TOWARD DEVELOPMENT AND PROTOTYPING OF A BIOLOGICALLY INSPIRED KNEE PROSTHESIS

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ABSTRACT

A novel design for a biomimetic knee prosthesis using variable stiffness actuators is described. Currently, there is a need in the field of prosthetics for reliable, energy efficient, and affordable lower limb prostheses to improve the mobility of above-knee amputees. The proposed design uses a compact, single degree-of-freedom, variable stiffness actuator mechanism analogous to the polycentric cruciate-bone-tendon complex of the anatomical knee, to achieve stiffness and position control across a large range of motion of the prosthetic knee.

Keywords: Prosthetics, Variable Stiffness Actuation, Knee Prosthesis

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VERS LE DÉVELOPPEMENT ET PROTOTYPAGE D'UNE PROTHÈSE DE GENOU D'INSPIRATION BIOLOGIQUE

RÉSUMÉ

La conception d'une nouvelle prothèse de genou biomimétique utilisant des actionneurs à rigidité variable est discutée. Actuellement, il existe un besoin pour des prothèses de membres inférieurs fiables, économes en énergie et abordables pour améliorer la mobilité des personnes amputées au-dessus du genou. La solution proposée utilise un mécanisme d'actionneur compact, à un seul degré de liberté et à rigidité variable, analogue au complexe polycentrique du genou anatomique (compris des os, tendons et les ligaments croisés), pour obtenir une rigidité et un contrôle de la position sur une large amplitude de mouvement du genou prothétique.

Mots-clés : prothèse de genou, actionneurs à rigidité variable

1 INTRODUCTION

The first and foremost goal in the field of prosthetics is to enable an individual who has suffered from some sort of limb loss to regain or achieve functional use through a prosthesis and to enhance quality of life (QOL). In the field of lower limb prostheses, QOL can be related to the ability of an individual to perform activities of daily living (ADL), participate in social events, behave in an athletic fashion, and other factors [1]. Failure of a prosthesis to allow the user to perform some or all of these activities can lead to issues such as prosthesis rejection. In most instances, individuals will still use their prostheses, but they may be limited in performing ADL due to complications arising from the fit of the prosthesis or improper usage/training. Gailey *et al*. claim that most people with amputation walk with at least one gait deviation resulting from fitting issues or compensation for a secondary physical limitation [2]. These issues and additional gait deviations to compensate for an imperfect nature of a prosthesis can lead to degenerative joint conditions such as osteoarthritis in the residual hip and joints of the intact limb, as a result of shifting body weight onto intact-limbs instead of onto the prosthesis [2]. It is reported that individuals with limb loss, specifically above-knee amputations, have a lower QOL compared to those with intact limbs and those with below knee amputations [3, 4].

These issues appear to persist regardless of the type of prosthesis [5], although QOL can be increased through using a more advanced, more expensive microprocessor-controlled prosthetic knee (MPK) [6]. The addition of a microprocessor to actively change the stiffness of the uniaxial knee joint increases the price of MPKs and can drive individuals towards a passive four bar knee, as MPK prices find a midpoint around $45,000 [7]. One of the most common designs of four-bar prostheses was introduced by Radcliffe [8], who proposed an open four-bar design that allows the user's gait cycle to "lock" and "unlock" the knee joint to allow for passive control of stance and swing phases. This inventive design can work well for individuals who have been properly trained and who are physically capable, as Radcliffe states that the design depends heavily on the activity level of the individual. An example of these four-bar knees (or "polycentric" knees) is the commercially successful Ottobock 3R20. Many of these four-bar knees are currently being fitted with some sort of hydraulic technology to assist in stance and swing phase control, also. Regardless of the technologies that are introduced to assist in ambulation, gait asymmetries exist regardless of the prosthesis [9] and therefore the risk of joint-related diseases, mostly at the hip, remains prevalent for amputees.

One of the factors that cause individuals to develop unhealthy gait patterns and compensations is that the gait provided by the addition of a knee prosthesis is not energy efficient. In the field of useable (not strictly experimental/academic) prostheses, energy efficiency can be measured through metabolic energy expenditure [9]. A non-natural gait pattern will increase the energy expenditure needed for ADL, and it has been shown that current prostheses cause some sort of diminished natural gait. Therefore, there is a gap in the field for a knee prosthesis that is capable of producing an energy efficient, natural gait pattern. Current prostheses can replicate human gait but are not able to efficiently transfer energy through the knee joint. The biological knee complex can be seen as an inspiration for these criteria, as it excels at regulating power that flows through it [10]. The knee joint actuators (muscles) can regulate the work done either by, or on the joint, by controlling the energy transferred between segments. Previous studies by groups such as Hugh Herr's team at MIT have shown that by seeking biological inspiration using a variable stiffness actuator as the position/stiffness control mechanism, energy efficiency can be increased when compared to an MPK [11].

