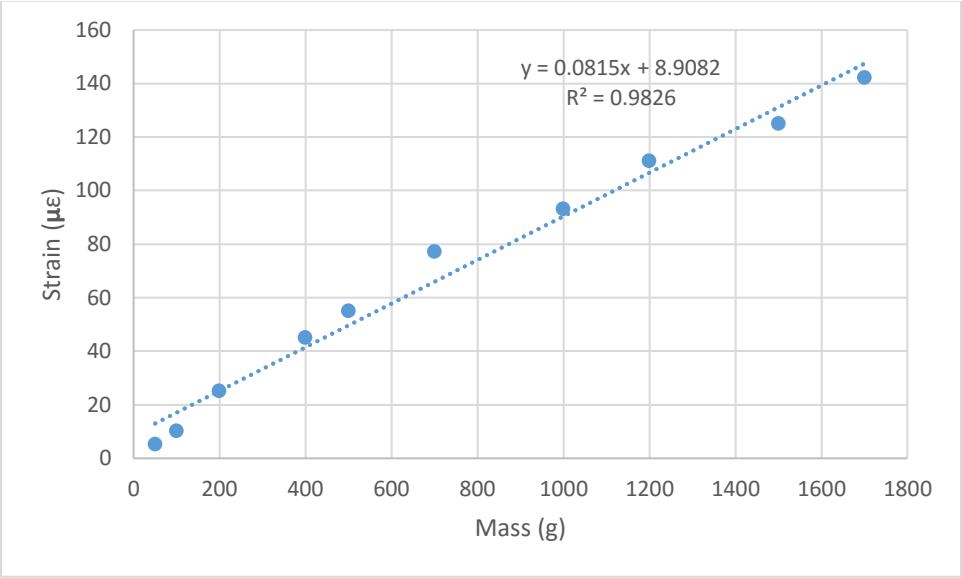

Figure 16. Plot of Strain Readings vs Mass.

Incorporating Design into Knee Model

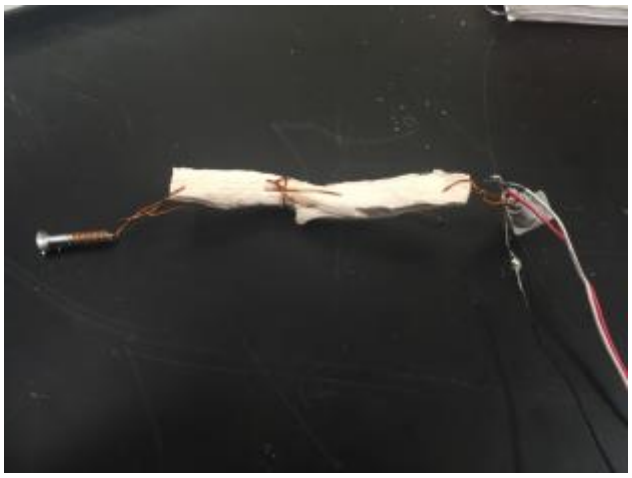

Figure 17. Graft that is to be used inside knee model.

As shown in Figure 17, on the left is a metal screw threaded with the copper wire, that is screwed in the femoral tunnel and will simulate the interference screw. On the right is the device attached through the hole on the male piece. The graft is the ACL taken from two knee models and sewn together with copper wire (approximately 80 mm in length).

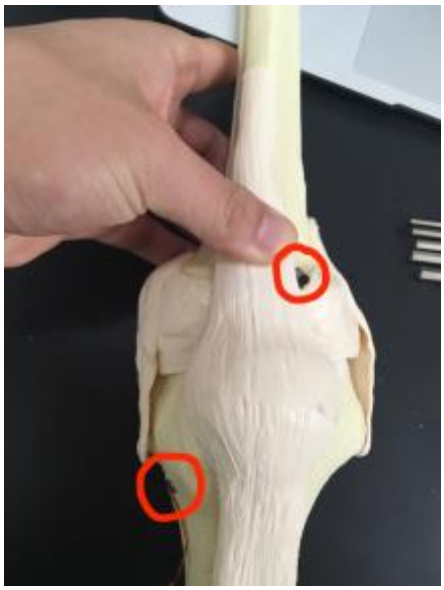

Figure 18. Graft fixtures attached to the knee model

As shown in Figure 18, the bottom left is the screw tied together with the copper wire and on the top right is the device flush with the outer bone. In order to implant the graft into the knee model, the graft had to be threaded through the tunnels with copper wire before it is attached to the screw and device fixture. While the device was able to be implanted into the knee, there were issues with the strain gage, as the lead wires from the gage were flimsy and would break.

Discussion

We were able to create a design of a fixture device, with adjusting capabilities that was implanted into a knee model. The device was hooked up with a strain gage and was able to take loads up to 20N of force, but because the strain gage wires are delicate, they had trouble being inserted into the tunnel without breaking. The epoxy did a great job in bonding both the metal pieces together as well as the strain gage to the device. The strain gage results indicated good agreement with a linear trend between the force applied and the resulting strain.

The advantages of this device include the ease for which the device can be manufactured, can change in length, and can withstand heavy loads. The device can be made using raw materials that are easily accessible. Also, the machining process is not particularly complicated and can be completed in under two hours. Using the set screw as a key, with a key slot proved to do an excellent job in preventing the device from rotating. By using a Hex-L wrench, adjustments can easily be made. Additionally, the device is able to withstand loads similar to ones placed on the ACL graft during surgery. Testing was only limited to one weight set, but the device was able to remain intact for all of the weights combined.

For some instances of strain gage implantation, and testing with strain indicator, strain readings would be oscillating and act very erratic. This all comes down to the surface and strain gage preparation. The surface needs to be chemically clean and neutral in order for the gage to bond properly and be able to pick up every strain value. Along with that, the wires must have a good connection with the strain gage, because any sudden shifts in resistance due to improper wiring will cause the indicator to show erroneous values. Additionally, because of the device's small size, and the small resolution of strain values, the strain indicator's output was extremely sensitive. There are other potential problems that may arise with no proper shielding for the strain gage with any protective coatings. Also, it could be the case that temperature and moisture absorption may play a factor in the strain gage results.

The device proved to be able to be implanted into the knee model; however, the combination of the device with a screw made it impossible to feed the graft through the outer bone and made it overall a challenging implementation process. The uniqueness of the endobutton is that it allows the ability to thread the graft, unlike an interference screw and this device. For practical applications if this device were designed like an endobutton loop, which can

be feed through the bone tunnel and rotated such that it lay on the outside of bone, it would make it easier for implementation. The copper wire also made it challenging to adjust the length of the graft with the fixtures because of its stiffness, so in any future work a thin rope would be better.

Because strain gage pre-bonded wires are too flimsy, future work could use strain gages without lead wires. That way a bondable terminal can be added and more solder can be applied to create a thicker wire to ensure that the wires stay on after the gage is implanted onto the device. As for improving the ease of installation, this device was created from a local machine shop. A big limitation in this design is the size of the dimensions, so it made it more challenging to work with. However, in more sophisticated machine shops and with better equipment, better, and finer crafted devices can be made such that the device would be able to be threaded through the tunnel, similar to the design and purpose of an endobutton.

Future work can be focused on studying the relationship between the graft's tension, elongation and stiffness to a distribution of contact pressure in the cartilage surrounding the tibiofemoral joint. By standardizing surgical procedures, it would allow surgeons to better quantify and characterize any relational effects that tension has on the integrity of the knee. More specifically, by establishing a baseline for normal knee kinematics in a healthy knee and comparing the changes in the graft tension with respect to loading and flexing, doctors will be able to confidently determine if any correlation exists. This device introduces the impact of standardizing not only the tension, but also of other factors that can contribute to the outcomes of the knee.

Chapter 6

Conclusion

As technology improves, it can be incorporated into the procedures of ACL reconstruction surgeries. There are factors such as material-body compatibility and load cycle testing that need to be accounted for in order for this device to be conceived to be used in humans, however, the idea that smart technology could be encompassed with implantable equipment could mean a better recovery and disease diagnostic process. Potential outcomes of smart technology could uncover insight into why older people are at higher risk of developing OA. Additionally, it could provide a better understanding of OA, its onset and appropriate response in a therapy or rehabilitation treatment procedure.