This work documents progress towards the development of a prosthetic knee design that provides efficient energy transfer through the knee complex and a natural gait pattern by using an antagonistic variable stiffness actuator (VSA) to control the knee joint. This is achieved by an optimally designed spring control mechanism that moves the knee in a biologically accurate fashion. More particularly, this paper focuses on the development of a benchtop prototype that will allow testing of different VSA setting. The device will be evaluated in terms of Key Performance Indicators (KPIs), which will be defined later. In what follows, some of the background work related to this project is described including prior models and prototypes of the basic concept. Then, the focus is turned to the bench top model with a VSA system.

2 BACKROUND

Biomedical engineering, specifically mechanical design of biomedical instruments, is a multi-faceted and interdisciplinary field. For an understanding of this project to be solid, a brief dive into fields such as kinematics, kinesiology, and anatomy is required. Kinematics will be discussed as it pertains to the mechanism by which the knee model moves through the knee's natural range of motion – a crossed four-bar mechanism. This crossed four-bar is one of the reasons why a discussion in anatomy must be explored, as the four-bar links are the biological anterior and posterior cruciate ligaments (ACL/PCL) and their respective attachment points on the distal femur and tibial plateau. Anatomy must also be referenced when talking about biomimicry within the design – as the human body uses various forms of VSAs in areas such as antagonistic muscle pairs (biceps/triceps, quadricep/hamstring). Finally, biomechanics must be explored to determine the amount of forces and torques that the biological knee experiences to have a basis for what the VSA device should be able to withstand/produce.

2.1 Anatomy and Biomechanics

Being a biomimetic design, it is important to research and understand the anatomy and biomechanics of the parts of the body that need to be replaced via a prosthesis. The knee joint is a more complicated mechanism than it may first appear, having its movement profile composed of both a rolling and a sliding motion. This is the reason why the four-bar design discussed above has remained relevant. Further work into this complex movement profile has even extended to mechanisms with a higher number of linkages [12]. The crossed geometry of the ACL and PCL form a four-bar linkage that governs anterior/posterior displacement of the femur relative to tibia [13]. This crossed four-bar behavior will serve as the biological inspiration for the movement profile of the proposed knee mechanism.

Much of the work relative to the four-bar mechanism used for the movement profile comes from the work of Goodfellow and O'Connor [13]. In their work, they describe and defend a theory wherein the ACL-PCL cruciate complex is directly related to the path of the knee during flexion. By using this theory, this cruciate four-bar can be used as a guide for the path of a knee prosthesis. This four-bar can be seen imposed onto a simplistic knee model in Figure 1.

The VSA mechanism that will be used to control the stiffness and position of the end effector (tibial component) can be likened to antagonistic muscle pairs within the body. These are pairs such as the biceps/triceps and quadriceps/hamstring. Taking the latter as an example, to swing the leg forward (anterior), the quadriceps must contract, and the hamstrings must extend. To stiffen the leg to not allow for any movement of the foot/tibia, both the quadricep and hamstring must contract. This will be mimicked by the control of the position and stiffness of the knee joint via a VSA.

2.2 Kinematics

The four-bar cruciate linkage that will serve as the guide for knee motion will be defined kinematically below. The parameters of the four-bar mechanism are shown in Table 1. As seen in Table 1, the links and link lengths are based on the anatomical ACL and PCL, and their attachment points on both the femur and tibia. As this is a simplistic planar four-bar, the kinematic analysis becomes trivial using vector loop and Freudenstein's equations. Matlab has been used in this work for kinematic analysis of the four-bar, but also beyond for modelling the actuation of the knee joint, which will be covered in later sections.

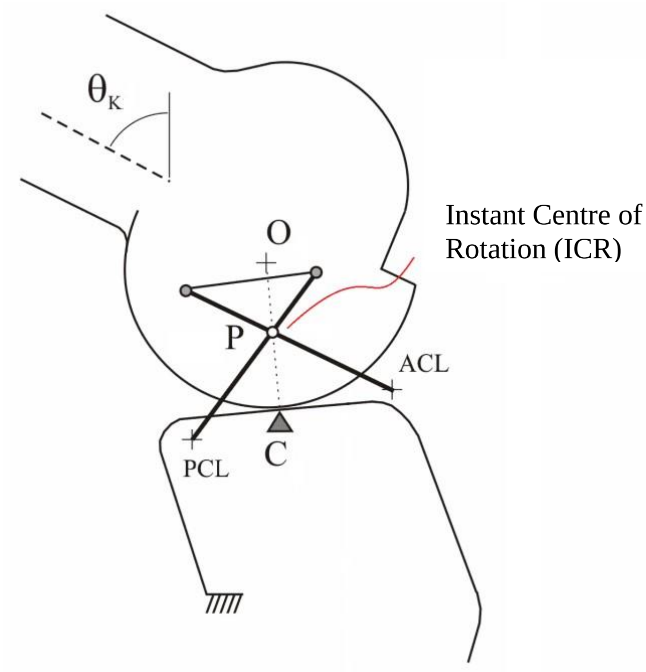

Figure. 1. Placement of four-bar mechanism in the biological knee.

Table 1. Parameters of the cruciate four-bar linkage [14]

Description of Parameter	Value
Length of tibial attachment link	3.05 cm
Length of PCL	3.22 cm
Length of femoral attachment link	1.28 cm
Length of ACL	2.99 cm
Angle of tibial attachment link	21.0°
Angle of femoral attachment line at full extension	121.0°

2.3 Variable Stiffness Actuator

By definition, a variable stiffness actuator is a specific type of variable impedance actuator (VIA). These devices introduce a mechanical element between the actuator and the object that is to be actuated. The work on VIA devices can be traced to Hogan [15], where the concept of an implementable impedance controlling device could be used to increase the robustness of traditional industrial robots. This idea has been further explored, and similarities to the body's own methods of controlling impedance in joints was recognized. In the research that serves as an inspiration for this project, a focus on VSA devices that use a spring element to store mechanical energy was used.

For this project, the VSA device will be acting as the antagonist muscle pair of the quadriceps and hamstrings. This antagonistic setup will give the device the ability to control both the stiffness and position of the knee joint. From research in this field, such as from Hugh Herr's team [11], the idea of an antagonistic VSA setup for biological joint actuation provides promising results in terms of energy efficiency – one of the goals of this work. The comparisons done in [11] show that an energy efficient gait can be achieved by using a type of VSA prosthesis. The limitations in the project done by this team lie in the lack of biomemetic architecture on which their prosthesis was built – being a uniaxial hinge-type prosthesis. By introducing an anatomically accurate way of controlling knee movement, both stiffness and position, an efficient method of gait may be achievable using the novel cam-and-pulley system described below. A full definition of the VSA mechanism and its integration with the four-bar mechanism will be defined below.

Figure. 2. Scaled up model of the four-bar driven knee model. Left: opened model to reveal mechanism. Right: drivable model with cables attached.

3 METHODS AND MODELS

3.1 Design Definition and Initial Prototypes

The current work for this project began in 2017 with an initial model to ensure the validity of the four-bar mechanism proposed in Section 2.4. The kinematics and positions of the end effector (tibial component) were verified through physical testing. A picture of a scaled-up model of the knee mechanism with the four-bar mechanism in place can be seen in Figure 2.

Not only did the large knee model provide verification that the tibial component would travel as desired from a knee prosthesis, but it also verified the use of the cam and pulley system that would actuate the tibial component.

The prosthesis can be broken down into two subsections – the four-bar, cam, and pulley section, and the VSA device and drive train to actuate the VSA and consequently the end effector of the mechanism. This separation of systems allows for further optimization to take place on either part while the other can remain unaffected.

3.1.1 Cam and pulley system – movement profile

The cam and pulley system work in the device to provide a sufficient moment arm for the VSA to accommodate the polycentric ICR of the four-bar. In this way, the device has the ability to move through the entire range of motion of the knee. This can be visualized by Figure 3. Similar to the biological muscle pair of the quadriceps and hamstrings, the flexor and extensor pulleys must wind or unwind in harmony to produce movement in the tibia. The black cables or belts are attached on one end to the pulley itself, and on the other end to the tibia. One can see then that the pulleys are the components that must be actuated to cause movement of the knee. In the case of the large initial prototype, actuation of the pulley wheels was performed by a simple gear train whose driven shafts protruded out from the top of the model (Figure 2 Right). There was no variable stiffness actuation in this model. This model was purely for kinematic and validation purposes, so this geartrain will not be explored further. As seen in Figure 3, the four-bar will be used as the connection between the femoral and tibial components, forcing the desired polycentric output characteristics from the tibial component.