Our device is one of the first proposed designs that can allow surgeons the capability to adjust initial graft tension during surgery. From our testing, we were able to see that the device is able to sustain loads similar to that experienced by a normal ACL graft. While the device does not have the convenience of threading the tunnel, like the endobutton, future designs could be constructed in order to facilitate ease of implantation. Although current methods of ACL reconstruction surgery have proven to be reliable in the short term, they are not designed for sustainability in the long-term. This proof of concept design shows that this type of adjustable fixture could provide important diagnostics to surgeons during surgery.

Appendix A

Tension Values by Participating Surgeons

COEFFICIENTS OF VARIATION & STANDARD ERRORS OF MEASUREMENT FOR ALL 6 SURGEONS						
PARAMETER	**SURGEON 1**	**SURGEON 2**	**SURGEON 3**	**SURGEON 4**	**SURGEON 5**	**SURGEON 6**
MEAN (N)	20.580	21.000	14.040	22.000	22.860	24.240
SD	5.459	6.828	9.010	3.484	3.616	4.330
CV	27%	33%	21%	16%	16%	18%
SEM	2.44 N	3.05 N	1.34 N	1.55 N	1.61 N	1.93 N
90%CI	15.38-25.78	14.49-27.51	11.17-16.91	18.68-25.32	19.41-26.31	20.11-28.37
95% CI	13.80-27.36	12.52-29.48	10.30-17.78	17.68-26.33	18.37-27.35	18.86-29.62
99% CI	9.34-31.82	6.94-35.06	7.84-20.24	14.83-29.17	15.42-30.31	15.32-33.156
MINIMUM (N)	15.8	9.5	8.7	17.2	18.3	19.6
MEDIAN (N)	18.5	24	15	21.3	23.8	25.5
MAXIMUM (N)	28.4	27	15.9	26.1	27.2	29.8

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EDUCATION

The Pennsylvania State University *Graduation, May 2017*
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LEADERSHIP EXPERIENCE

Treasurer *Engineering Undergraduate Council,* Spring 2014 - Present, Penn State
- Managed over $25,000 for expenses, trips, and events as well as allocating funds to other clubs.
- Organized subcommittees and Leadership in Freshman Engineering to empower underclassmen.
- Interacted with students and the Deans of the College of Engineering to help resolve any issues.

Mentor *Millennium Scholars Program*, Fall 2015 – Spring 2016, Penn State
- Provided advice and support for high achieving STEM students to increase diversity in their fields.

EXPERIENCE

Undergraduate Research Assistant, January 2016 - Present**,** University Park, PA
Project: Smart Fixtures for Anterior Cruciate Ligament Reconstruction
- Designing an intraoperative method to adjust and measure the tension applied to the ACL during surgery.
- Analyzed the effects of a newly reconstructed ACL on the knee's kinematics and its relationship to the onset of osteoarthritis.
- Correlate and draw conclusions from data of ultrasound and shear wave electrography of muscles.

NSF Project Research Scholar, Summer 2015, Lehigh University REU Program**,** Bethlehem, PA
Project: Designing a Microfluidics Device
- Designed a functional microfluidics system from easily accessible parts and equipment.
- Utilized critical thinking and trial-and-error skills for the design of micro-channels and chip fabrication.

Undergraduate Research Assistant, February 2014 - Fall 2015, University Park, PA
Project: Computational Calculations for Solar Cell Molecules
- Proposed a method to discover more efficient sensitizing dyes by examining and optimizing the electrons states and molecular orbitals.
- Collected data which resulted in published research paper, "Koopmans-Compliant Self-Interaction Corrections".

COMMUNITY SERVICE

Discovery Space Children's Museum, Summer 2016, State College, Pa,
- Organized and assisted in local events to interact with children and promote science education.
- Helped design and fix exhibits displayed in museum floor.

Penn State THON Rules and Regulation Committee, 2015-Present, State College, PA
- Committed over 80 hours of service to raise awareness for pediatric cancer and to make sure the Penn State IFC/Panhellenic Dance marathon is run smoothly.

SKILLS

- **Software**: SolidWorks, MATLAB, PostgreSQL, MySQL, Microsoft Office
- **Programming Languages**: C++, Java, SQL, Swift, Linux Bash, LaTeX, Visual Basic