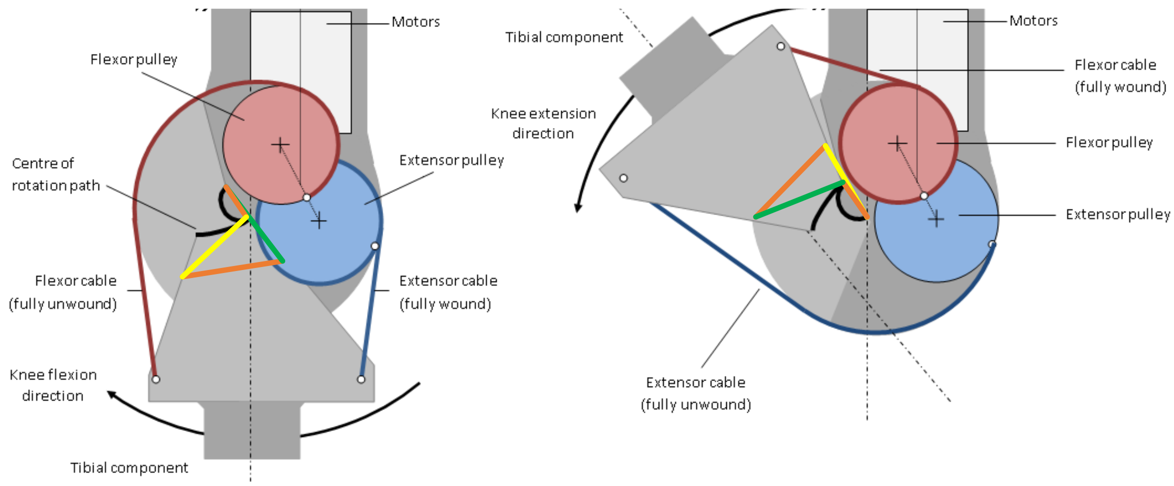

Figure. 3. Example of the cam and pulley system

3.1.2 VSA device implementation

As the model is driven via cables being actuated by pulley wheels, the pulley wheels themselves must be the location of variable stiffness elements. Multiple iterations of solutions to the issue of introducing a rotating mechanical energy storage device (spring) to the pulley wheels have been considered. It was decided that torsional springs (such as in a mousetrap or a self-closing door hinge) will be used to introduce the desired torque and energy storage. Currently, the design for introducing variable stiffness to the actuated pulley wheels can be seen in Figure 4. The mechanical energy storage takes place in the spring that is wound around the shaft connecting to the vertical bevel gear. The levers would be actuated about an axis passing through the shaft, tensing the torsion springs. This would provide a variable stiffness element that would be seen by the pulley wheels.

3.2 Numerical Models

To establish the kinematics of the entire system, a model was built in Matlab that allows for visualization of the knee mechanism throughout the entire range of motion. This model served as a 2D tool that helped shape the final physical model. Alongside the position analysis performed in Matlab, the script also analyzes the stiffness of the joint throughout its ROM. The stiffness at any given input angle was calculated using both a perturbation method and an analytical method. The perturbation method finds the stiffness of the joint at each setpoint by applying a small displacement, both positive and negative, at the end effector. Then the resulting torque response to the perturbation is used to find stiffness. The analytical method uses analytically derived PDEs to calculate an equivalent stiffness through the mechanism given a valid setpoint.

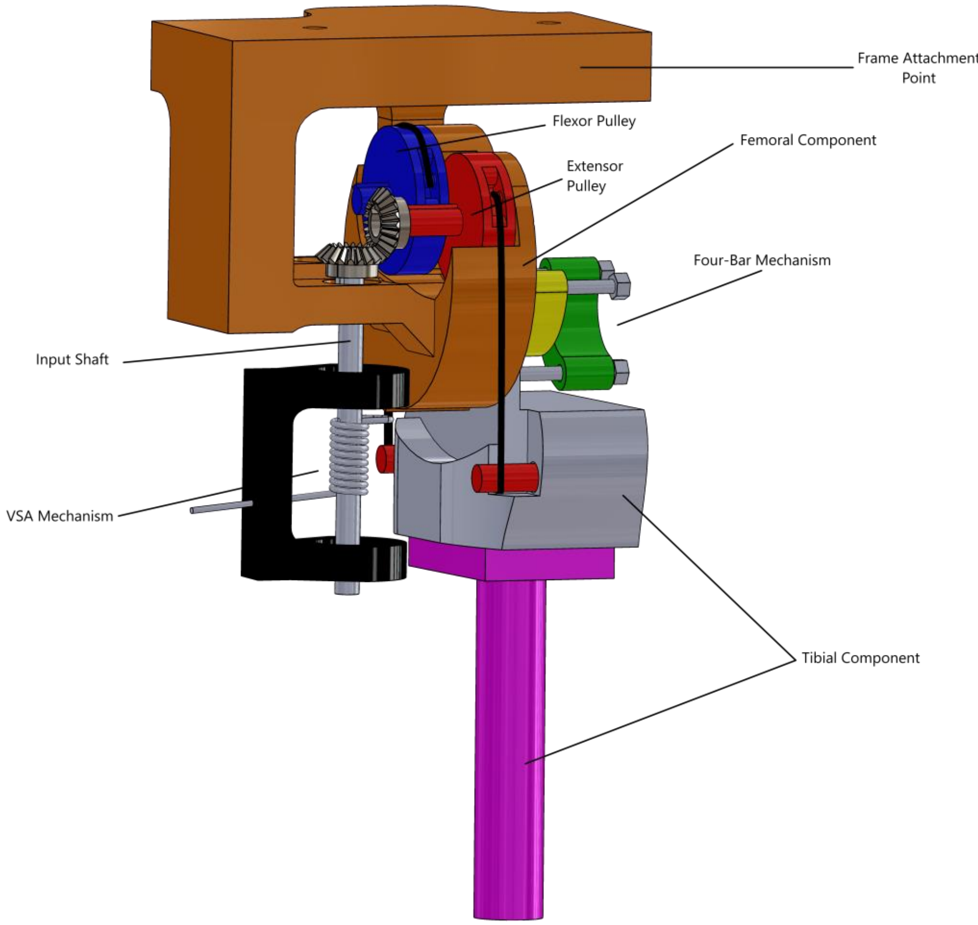

Figure. 4. Variable stiffness device

3.3 Current Design

For the complicated geometric designs in this system (for example the orange piece in Figure 4) 3D printing has been utilized. This also allows for rapid prototyping and iterative design. CAD models using Solidworks have therefore been utilized. Highlights of the CAD work are shown. The assembly shown in Figure 4 will be placed inside an extruded aluminum frame for support. The addition of extruded aluminum as a frame allows for placement of power supplies, ground reference, and a stable base for the mechanism.

The orange section of the model shown in Figure 4 will serve as the method of attachment to the frame connector, support for the gear train to actuate the pulley wheels, and the femoral component of the four-bar. This orange component also will have cables wrapping from the pulleys down to the red shafts extruding laterally from the tibial component. Due to its complicated and specific geometry, this part will be 3D printed.

The tibial and shank components are shown in gray and magenta. The tibial component serves as the attachment point for the curved four-bar members (yellow and green), and houses rods that will be connected to the pulleys via belts. Below the tibia is the shank, where instrumentation will occur for both position and force sensing during actuation. The VSA device is shown in black on the left-hand side.

To transfer power from the VSA device to the pulley wheels, gearing will need to be considered as it is infeasible in this design iteration to have the VSA drive shaft be in line with the pulley wheel. This gear train is simplistic, only containing one set of bevel gears to transmit movement 90 degrees. One advantage of introducing a gear train between the VSA and pulleys is to allow for possible variation in gear ratios, if more or less power is needed by the pulleys.

3.4 Instrumentation

The bench model that is to be constructed using the parts and assemblies in section 3.3 will need to be instrumented in such a way that valid, relevant data can be extracted from the system.

Key performance indicators (KPIs) of this project will be how well the VSA mechanism can regulate both position and stiffness of the prosthetic joint. By adjusting the neutral position of the flexion and extension springs in the same direction, new equilibrium positions of the tibial component are achieved. At a set equilibrium point, adjusting the neutral position of springs in opposite directions will hold the position and modify the stiffness.

We will use a 6DOF IMU to record the global orientation (position) of the tibial component relative to the stationary frame (femoral component) and a force transducer mounted normal to the tibia component to measure a perturbing force. From this we will determine the relationship between the input spring neutral position and the output position of the tibial component, and the range stiffness achievable at each position.

Data processing and analysis will be performed using Matlab.

4 FUTURE WORK

4.1 Building and Instrumenting a Bench-Top Model

A bench model of the mechanism will need to be assembled in order for data acquisition and validation to take place. Ideally, this bench model will be more closely related in size to the anatomical knee than the previous large model. This will require a merger of both 3D printed parts and fabricated metal parts.

The assembly of the VSA mechanism will be as follows. First, the shafts and springs will be sourced, and it will be ensured that the spring can fit around the shafts. Then, the shaft will be fitted into the actuating lever through bearings to allow the shaft to spin freely inside the lever. Next, the spring needs to be bent specifically so it can be connected both to the input shaft and to the lever that will actuate it. Next, bevel gears will connect the top of the shaft directly to the pulley wheel. As the pulley wheel sits inside the femoral component of the knee, which itself is mounted to an external frame, supports will be needed for the VSA assembly to ensure constant mesh of the deriving bevel gears.

With the VSA connected to the pulley wheels and properly supported, the 3D printed pieces can be assembled. The femoral component, along with housing the pulley wheels, also serves as the femoral link in the four-bar mechanism that guides the knee’s swing trajectory. The four-bar can be attached to the femoral component via press-fit nuts and screws to hold the ACL/PCL bars in place. The tibial component will attach to the opposite ends of these ACL/PCL bars. Finally, cables can be wound from the pulley wheels around the cam surfaces and attached to specific locations on the tibial plateau. In this way, driving the VSA device will cause actuation of the tibia. A link of known properties can be attached to the bottom of the tibial component to be able to measure data that was described in 3.4.

Relevant data for this project is described in 3.4. Instrumentation of the model will be sectioned into two parts – position instrumentation and force instrumentation. Position instrumentation will be done first to ensure specific positions can be reached for quasi-static force testing. In this scenario, quasi-static testing refers to force testing at incremental knee angles throughout the ROM of the device. It is important during stiffness testing that forces be applied perpendicular to the tibia.

4.2 Testing and Data Analysis

First, the recordings from the IMU and force transducers will need to be filtered and useable data will be extracted. KPIs such as input angle vs. stiffness, input angle vs. output position, and a stiffness map over a range of input parameters will be evaluated. As this is a biologically inspired prosthesis, comparisons will need to be drawn between the collected data and analytical values. Multiple methods of data comparison and validation are explored below.

Discussed in section 3.2, the input angle vs. stiffness data will be compared against the analytical standard for the specific kinematic conditions of the system. Differences here are to be expected, as the Matlab code can specify an exact spring constant, while in practice it will be difficult to ensure any spring behaves perfectly. Stiffness in the knee joint is vital to proper human gait, especially during heel strike where the knee needs to be sufficiently rigid to not allow for buckling. Therefore, the torques experienced at the input shafts due to tibial perturbation (3.4) will be compared to the moments seen by the knee during normal gait to determine if adjustments need to be made for either the spring stiffness or gearing ratios.

4.3 Summary of Design Milestones

1. Create a functioning benchtop model capable of creating a variable amount of stiffness at the mechanism's output link (tibia).
   a. This is to be done using torsional springs that control the amount of tension placed on cables that pull the tibia anteriorly and posteriorly.

2. Instrument the benchtop model to determine the input angle/output stiffness of the device.
   a. This is to be done using an S-type strain gauge based load cell placed at the distal end of the tibial component. The load cell will be oriented such that when the tibia is actuated, it will press against a rigid surface to provide the amount of normal force being provided by the VSA device
   b. Input angle will be tested at 10 degree increments from 0 degrees through 180 degrees. Both the extensor and flexor shafts will be tested at these increments, so each combination of input angles on each shaft will be recorded. This is a result of 18x18=324 possible input combinations to be tested.

3. These tests will provide a map of inputs to outputs of the device, which will be used to determine if the proposed device is capable of providing sufficient stiffness values necessary for walking.

4. These tests will also determine if the device is capable of independently controlling stiffness and position

5 CONCLUSION

The proposed work describes a novel knee prosthesis for individuals living with a trans-femoral amputation who require a self-contained, actuated, energy efficient knee. This knee prosthesis is in development and will be created and analyzed before the fall of 2023. Background information such as the biological inspiration, kinematics, and variable stiffness actuation method have been described. The previous and current models have been described, as well as an assembly plan for a bench model prototype.

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